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ENDP - Q3 2016 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 3Q16 GAAP net loss from continuing operations of $191m and GAAP loss per share of $0.86. Expects 2016 revenues to be approx. $3.87-4.03b and adjusted EPS to be $4.50-4.80.

CORPORATE PARTICIPANTS

Keri Mattox *Endo International PLC - SVP of IR & Corporate Affairs*

Paul Campanelli *Endo International PLC - President & CEO*

Blaise Coleman *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Joe Ciaffoni *Endo International PLC - President, Endo Pharmaceutical*

CONFERENCE CALL PARTICIPANTS

Elliot Wilbur *Raymond James Limited - Analyst*

Brandon Folkes *Guggenheim Securities LLC - Analyst*

Jason Gerberry *Leerink Partners - Analyst*

Randall Stanicky *RBC Capital Markets - Analyst*

Marc Goodman *UBS - Analyst*

Dana Flanders *JPMorgan - Analyst*

Donald Ellis *JMP Securities - Analyst*

Liav Abraham *Citigroup - Analyst*

Stephan Stewart *Goldman Sachs - Analyst*

Andrew Finkelstein *Susquehanna Financial Group - Analyst*

Christ Wolpert *BMO Capital Markets - Analyst*

Esther Hong *Stifel Nicolaus - Analyst*

Sumant Kulkarni *BofA Merrill Lynch - Analyst*

Greg Fraser *Deutsche Bank - Analyst*

David Ansellem *Piper Jaffray - Analyst*

Douglas Tsao *Barclays Capital - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the third quarter 2016 Endo International PLC earnings conference call.

(Operator Instructions)

As a reminder, this call may be recorded. I would now like to introduce your host for today's conference, Keri Mattox, Senior Vice President, Investor Relations and Corporate Affairs. Please go ahead.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thank you. Good morning, and thank you for joining us to discuss our third quarter 2016 financial results. With me on today's call are Paul Campanelli, President and CEO of Endo, Blaise Coleman, Senior Vice President of Global Finance Operations, and appointed Interim Chief Financial Officer, and

Joe Ciaffoni, President of Endo Pharmaceutical, our US branded business. We have prepared a slide presentation to accompany today's webcast, and that presentation, as well as other materials are posted online in the Investor section at endo.com.

I would like to remind you that any forward-looking statements by management are covered under the Private Securities Litigation Reform Act of 1995 and Canadian Securities Litigation Act and are subject to the changes, risks and uncertainties described in today's press release, and in our US 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 the accounting principles generally accepted in the United States, and it 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 today, 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. With that, I would now like to turn the call over to Paul. Paul?

Paul Campanelli - *Endo International PLC - President & CEO*

Thank you, Keri. Good morning, everyone, and thank you for joining us for today's call. I hope that you've all had a chance to review the Company's earnings press release that we issued earlier today. Let me now turn to our third quarter 2016 earnings presentation.

To start, here is a brief agenda for today's call. Moving to slide 3. As you know, the third quarter brought some changes, and I believe a sharpened focus on operational execution at Endo. Despite some headwinds for our generics-based business, the overall diversity of our portfolio did enable us to deliver solid revenue and adjusted earnings per share results in the third quarter, with revenue performance across all business units broadly in line or ahead of Company expectations.

I recently took on the role of CEO, and I am working to realize the potential for Endo moving forward. Our product by product assessment of the business and our portfolio is in progress, and we are working on the development of a strategic plan. Importantly, we're once again pleased to reaffirm our 2016 revenues and adjusted EPS guidance.

On slide 4, you will see a snapshot of our segment revenues for the third quarter. Moving to slide 5. Let's discuss our branded business. Our branded performance in the third quarter was stronger than our expectations, which underlies our segment revenue and margin guidance provided earlier this year. We delivered solid XIAFLEX demand, particularly in Peyronie's disease, and our revenue growth expectation for XIAFLEX continues to be in the low double-digits for the year. The BELBUCA launch is progressing, and we are evaluating how to maximize the value of this differentiated product within a challenging opioid market. We did see outperformance by select US branded products including Voltaren Gel, Lidoderm, and some products in our other branded portfolio.

Moving to slide 6. Let's talk about our international pharmaceuticals. Our results were in line with the expectations that underlie our revenue and margin guidance provided in May for Paladin, Litha and Somar. At Paladin, we drove solid performance across our base business, launched Nucynta, and secured the Canadian rights for XIAFLEX. The additions of these products is to provide a longer term growth as we continue to manage the expected loss of exclusivity on select products in the Canadian market this year. In our Litha and Somar businesses, our underlying revenue growth is outpacing market growth rates largely driven by volume, and we continue to improve our adjusted operating margins.

Turning to slide 7, and our generics business. We continued to deliver overall segment performance in line with our expectations. Our sterile injectables business continues to grow led by Vasostrict. In new launches in alternative dosages, we saw better than expected performances from alternative dosages, especially the Lidoderm authorized generic, and we have launched 15 products since the beginning of the year.

We continue to file new ANDAs with the FDA, while replenishing our R&D pipeline. Our base business declined approximately 20% sequentially from the second quarter 2016, driven by higher than expected consortium pricing pressures, evolved consortium structure, and certain competitive generic entrants late in the quarter. Excluding stocking and one-time factors, this decline was approximately 15% from the second quarter of 2016. We now expect full year base business decline to be in the low [30s] percentage range.

