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ENDP - Q2 2017 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 2Q17 GAAP net loss from continuing operations of $696m and GAAP diluted loss per share from continuing operations of $3.12. Expects full-year 2017 revenue to be $3.38-3.53b and reported diluted GAAP loss per share from continuing operations to be $4.76-4.46.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q2 2017 Endo International Earnings Call. (Operator Instructions) As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Mr. Stephen Mock, Senior Vice President of Investor Relations and Corporate Affairs. Mr. Mock, you may begin.

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

Thank you, Jimmy. Good morning, and thank you for joining us to discuss our second quarter 2017 financial results. Joining me on today's call are Paul Campanelli, President and CEO 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 morning, 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 morning.

That said, I'm pleased to report a very solid quarter of operating performance with impressive contributions from key areas of each of our business units as sterile injectables, Branded Specialty Products and Paladin achieved double-digit growth in the second quarter. This performance is the result of strong operational execution in our core areas of focus on future growth.

Before we begin to discuss our second quarter performance in greater detail, I'd like to take a couple of minutes to touch on recent events over the last few months.

As you're well aware, we were requested by the FDA to remove reformulated OPANA ER from the market in early June. While we were disappointed by this request, after careful consideration, we decided the most constructive path forward was to voluntarily withdraw reformulated OPANA ER from the market. We plan to cede shipments to customers by September 1, 2017, in order to provide enough time for physicians and patients to evaluate treatment options. Yesterday, the company announced that it reached agreements to resolve virtually all known U.S. mesh product liability claims.

Beginning in the second quarter of 2017, we aggressively executed a settlement strategy in connection with Endo's mesh litigation. We believe that these efforts, which include global resolution with all key plaintiff attorneys, case management orders issued by courts overseeing mesh cases and our goal of having additional orders entered by other courts, our decision to stop selling mesh products in March of 2016, settlements recently entered into by other mesh manufacturers and the corresponding decrease in attorney advertising as well as the continued running of statutes of limitations, will collectively deter future filings. Importantly, we believe these actions will assist most mesh claimants to move forward with their lives and permit Endo to move forward with an even greater focus on executing against our core strategic priorities. We increased our mesh liability accrual by $775 million in the second quarter, which is expected to cover approximately 22,000 U.S. mesh claims subject to a claims validation process for all resolved claims as well as all of the known international mesh claims in other mesh-related matters. I'll let Blaise address this more fully as he discusses our financial performance.

In February, we told you that among Endo's key priorities were reshaping our organization for success and driving margin expansion. In recent months, we made the hard decisions that we believe were necessary to better position our company for future success. Last month, we completed the sale of Litha Healthcare Group in addition to announcing the planned divestiture of Somar, which we expect to close at the beginning of the fourth quarter this year. In divesting these noncore assets, we can better direct resources and attention to those areas of our business that we've identified as our core areas of future growth. These areas include our Branded Specialties Product portfolio that includes the promising potential of collagenase clostridium histolyticum also known as CCH for cellulite and a generics business with more differentiated capabilities and products such as sterile injectables. Also last month, we announced our intention to close our Huntsville, Alabama manufacturing and distribution facilities over the next 12 to 18 months. While this decision was not an easy one, it was necessitated by declining volumes of commoditized products that affected the Huntsville location. We expect to transfer majority of the products to other sites while discontinuing approximately 15 products, starting in the fourth quarter of 2017 and continuing through 2018. This restructuring is intended to better match manufacturing capacity to projected future demand.

Now I'll turn to our second quarter 2017 earnings presentation. Beginning on Slide 2. Here's a brief agenda for today's call.

Moving to Slide 3. Again, we're very pleased with our second quarter operating performance. Our focus on hard to produce products in our generics division, growth in our Branded Specialty portfolio as well as cost savings from previously announced restructurings drove strong adjusted EBITDA and solid adjusted EPS. Based on all the news announced year-to-date, we are updating our guidance to reflect the withdrawal of OPANA ER, the sale of Somar as well as the restructuring of all of our manufacturing network. Blaise will discuss our financial guidance in greater detail later in our presentation.