Given the steeper than expected erosion for our base business for the quarter and the year, our base business erosion rate in 2017 may be larger than our previous assumption of a return to historic Par annual erosion rates of 10% to 12%. We will update our assumptions on 2017 base erosion, as part of our full year 2017 guidance on our year-end earnings call. It is important to note that Par strategy is focused not on this base segment, but on prioritizing and growing higher quality, higher barrier-to-entry products, and continuing to advance and replenish our differentiating R&D pipeline.

Moving on to slide 8. You will see a chart tracking our new product launches. We have updated to show the 15 products that we have successfully launched so far in 2016. We've had a number of smaller product launches shift into early 2017, and others that we have rationalized due to commercialization assessments and our ongoing portfolio prioritization, but still anticipate that we will launch approximately 20 new products this year, including our first-to-file exclusive products, generic Seroquel XR and generic Zetia.

Let's turn to slide 9, to talk about those two key fourth quarter launches. Importantly, we've now launched our generic Seroquel XR product. The initial launch has gone smoothly, and all manufacturing, launch activities and product shipments are on track. Our expected December 2016 launch of generic Zetia is also progressing on track. We have received final approval from the FDA, and have and agreement with Merck through our partner Glenmark.

This product is manufactured through that partnership with Glenmark, and we have a product in our warehouse, [that] we're ready to launch with marketing exclusivity. Together we expect these two first-to-file launches to contribute in line with our previously communicated projections. With that, let me turn the call over to Blaise Coleman to discuss the financial performance of the Company and the quarter, and our projected outlook. Blaise?

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Thank you, Paul, and good morning, everyone. First, on slide 11 you will see a snapshot of the third quarter GAAP to non-GAAP financial results. Paul covered Company and segment revenues earlier, so I will not review that here.

On a GAAP basis, we have a loss per share of $0.86 in the quarter, versus a loss of $3.84 in the third quarter of 2015. GAAP net loss from continuing operations in the third quarter of 2016 decreased to $191 million, compared to a GAAP net loss from continuing operations of $804 million during the same period in 2015, primarily due to goodwill and intangible asset impairment charges recorded during third quarter 2015.

On an adjusted basis, overall third quarter results are better than previously guided. To summarize the points that Paul made, the revenue was strong due to continued performance from XIAFLEX, and better than expected due to outperformance by sterile injectables, alternative dosages, and select other branded products. Adjusted net income and EPS are better than guided as a result of higher revenues, better gross margin percentage due to product mix, and lower operating expenses primarily due to timing.

On slide 12, we are again reaffirming our revenue and adjusted EPS full year guidance. We expect revenues to be approximately $3.87 billion to $4.03 billion, and adjusted EPS to be between $4.50 and $4.80. Given our overperformance in Q3 versus our expectations, we have increased confidence in our overall full year guidance range which takes into account several moving parts, including the range of our launch forecast for our first-to-file generic versions of Seroquel XR and Zetia, projections around year-end timing of product sales and shipments, and continued pricing pressure for our US generics-based business.

Moving to cash and liquidity on slide 13, on a year-to-date basis cash flow from operations totaled approximately $443 million. We've also highlighted the material moving parts that have impacted our cash flow from operations on a quarterly and September year-to-date basis. On slide 14, we are updating our view on estimated free cash flow in 2016. We now project debt pay down of approximately $330 million in 2016, and to exit the year in the high 4 times range for our net debt to adjusted EBITDA leverage ratio.

While I've provided some color in the past on potential free cash flow headwinds and tail winds in 2017, given our dynamic sector environment, and our ongoing strategic assessment, both of which could impact cash flows in 2017 versus previous expectations, we will wait to provide any details or updates for next year, until we provide our full year 2017 financial guidance in late February. As noted in our press release, we ended the

quarter with approximately $562 million in unrestricted cash, approximately $276 million in restricted cash, and a net debt to adjusted EBITDA leverage ratio of approximately 4.9 times. Now let me turn it back over to Paul.

Paul Campanelli - *Endo International PLC - President & CEO*

Thank you, Blaise. Moving to slide 16, there are some strategic updates regarding the 2017 market environment that we believe are important to discuss. First, the US generics competitive landscape and pricing pressures continue to be challenging. Deeper than expected base erosion trends that we see and saw in the third quarter indicate stronger headwinds on the front as we exit the year.

Steeper than anticipated consortium pricing pressures, both in and out of formal bid cycles that we expect to weigh on our generics business moving forward, could impact our adjusted gross margin profile, and our 505(b)(2) expectation and longer term 505(b)(2) strategy has been impacted by the competitive landscape, regulatory actions, and the pricing environment. We will provide more detailed insights into the expected impacts of these trends on our 2017 financial outlook, when we provide full year guidance in late February 2017. I would like to note that deeper than expected erosion and demand for our products, and/or changes to our resource allocation resulting from our strategic assessment could result in changes in the carrying values of assets across our segments.

Next, XIAFLEX. We've identified XIAFLEX as a core US branded product and growth driver for Endo moving forward. We continue to put resources and efforts behind accelerating traction and growth in our trends in Duputren's contracture and Peyronie's disease indications. We're also analyzing our R&D pipeline. Cellulite remains the primary focus there, and we look forward to reporting out on our Phase 2b data upon the completion of that trial.

Other potential indications are currently undergoing a full commercial assessment and analysis, so that we can best prioritize our R&D efforts and determine clinical trial time lines moving forward. The launch of BELBUCA is also progressing. We continue to believe that BELBUCA offers a compelling and differentiated product profile, and want to ensure that we are best positioning it moving forward. Finally, as the new CEO, I am spending a lot of time evaluating and working with our legal team, to further develop and execute on our strategy with respect to the ongoing mesh litigation.

On slide 17, let's talk about my CEO assessment process. As I mentioned, we are pleased to reaffirm our revenue and adjusted EPS full year 2016 financial guidance. Overall, business performance continues to be broadly in line with our expectations.

We are in the process of conducting a bottoms up, product by product assessment of all three of our business units. We expect that we'll be ready to communicate our evolved corporate strategy in the February 2017 time frame, of our fourth quarter 2016 earnings announcement. As we've done in the past, we expect that we'll also communicate our full year 2017 financial guidance and expectations for our business at that time.

In closing, Endo is sharpening its focus on operational execution, and I am excited to be leading the Company. I want to take a moment to thank all of our dedicated employees whose hard work and commitment to the Company make what we do possible. We continue to believe that this is a time of significant opportunity for Endo, our employees, the patients we serve, and our shareholders. That concludes our prepared remarks. Now let me turn the call back over to Keri to manage our question and answer period. Keri?

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thank you, Paul. We'd like now to open the lines to your questions. In the interest of time, if you could limit your initial questions to allow us to get in as many as possible within the hour, we would appreciate it. Kristi, may we have the first question, please?

QUESTIONS AND ANSWERS

Operator

Our first question is from the line of Gregg Gilbert of Deutsche Bank.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Gregg, you may be on mute. We can't hear you. Kristi, can we move to the next question in queue, and Greg maybe you can get back into the queue for later?

Operator

Our next question is from Elliot Wilbur of Raymond James.

Elliot Wilbur - *Raymond James Limited - Analyst*

Thanks, good morning. Just basically one question for you, Paul. Could you maybe just provide a little bit more color, go into a little bit more detail in terms of the evolving consortium pricing pressures that you've referenced several times in the release, and during your prepared commentary? Just trying to figure out, is this a result of a renewed bid cycle, or some structural change on the consortiums with some of the recent movement? Or is it simply just existing competitors be a lot more aggressive in current product markets, or the impact of new competition or maybe all three? But if you could just maybe give a little bit more clarity behind that, it would be helpful? Thanks.

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, thanks, Elliot, and I think that's right, and I think you hit the nail on the head. In essence, it's all three of those. So the starting point is that really frankly, we want to start the tone and set the tone of credibility, and really taking a real prudent approach here. But when we look at what's happening, we did have anticipated, essentially higher than anticipated pressure from the consortiums. And we did in essence, see a little more discounting for some of the more established generic competitors. So a little bit of that going on as well.

When we see the 20% erosion factor that we talked about, in essence, if we exclude a couple of one-time events, we were more in the 15% erosion for the quarter. And specifically, when you look at the area in which we were effected, we had two products that were authorized generics, right? So these are products that you know that we, that are revenue drivers, but in essence they are lower margin contributors to the Par franchise. So [metoprolol] and [budesonide] were two products that we received additional competition from budesonide.

And then we had a little heavier than expected competition at Red Oak from a competitor on the metopoprol AG, and structurally we're seeing some changes at McKesson. As you know, they are moving away from their San Francisco operation, and you're going to start to see a shift in McKesson to their European operation that I referred to, Claris One. So they're starting to kick in, and you'll see a change on a go forward basis as they kind of unite with Wal-Mart.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, Kristi. Can we move to the next question?

Operator

Our next question is from the line of Louise Chen of Guggenheim.

Brandon Folkes - *Guggenheim Securities LLC - Analyst*

Hi, it's Brandon Folkes on for Louise. Could you just talk about the magnitude of stocking benefit in quarter for XIAFLEX? And then secondly, could you just talk about some of the drivers of gross margin strength in the quarter, and whether they're expected to continue? Thank you.

Paul Campanelli - *Endo International PLC - President & CEO*

Okay, great. So I'm going to pass the first question over to Blaise.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes, Brendan, so for the quarter from a XIAFLEX perspective, we did see some stocking benefit. We saw a benefit in the quarter of about 2 days. So in absolute terms, that's about a little over $1 million of benefit in the quarter. When you look at our growth rate sequentially for XIAFLEX, at a total molecule level, we grew about 12%. And the majority of that was due to a stocking movement, as at the end of Q2, we had about 6 days on hand, and at the end of Q3, we had about 8 days on hand.

In terms of gross margin, we had favorable mix during the quarter. Again, a little bit stronger in the sterile injectables and some of the areas that Paul talked about. If you look at our full year guidance, we did change our assumption to be at the upper end of our gross margin range. So we would expect to see the benefit we've seen on a year-to-date basis playing through on a full year basis.

Brandon Folkes - *Guggenheim Securities LLC - Analyst*

Great, thank you.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, Brandon. Kristi, can we move onto the next question, please?