Moving to Slide 4. You will see a snapshot of our segment revenues for the second quarter. Our U.S. generics and international segments were virtually unchanged from prior year, while U.S. Branded revenue declined due to continued generic competition impacting the Branded Established Products portfolio. However, the overall revenue decline was partially offset by strong sales of higher-margin products in our sterile injectables and Branded Specialty portfolio as well as new launch revenue.

Now moving to Slide 5. As I just mentioned, our generics business was virtually unchanged versus prior year. Despite significant decline in our base business, sterile injectables in new launches and alternative dosages grew 27% and 70%, respectively. Sterile injectables was driven primarily by the continued growth of VASOSTRICT as well as the strong performance of ADRENALIN in the quarter. VASOSTRICT sales were $96 million, a 24% increase versus prior year. As I mentioned last quarter, unapproved sources of ADRENALIN were expected to exit the market. As residual unapproved inventory in the trade channels has declined, we're beginning to gain additional market share for the product, with net sales for ADRENALIN reaching $19 million in the quarter. Based on our strong year-to-date performance, we now project full year sterile injectable revenues growth in the low to mid-20% range.

The strong performance of new launches and alternative dosages was driven primarily by ezetimibe in addition to continued uptake of potassium chloride liquid and powder in new sterile injectable launches. Our base generics business declined approximately 34% compared to second quarter 2016, which is in line with the guidance we provided in February. The decline in the second quarter was driven in part by the annualization of 2016 competitive events as well as product discontinuations. Price erosion in the second quarter continued to be in line with our expectations. As guided previously, we expect our base business to decline in the low 30% range and continue to expect our total generics segment to decline in the high single to low double-digits percentage range in 2017. We continue to expect adjusted gross margin improvement versus prior year, driven by the favorable shift in product mix and the benefits of our manufacturing restructuring initiatives. We expect our generics adjusted gross margin to be in the high 50% range.

Turning to Slide 6. Par launched 9 new products and made 6 regulatory submissions year-to-date. We continue to expect more than 20 launches and approximately 20 regulatory filings in 2017. We launched neostigmine for injection in May, and we plan to launch vigabatrin for oral solution during the third quarter.

To provide a little color on our pipeline, we currently have approximately 110 ANDAs with the FDA, and about 1/3 of them are either first-to-file or first-to-market opportunities. We continue to be extremely excited about our generics portfolio and how it's becoming a more differentiated portfolio.

Turning to our U.S. Branded Pharmaceuticals on Slide 7. We continue to see strong growth across our specialty portfolio with a 16% increase overall driven by our flagship brand, XIAFLEX, which grew 18% and SUPPRELIN LA up 11%. As expected, second quarter performance was more than offset by continued generic competition impacting the Branded Established Products portfolio, including VOLTAREN Gel, LIDODERM and OPANA ER as well as the third quarter 2016 divestiture of STENDRA. As mentioned earlier, we decided to voluntarily withdraw reformulated OPANA ER from the market. Again, while we are disappointed by this result, OPANA ER was a declining asset and a small part of the Endo portfolio, representing a little under 4% of 2016 revenues.

Earlier this week, Endo entered into a settlement agreement with Impax Labs regarding the original formulation of OPANA ER. As part of that settlement, Endo will receive a royalty rate that splits Impax's gross profits for its sales of oxymorphone hydrochloride ER products beginning on January 1, 2018. We believe this settlement fairly balances Impax's efforts for making and selling the generics and Endo's efforts in developing OPANA ER. We're pleased to be able to execute on this option, settle our litigation and to realize the value of our intellectual property.

We continue to expect our full year Branded Specialty Products and XIAFLEX revenue to grow in the high single to low double-digits range.

In terms of overall branded revenue, we now expect it to decline in the mid to high teens percentage range year-over-year based on continued generic competition and the withdrawal of OPANA ER. Adjusted gross margin for our branded segment is expected to remain in the high 70% range.

We are extremely pleased with the performance of our specialty products and will continue to invest in additional initiatives to grow that portfolio. We intend to initiate Phase III studies in cellulite toward the end of 2017. CCH has demonstrated very encouraging Phase IIb results, and we are excited to move this promising drug forward into pivotal trials.