Operator

Our next question is from David Amsellem of Piper Jaffrey.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

David, are you potentially on mute? We can't hear you. Kristi, do you want to move to the next call in queue?

Operator

Our next question is from Jason Gerberry of Leerink Partners.

Jason Gerberry - *Leerink Partners - Analyst*

Hey, thanks for taking my question. I just want to make sure I'm getting this right on XIAFLEX. So if I mean, if you're at low double digit full year growth that would imply fourth quarter is down somewhere like 15% to 20% year-on-year. So I just want to make sure I'm understanding that, because fourth quarter is usually a little bit seasonally strong? And then second question, Paul, maybe can you provide a little bit of framework for

this DOJ process? I mean, just how you think in general these processes play out from a time line perspective, how long before investors can get some visibility regarding how this process may evolve?

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, so Jason, I'm not going to really -- I'll start with the DOJ question, and I'll pass the XIAFLEX back to Blaise in a second. So we're not going to be able to comment a little bit specifically on the DOJ process. And maybe what we can do, is maybe just talk to the facts here.

So this is a subpoena that we received over two years ago. And I think that it's safe to say, that we believe that we've cooperated with the DOJ, and that there's in essence, there's no new information. And as it pertains specifically to Par, it was a focus around two products, and one product of which we do not even sell. So from that standpoint, we're feeling reasonably confident in our position. At least that's what we believe, and to be specific, the issue deals with a product called Doxycycline Hyclate, it's product we do not even sell.

There maybe confusion at the DOJ, but we sell a product was called Doxycycline Monohydrate. And then, the second product is a product called Digoxin. In essence, what occurred there, Par came into an already established market with two generic competitors plus the brand. We were the fourth entrant into an established market, and we never took our price -- there was never a price increase with respect to Digoxin. So I think that's probably a statement of fact here by Par, and that's our position.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes. Jason, then on the XIAFLEX question. So our guidance again has been low double-digit for the year. We do anticipate for that Q4, what that implies is that we would see sales similar to Q3 of 2016, so flat to slightly up. And our Q4 sales last year on a pro forma basis, and this is all on a pro forma basis, were around $50 million.

Jason Gerberry - *Leerink Partners - Analyst*

Okay, thank you.

Operator

Thank you. Our next question is from Randall Stanicky of RBC Capital Markets.

Randall Stanicky - *RBC Capital Markets - Analyst*

Great. Thanks, guys. Paul, is this heightened generic erosion, is this cyclical or secular? And the reason I ask the question, is because, as you're looking at your asset base of branded generic assets, obviously if this is a shorter term dynamic, then moving towards the generic side could make sense, if we're looking a couple years down the road. But I guess, the question specifically, do you have visibility or a comfort level that 2017 could be the low watermark for some of these challenges and headwinds? And then I have one quick follow-up.

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, so Randall, I think right now, and we're going to come back in February earnings call, and provide a little bit more insight. And I think the way we're looking at it, granted the erosion factor here was greater than we had originally assumed, and we had communicated earlier, that we thought we were going to be in the 10% to12% range for 2017. The reality is, is that it will be likely a little more steeper than that, and we just want to be a little bit mindful and thoughtful on how we communicate this. But when you look at the Par portfolio, it's not the base is really not our focus. When look at the products in our pipeline, products that we're launching, we're looking at more differentiated products.

So we are as you know, as we culled the portfolio out of some of the historical Qualitest products, we're now really moving to more technically challenging products that should be able to withstand more, be able to withstand pushback on either the trade or competitors. So we're shifting away from a highly commoditized portfolio, as we move forward. So I feel we're going to have more erosion to deal with, because the portfolio is still quite large. But over time, as we launch more products, we should be in a better position to keep our margins at the historical 50[%], low [50] percentage on a go forward basis.

Randall Stanicky - *RBC Capital Markets - Analyst*

So can we just narrow that cap a bit? So you were talking about a 15% erosion factor net of one-timers in 4Q. You've previously talked about 10% to 12% on an annual basis. That's a pretty big divide, right from the sequential to an annual. How do we think about the nearer term, what -- relative to what we're seeing currently versus what you previously thought you would see?

Paul Campanelli - *Endo International PLC - President & CEO*

Okay. So again, we'll come back in February, and we'll provide color with respect to that. But as we move forward, when you look at the Par legacy portfolio, there has been a fair share of authorized generics in that portfolio. And as you know, on the authorized generics side, Par is holding a small percentage on gross margin, yet we booked the sale. So when we get hit on competition, it's not all uncommon to see a higher erosion factor. Now as the portfolio swings away from AGs into more differentiated products, the likelihood is, is that we will be able to push back. But I just want to be a little mindful, that there's still a fair number of commodities in the portfolio and we'll come back and provide more color in 2017.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Thanks, Paul.

Operator

Thank you. Our next question is from Marc Goodman of UBS.

Marc Goodman - *UBS - Analyst*

Good morning, Paul. When you were talking about 2017, you mentioned 505(b)(2) expectations, and can you put a little more color on that? You said the longer term strategy could be impacted, so what does that mean? So competitively, are there more people doing 505(b)(2)s? Is the FDA more against approving these 505(b)(2)s, or basically the pricing is going to get worse for these things? So is it all three of them, or one versus the other, just give us more color?

Paul Campanelli - *Endo International PLC - President & CEO*

So sure. So Mark when I look at 505(b)(2)s, I like to break them into three categories, right? And we got to be real specific here. So 505(b)(2)s has been and will continue to be a part of the Endo Par strategy, but I'd break them into two categories. When you look at portfolios that are historically in either the injectable portfolio, or even some of the legacy Par brands that have shifted over to Endo, those are pure 505(b)(2)s. And we had the resources and the R&D to continue to develop those products.

But just to drill into specifically where I think you're headed is, when Par undertakes a conversion of an unapproved drug to approved status, and those I break into two categories. I'll break those into a category whereby we will continue our 505(b)(2) strategy of taking unapproved drugs, and converting them, and running the requisite clinical trials, and putting a brand strategy behind that, where that may be detailed either through Joe's Endo team or Tony Pera's injectable team. That we will fight for intellectual property. That falls into one category.

When we have intellectual property, it should be normal course. We'll launch the product, it will be priced appropriately for the work in which we've done to gain approval for. And then hopefully, our intellectual property will stick and we have something that we can build upon. Where we are getting some challenges is, in the third category where we develop a 505(b)(2), where we've now have a brand. We're working with the FDA to remove the unapproved sources, yet we don't have intellectual property. So now we have a timing issue.

That's an area that we just need to pause a little bit, because the window is a shorter period of time for contribution. So now in today's environment there are pricing pressures, and we've got to be a little bit mindful of that. So we will continue with a strategy, understanding that when we can't get intellectual property, that these 505(b)(2)s in essence will behave like a super generic. Where we'll have the benefit and contribution driven by volume, but the pricing environment is going to be a little bit tighter, and likelihood is that we will see ANDAs coming at a quicker rate. But that's fine. That's still a meaningful product for the Par portfolio, and we will continue to do that. But that's where we will see a little pressure.

Operator

Thank you. Our next question is from Chris Schott of JPMorgan.

Dana Flanders - *JPMorgan - Analyst*

Hi. Thanks for the questions. This is Dana Flanders on for Chris. Just my first one. Can you talk a little bit more about just the generic pipeline, and I know it's early, but any views on outlining key launches into 2017? And then, if we are seeing greater base business declines, just how would you characterize replenishing the pipeline, and expanding the alternative dosage form business? And then my second quick one, just on Vasostrict, the competitive landscape, just any updates there, or is this still status quo, and you're feeling pretty confident on exclusivity for the next year or two? Thank you.

Paul Campanelli - *Endo International PLC - President & CEO*

Great. So I'll take the first one on Vasostrict is pretty simple. As of today, we have not received any notification of a Paragraph IV. There's been no update to the FDA's Paragraph IV website. So at this point in time, there's really not much to do. The product is running. It's converted nicely, and in essence there's no update, and I'll view that as a positive.

Regarding the 2017 pipeline, we've kind of touched on this, where we're not going to disclose specifically our products, because we don't want to place ourself at a competitive disadvantage. What I will call out is, we don't have the two blockbusters that you're seeing right now in Zetia and [Quetiapine]. That we don't have, but you need to remember that we are getting the benefit and the carryover of those two products from the fourth quarter of 2016 into the first quarter. So that's going to help us project into 2017. We've got a solid pipeline, but they are smaller products. Some of them contain Paragraph IVs, some are first-to-market opportunities. But at this point in time, we're not going to disclose them, because we're not going to place ourselves at a competitive disadvantage.

We're going to continue with our 505(b)(2) strategy. We are -- we're doing very nicely with our potassium liquid product. We're starting to build momentum with our potassium powder product. Vasostrict continues to perform, the injectable portfolio continues to perform. And as I indicated before, our strategy as we pick our R&D pipeline targets for the generic sector, we are going to continue to fund more opportunities into the injectable hard to manufacture category. And we're going to continue with our modified release solid oral dosage approach, whereby we are hoping that we'll get less competition.

Operator

Thank you. Our next question is from Donald Ellis of JMP Securities.

Donald Ellis - *JMP Securities - Analyst*

Thank you, and good morning. A couple quickie questions. First of all, can you give us a break down in the quarter of Duputren's versus Peyronie's? And then can you also explain to us, are you getting -- is the reimbursement landscape improving for BELBUCA? And then it looked like there was a draw down in overall corporate (inaudible) inventory in the quarter. Would you be able to quantify that? Thank you.

Paul Campanelli - *Endo International PLC - President & CEO*

Okay. So Don this is Paul. I'm going to pass the first question on XIAFLEX, the break down between PD and DC over to Joe. He also can talk a little bit about BELBUCA.

Joe Ciaffoni - *Endo International PLC - President, Endo Pharmaceutical*

Yes, thanks for the question, Donald. From a XIAFLEX perspective, the break down of Duputren's and Peyronie's is essentially 50/50. When you look at BELBUCA reimbursement, the best way to think about it is from a commercial perspective. We generally have broad availability in line to the label, and where we are working on improving the reimbursement is both in Medicare and Medicaid.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

In terms of the inventory question, we already talked about XIAFLEX. From a generic standpoint, we did see some destocking in the quarter. So at the end of the quarter, we saw destocking of approximately 2 days, and that was worth about $10 million.