Now moving to Slide 8. Let's address International Pharmaceuticals. Second quarter international revenues of $67 million were virtually unchanged compared to the same period a year ago. Paladin's second quarter performance increased 10% due to uptake on Nucynta and XIAFLEX in addition to delayed generic competition on certain established products. A divestiture of Litha closed in early July and the previously announced divestiture of Somar is expected to close at the beginning of the fourth quarter of this year.

In 2017, we now expect international revenues to decline in the low 20s percentage range, reflecting the sale of Somar in the beginning of fourth quarter. We had previously assumed Somar revenues for all of 2017.

Now let me turn the call over to Blaise Coleman to further discuss the company's second quarter financial performance and provide more detailed 2017 financial guidance. Blaise?

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

Thank you, Paul, and good morning, everyone. First, on Slide 9, you will see a snapshot of the second quarter GAAP and non-GAAP financial results. Paul covered company and segment revenues earlier, so I will not review that again.

On a GAAP basis, we had a diluted loss per share from continued operations of $3.12 in the quarter versus diluted earnings per share from continuing operations of $1.75 in the second quarter of 2016.

GAAP net loss from continuing operations in second quarter 2017 was $696 million compared to GAAP net income from continuing operations of $390 million during the same period in 2016. These results are primarily due to the total combined pretax noncash asset impairment charges of $725 million the company recorded in the second quarter, including $501 million of non-restructuring goodwill and intangible asset impairments related to our U.S. Generic and Branded Pharmaceuticals segments, which included the planned market withdrawal of OPANA ER, $115 million of goodwill and other intangible assets related to the planned sale of Somar and $90 million related to intangible assets and property and plant equipment associated with our recently announced planned closure of the company's Huntsville, Alabama manufacturing distribution facilities.

The 2016 GAAP net income from continuing operations included the recognition of certain net tax benefits. On an adjusted basis, second quarter results were solid. Adjusted net income from continuing operations of $207 million and adjusted diluted earnings per share from continuing operations of $0.93 both increased 8% versus second quarter 2016, primarily due to improved adjusted gross margin and lower adjusted operating expenses.

Turning to Slide 10. Let's discuss our recently announced manufacturing restructuring. On July 21, we announced our intention to close our Huntsville, Alabama manufacturing and distribution facilities over the next 12 to 18 months. As part of the manufacturing restructuring, we will be transferring most products to other locations and discontinuing approximately 15 products. We expect these product discontinuances will begin in the fourth quarter of this year and continue throughout 2018. We expect a reduction in our generics-based business revenue of approximately $10 million to $15 million in 2017 and approximately $60 million by the end of 2018. Operating savings, net of revenue reduction, is expected to be approximately $5 million to $10 million in 2017 and $55 million to $65 million cumulatively through 2018. We intend to reinvest these savings in our core growth -- core areas of future growth as we initiate Phase III studies for CCH in cellulite, drive continued growth of our own market XIAFLEX indications and further invest in our generics new product pipeline. Of the approximate $325 million of onetime estimated charges associated with this restructuring, approximately $109 million of charges were recognized in the second quarter of 2017.

Moving to Slide 11, on the mesh litigation settlements. Paul already discussed, we have reached agreements to resolve virtually all known U.S. product liability claims relating to the transvaginal mesh products sold by Endo's AMS subsidiary. As to the financials, in the second quarter 2017, Endo recorded a $775 million mesh product liability charge, reflecting an estimate for the expected future payments related to the resolved U.S. mesh product liability claims, the small portion of known unresolved U.S. claims and all of the known international mesh product liability claims and all other mesh-related matters. As of June 30, 2017, the mesh liability accrual was approximately $1,295,000,000 with $359 million in the Qualified Settlement Funds, leaving approximately $935 million to be paid into Qualified Settlement Funds. We expect to pay approximately $160 million to $185 million into the Qualified Settlement Funds or directly to plaintiffs during the second half of 2017, with the remaining payments into the Qualified Settlement Funds continuing through the fourth quarter of 2019.