Donald Ellis - *JMP Securities - Analyst*

Thank you very much. Appreciate it.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Kristi, can we move onto the next question, please?

Operator

Our next question is from Liav Abraham of Citi.

Liav Abraham - *Citigroup - Analyst*

Good morning. Can you just remind us of the pushes and pulls in cash flows, in free cash flow outlook in 2017 versus 2016? And then also of your incremental debt capacity, before you hit your covenants? Thank you.

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, Liav, hi, this is Paul. I'm going to pass that question on the free cash flow over to Blaise.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes, sure. So in 2017, as we said in our scripted remarks, again as we're conducting this strategic assessment that Paul is undertaking, and for some of the other dynamic environment issues we talked about, we're not going to be providing any forward-looking comments for 2017, either from a P&L or a cash flow standpoint. In terms of your question on covenants, right now, just to remind you, we do have two maintenance covenants on our secured debt which is our term loans A and B and our revolver. And so, our secured leverage covenant is less than 3.85 times adjusted EBITDA, and we're currently at 2.1 times. And we also have an interest coverage covenant, which that is that the covenant is greater than 2.5 times, and we're currently at 3.8 times.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Kristi, can we go on to the next questions, please?

Operator

Stephan Stewart of Goldman Sachs, your line is open.

Stephan Stewart - *Goldman Sachs - Analyst*

Good morning, guys, and thanks for the questions. Just wanted to follow-up on this pipeline question. Without disclosing product opportunities, are you confident that the pipeline has enough to offset the base erosion and the eventual competition on Seroquel and Zetia to drive overall growth for the generics business beyond first half of 2017?

Paul Campanelli - *Endo International PLC - President & CEO*

Again, I think right now, we're going to come back in February of 2017, and we'll be able to add a little bit more color in that regard. Clearly, there are some headwinds on base erosion. We don't want to -- we do want to underscore that there's been some challenges. But ultimately I'm going to point right back to the 505(b)(2)s and products like Vasostrict and adrenaline have served us well. But Stephan, I think right now what we're going to do, is come back in the February time frame and provide a little bit more color.

Stephan Stewart - *Goldman Sachs - Analyst*

Thanks. Just one follow-up on the DOJ investigation. I guess, how confident are you that it's ring-fenced around the products mentioned, versus being just a start of something broader?

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, again, Steve, I'm not going to comment on the DOJ, in my opinion on the DOJ investigation. I think right now what I communicated earlier are statement of facts. We don't sell one product, and we didn't take our price up on Digoxin, and I think that's our position.

Stephan Stewart - *Goldman Sachs - Analyst*

Great. Thanks for the questions.

Operator

Thank you. Our next question is from Andrew Finkelstein of Susquehanna.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Andrew, you may be on mute. We can't hear you. Kristi, why don't we move to the next, and Andrew if you -- (multiple speakers).

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Oh, hi. You got me?

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Oh, here we go, yes.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much. Thanks for taking the question. I was just hoping specifically on the outlook for Vasostrict, how you're thinking about pricing going forward over the next year? Thanks.

Paul Campanelli - *Endo International PLC - President & CEO*

Sure. I think our price -- we want to think of ourselves as rational players in the current pricing environment. So I think the way we would be looking at this is that we have the product positioned where we need it to be. And anything that we consider on a go forward basis would be more mindful and thoughtful of the current environment. I think that's probably the best way I would characterize our pricing strategy on Vasostrict.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

And nothing to suggest pressure relative to the kind of net pricing or volume you're seeing now?

Paul Campanelli - *Endo International PLC - President & CEO*

I'm not sure I understand what you mean by o[n] pressure?

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

I mean, absent a competitor, you're not -- you would expect the gross to nets to be comparable to how they exist now?

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, right. It's status quo.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Yes, thanks very much.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thank you. Kristi, can we take the next question, please?

Operator

The next question is from Gary Nachman of BMO Capital Markets.

Christ Wolpert - *BMO Capital Markets - Analyst*

Hi, this is actually Chris Wolpert on for Gary. I just wanted to maybe get a little bit more clarity around the other branded revenues? That was a pretty good percentage of US brands, so if you could go into some of those pieces?

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, okay. Sure. So we'll pass it over to Blaise.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes, so Chris, just in terms of the other branded revenue, just in terms of the quarter again, we did have better expectations or performed better than our expectations. A couple products in there that performed well, Testim and Testim AG performed well, and our Fortesta franchise played -- performed well.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Great, thank you. Kristi, can we move to the next caller, please?

Operator

Thank you. Our next question is from Annabel Samimy of Stifel.

Esther Hong - *Stifel Nicolaus - Analyst*

Hi, this is Esther in for Annabel. I just wanted to get your thoughts on divestments, have you made any further decisions on the direction you're going to go? Thanks.

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, sure. Right now, we haven't made any clear decisions on monetizing any assets right now. I mean, what we're doing here is my first 30 days or so, where we are -- we're assessing our businesses, and we're assessing -- when I say our business, that includes the brand and international and the generics business, we're looking at all components, and all our assets. And frankly at this point in time, we're putting together a strategy plan, and we will come back. But at this point in time, there's been no decisions to divest any asset. And we're -- as we get closer to our February earnings

call, we will provide more color, whether this is something that we will be considering. But at this point in time, there has been no movement on divesting any assets.