This brings us to our guidance slide on -- Slide 12. We're updating our full year 2017 revenue, adjusted EBITDA and adjusted diluted EPS financial guidance to reflect the sale of Somar, the OPANA ER market recall and the discontinuation of products associated with our recently announced manufacturing restructuring. We lowered the revenue guidance range by $70 million and now expect the range to be $3.38 billion to $3.53 billion. Reported diluted GAAP loss per share from continuing operations are projected to be between $4.76 and $4.46, reflecting additional impairment and restructuring charges. We're updating adjusted diluted earnings per share from continuing operations to range between $3.35 and $3.65. And adjusted EBITDA from continuing operations to be between $1.48 billion to $1.56 billion, which is lower than our previous guidance by $0.10 and $20 million, respectively. The impact of the lower forecasted revenue on adjusted EPS and adjusted EBITDA guidance has been partially offset by lower full year operating expenses.

The company's financial guidance is based on the assumptions that are on this slide.

From a phasing perspective in the second half, we expect approximately 50% of our total enterprise second half revenue and approximately 45% of our second half adjusted diluted earnings per share from continuing operations to be realized in the third quarter. We continue to expect approximately $15 million in net cash tax receipts in 2017.

Lastly, in terms of our projected cash flow on Slide 13, we had $119 million in cash flow prior to debt payment in the first half of 2017 and now expect the full year 2017 cash flow, prior to debt payment range, to increase to $265 million to $345 million. This increase is primarily due to the expected proceeds from the sale of Somar, partially offset by additional mesh payments, higher restructuring payments and lower EBITDA, mainly due to the planned withdrawal of OPANA ER. We continue to estimate our ending net debt to adjusted EBITDA leverage ratio to be in the high 4x range at 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, this was a very solid second quarter of operating performance for Endo. This also was a very productive quarter at our company. During the past several months, we've taken decisive actions that we believe will reshape our organization to better position it for long-term success. These actions required us to make some very difficult decisions. Nevertheless, we remain steadfast in our commitment to follow through on the strategy that we laid forth earlier in the year. As you know, the generics industry is facing some significant challenges that had been recently highlighted. I firmly believe that our company is as well equipped as any to weather these headwinds. Our management team recognized these challenges early, as we communicated to you in early 2017, and have been taking proactive steps to put ourselves in a better position to address the challenges going forward. I am confident that we have the experienced leadership team in place to map our path forward, and I thank them for their commitment to Endo's future success.

I would especially like to express my gratitude to all our Endo colleagues for their tireless efforts to reshape our organization for success and to thank our shareholders for their continued support.

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) Jimmy, may we have the first question, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) First question comes from Liav Abraham of Citibank (sic) [Citigroup].

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

A couple of questions. Firstly, Paul, you alluded to this in your closing remarks, but perhaps you can talk a little bit more about what you're seeing in the U.S. Generics pricing environment. There were some cautious comments made by one of your peers last week. I noticed that you haven't changed your pricing assumptions. So is this just something that you'd better anticipated than your peer? Any thoughts there would be helpful. And then secondly, on your settlement on mesh. Congrats for closing this out. Just a couple of clarifications. The amount that you -- the settlement amount that you announced, is this a posttax amount or pretax? I assume it was pretax, so what would the tax shield be on that? And I also noticed that the number of claims covered by the agreement that was announced yesterday of 22,000 was a lot higher than what was disclosed in Q1 of 10,500. So was this just a significant step up in the number of new claims in the recent past few months?