Operator

Thank you. Our next question is from Sumant Kulkarni of Bank of America.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Good morning. Thanks for taking my questions. Both are fairly bigger picture strategic ones for Paul. We know you have base business and the -- your erosion in the base business seems to be trending higher than you'd forecasted. At what point, do you think that erosion could also start affecting sterile injectables and alternate dosage forms? And secondly given, that Par does not have, or Endo does not have a biosimilar strategy now do you think your R&D spend is appropriately focused to get the best possible use of the opportunities that are out there on small molecule generics?

Paul Campanelli - *Endo International PLC - President & CEO*

Yes, so the first question, in terms of the erosion, in terms of on the injectable side. So I think right now, I'll start with the erosion factor on the injectables. So clearly, it's an area that other companies are starting or trying to break into, but Sumant, I think one of our advantage is, and I said this repeatedly, I think it is a good time for Endo to have a sterile injectables facility on US soil. I think that separates us from the competition.

So I'm seeing a lot of quality compliance issues with our competitors. I'm seeing a lot of back order issues and I think this gives us an advantage. And also I think having a facility on US soil with the R&D team and the manufacturing and quality teams that we have, I think that's an advantage for us. When I look at our product launches, we are always first-to-market in our categories in which we choose to play. And I think that provides a good set point for us as we move forward, and ultimately execute on our GPO contracts. So once we do that, we're holding the contract, and it's ours to defend. I think that differentiates us.

Regarding the question on biosimilars, I know we'll come back -- and I've missed one. But the questions on the biosimilars, while maybe that's not a primary strategy of Pars today, an area that we have focused in on and I'm not going to get too deep into it, but we are focusing on polypeptides. That is challenging chemistry, and I think that's going to start to set us apart, and that's going to leverage our capabilities, both on the internal R&D side, partnerships we've established, and taking advantage of the Rochester facility. And I apologize, I think I missed maybe your first question?

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

It was just on the R&D side, on small molecules, do you think you're appropriately funded right now, or would that require any kind of bolstering going forward?

Paul Campanelli - *Endo International PLC - President & CEO*

So we are evaluating our capital allocation, in putting some more resources behind generic R&D. So that's something that we are considering, and we again will communicate in the February time frame. What we are doing is focusing on those harder to make products, and whether they are topicals, creams, ointments, ophthalmics and things that may take smaller clinical trials. So that to us is an area that we have the skill set with our teams in place, and it's something we're starting to do well. That coupled with our Paragraph IV strategy, I think places us in a position to deliver higher value generics on a go forward basis.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Thank you. (multiple speakers)

Operator

Our next question is from Gregg Gilbert of Deutsche Bank.

Greg Fraser - *Deutsche Bank - Analyst*

Thank you. It's Greg Fraser on for Gregg Gilbert. I think that you mentioned you expect the generics base business to decline in the low 30% range for 2016. I just want to make sure that's what you had said? And if so, what were pro forma sales for generics base in 2015 that, that erosion would be off of?

Paul Campanelli - *Endo International PLC - President & CEO*

So what we said was our full year base erosions now in the low [30s] percentage, so that's what we've communicated. And just give us a second, and we'll get you that.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes, the pro forma base business in 2015 is [17 52].

Greg Fraser - *Deutsche Bank - Analyst*

Great. That's helpful, can you also give us a sense of how much contribution from generics launches is factored into the guidance for Q4?

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

For this year?

Paul Campanelli - *Endo International PLC - President & CEO*

I'm sorry, can you repeat that question?

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Yes, just trying to get a sense of how much contribution from new generic launches in 4Q is factored into your full year guidance?

Paul Campanelli - *Endo International PLC - President & CEO*

Well, we have Zetia and Quetiapine. So have we given that number because we --?

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

You've given it for the second half, the launches.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

(multiple speakers) Yes, o we're saying that number, so sorry Paul. The second half launches is a number we communicated before, which includes Quetiapine and Zetia, and that's around $425 million. And there's a range around that, but sort of in the mid point.

Paul Campanelli - *Endo International PLC - President & CEO*

But the $425 million was the total.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

That's total, all-in, yes.

Greg Fraser - *Deutsche Bank - Analyst*

Okay. And just a couple quick ones, did you book any sales for BELBUCA during the quarter? And on mesh, has your pretax cash call estimate for 2017, which I think was $550 million to $650 million, has that changed? Thank you.

Blaise Coleman - *Endo International PLC - SVP of Global Finance Operations and Interim CFO*

Let me take the mesh question first. In terms of how we look at that for 2017, let me just give you an update. So right now at the end of the quarter, we have $1.2 billion accrued from the balance sheet. We have about $300 million in restricted cash. So that leaves about $900 million of liabilities still to be serviced. We would expect about $300 million to be paid in Q4. And then, the balance of that to be paid in 2017, fairly evenly over the first three quarters of 2017.

In terms of modeling any sort of cash benefit or shield around that, we recommended and continued to that from a modeling standpoint, to model our cash tax rate as a percentage of adjusted income at the enterprise level, and our guidance previously still stands, which is in the low single-digits.

Joe Ciaffoni - *Endo International PLC - President, Endo Pharmaceutical*

And with regards to BELBUCA, we booked low single-digit millions.

Greg Fraser - *Deutsche Bank - Analyst*

Great, thank you.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, Greg. Can we have the next question, please?

Operator

Our next question is from David Amsellem of Piper Jaffrey.

David Ansellem - *Piper Jaffray - Analyst*

Hi, can you hear me?

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Yes, we can, thanks, David.

David Ansellem - *Piper Jaffray - Analyst*

Okay, thanks. So just wanted to drill down on the potassium products and the opportunities there. And really specifically, a couple questions there, is how should we think about the size of the opportunity relative to Vasostrict? I know Paul, that you said it's smaller, but what's the right way of thinking about it in terms of orders of magnitude smaller? And then, how should we think about the competitive dynamics, that product, just trying to get a sense of how important that is in terms of a 2017 contributor? Thanks.

Paul Campanelli - *Endo International PLC - President & CEO*

All right, so first of all, it is an important contributor for 2017, and I think the easier one for you to understand is right now, there's two forms. There's a liquid form, and there's a powder form. The liquid form, you can easily go to IMS data and calculate the units there. We have in essence, converted the entire market. Maybe if I say the entire market, it's probably in the very high [90%s]. So what I'm politely saying is that we've executed, and all of the unapproved sources have been off the market for a couple of months. So that to me is running nicely.

But there's no barrier-to-entry, so you just have to be aware that an ANDA can be filed, and that product has been approved since I believe around 2014. So, you just got to make an assumption at some point a company that has liquid capabilities can enter the market. The powder is the one that probably has created the most questions, because there's so many different forms of powder. And I think in terms of sizing that, and I think that it safe to say that we -- it's probably easier for us to communicate the number of packets in the market, and then you can go back and do the math. In essence, this is an 18 million pack market, right?

And they're broken into 30s and 100s. I would tell you that's probably irrelevant, but for your math -- go back, you're using 18 million packets. And then you can look at standard single source type generic pricing wallets of 505(b)(2). I would make the assumption that it's a single sourced highly genericized type product. That's the way I would think that you should look at the powder.

Now having said that, there are still pull through of unapproved sources. So the unapproved sources were asked to exit the market back in the June time frame, and I believe that they had two months to [reduce] product, and three months to sell-through product. So there's going to be a period of time where it's probably going to take us to Q1 before we see that conversion. So I think those are your levers, in order to calculate the powder opportunity.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, David. Kristi, I think we have time for one more question.

Operator

Douglas Tsao of Barclays.

Douglas Tsao - *Barclays Capital - Analyst*

Hi, good morning. Thanks for taking the question. So Paul just curious, when you think about your expectations for Zetia and Seroquel, those launches which are obviously very important for fourth quarter. If we just think about some of the generic conversions we've seen recently, brands have been retaining 60%-plus, until these products have gone multi-sourced. So just curious in terms of your confidence, that those will pick up traction as much as you want? And then also, just if you could provide some comment, if I look at the IMS data, didn't get much traction with the Crestor product launch. Just curious if you have any sort of perspectives on what might have happened there? Thank you.

Paul Campanelli - *Endo International PLC - President & CEO*

So Crestor is probably the easier one. I mean, I think there's about 11 approvals on, I would say that second tranche. So I believe Actavis came in, with maybe five week head start based upon a settlement agreement. And then about maybe 9 or 10 companies followed on. So the reality is that while it was a large product, it was -- there was an awful lot of competition. And we had a short burst, and at the end of the day, pricing fell to probably somewhere around 98.5% to 99% off a brand WAC. And again, that's an area we don't want to compete. That was a decision that was made many, many years ago, and the market dynamics changed in that regard.

On Quetiapine, Quetiapine launch is behaving as we expected, so I feel pretty confident about that product on a go forward basis. The product launch came out on November 1, and we've already taken on around 96% to 97% of the market in term of signing on accounts. So it's behaving as we expected. Then in the case of Zetia, the reference that you're making in terms of brand retention, we've taken our -- what we believe is an appropriate approach to the fact that perhaps the brand could retain some percentage based upon maybe some PBM contracts.

So that's been taken into consideration. I think what's maybe important is in this particular product, about 88% of the product is handled through the retail chains. I think that's an important factor. So we feel pretty good about how this product is going to behave, and we've taken in generic conversion, in terms of what I think is appropriate. So I feel good about where Zetia will head. No guarantees, but I feel good.

Douglas Tsao - *Barclays Capital - Analyst*

Okay, great. Thank you very much. That's helpful, Paul.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, Doug.

Operator

Thank you, and that concludes our Q&AA session for today. I'd like to turn the call back over to Keri Mattox for any further remarks.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thanks, Kristi, and thank you all for joining us. I'll turn it over to Paul to close out the call.

Paul Campanelli - *Endo International PLC - President & CEO*

Thanks, Keri. I mean, as I said this is really an important time for Endo, and we do appreciate your continued interest, and support of the Company, and we look forward to provide you with updates as we move forward. Thank you for joining us for today's call, and we will see you back at our February earnings call. Thank you all.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program, and you may all disconnect. Everyone have a great day.