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

So I'll take the environment question, then I'll talk a little bit about the increase in claims to 22,000, and Blaise will talk a little bit about your financial question. So regarding the pricing environment, the reality is, I don't have a material update to really opine on. And I would view that as a good thing because what we communicated very early in 2017 was we spoke about the headwinds, we spoke about the impact of ClarusONE. And I think it's important that as we saw this come to fruition with Walmart joining ClarusONE, we built it into our guidance. So from a base erosion standpoint, we gave our range, we gave our views, and I think we're pleased to say that, ultimately, what we communicated came to fruition. So there's really no surprises in the quarter. So that's probably about as far as I can take it. I don't really view -- specifically, there's been a lot of questions going around about ClarusONE. I don't really view it as a win or a loss. It's just in line with what our expectations were, and we built it into our forecast and our plan. Regarding the mesh update in terms of the increase from 10,000 to -- 10,500 to 22,000, the starting point was, is when I was asked to take over as CEO in late September and early October, it took me a period of time to evaluate the current strategy that Endo was pursuing. And then after careful consideration, looking at where we're heading in terms of looking at this for a series of years, looking at -- opining with internal and external counsel, as you know, we made some disclosures early in -- I guess, mid to late second quarter, probably be a better way that we disclosed at that period of time, that there was approximately 10,500 claims that had been filed or asserted or that we believe that were more likely to be filed or asserted. And that was our starting point. However, later in that period of time, we did change our strategy. I got closer involved, and we had an opportunity to meet with private plaintiffs, and we started to negotiate. At that point in time, we received more information that we do not have early in that period of time. And we learned a lot more about unfiled claims that totaled approximately 22,000 claims. So we had to make a business decision. We look at where the company was headed, we were looking at distraction, we were looking at the amount of time that we were investing into resolving the mesh claims. So at that point in time, we looked at the number of claims, and we negotiated to this -- the $775 million accrual. And we view this as an inflection point for the company. So while it was a difficult negotiation, we are now moving forward as a company. We're focused on operational execution, and we can focus on our business. So with that, I'll pass it over to Blaise and he can talk a little bit of the financial aspect.

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

Sure. So just in terms of the pre and posttax question, just as a reminder, as we've previously discussed, one really needs to model taxes at a total enterprise level. So as we said, for 2017, we expect to be in a net tax cash receipt position of $15 million. And for modeling purposes, for 2018 and

'19, we're providing a range that our cash taxes paid will be between $15 million and $30 million at a total company level, and that would obviously include everything, including the mesh payments that are new here that we'll have in '18 and '19.

Operator

Our next question comes from Greg Fraser from Deutsche Bank.

Gregory Daniel Fraser - *Deutsche Bank AG, Research Division - Research Analyst*

It's Greg Fraser on for Gregg Gilbert. First on the Impax deal. Is there any outstanding patent litigation on the old OPANA ER? I'm just curious how you're thinking about the durability of Impax's generic.

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

There's no outstanding. The short answer is there's no outstanding litigation or liability.

Gregory Daniel Fraser - *Deutsche Bank AG, Research Division - Research Analyst*

Okay. And on OPANA ER and the guidance, can you just help with how much is factored in, in the second half into your guidance?

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

We have -- Greg, we have 2 months of sales for OPANA factored in.

Gregory Daniel Fraser - *Deutsche Bank AG, Research Division - Research Analyst*

Okay. And then just a couple of other quick ones. How do we think about the cost and duration of the XIAFLEX cellulite study? And then can you help would how to think about the sales potential for ADRENALIN once all the unapproved products are off the market?

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

You take the XIAFLEX -- go ahead. The XIAFLEX question was on the -- okay -- I'm sorry, Greg, just -- could you repeat your question on the XIAFLEX cost question?

Gregory Daniel Fraser - *Deutsche Bank AG, Research Division - Research Analyst*

Yes. Just -- how should we think about how long the studies will last and how much they will cost?

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

Okay, so...

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

Yes, all right. I mean, at the end of the day, we are still evaluating -- negotiating with the FDA on the protocol, so I don't think can technically disclosed the entire R&D budget, so you're going to have to be a little patient in that regard. The duration of the study is about 1 year. But again, that's subject to negotiation with the FDA. That should give you a little bit of the goalpost on the duration.

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

And ADRENALIN.

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

And the ADRENALIN question, in terms of the sales, we disclosed -- I think our run rate was about $19 million for the quarter. So we've got about 50% share. We're building momentum as you're starting to see the unapproved source inventory start to kind of drain out of the trade. You're seeing the uptick there, and we're moving to about 50% of share. And as I said, we did about $19 million in sales for the quarter.

Operator

Our next question comes from Andrew Finkelstein of Susquehanna Financial.

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

I was hoping -- this may be a repeat, but can you talk a little bit more about the impact of the ClarusONE consortium and the visibility you have in guidance for the pricing across the portfolio? And then any views, updates on the testosterone litigation in view of the verdict there was for AbbVie and how you're thinking about managing those cases going forward?

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

Okay, so Andrew, I'll probably start with the testosterone litigation. So I mean, it's very early. And I think the policy here is that we're not going to comment on current litigation. So while we are well aware what the verdict was in the first trial against AbbVie, at this point in time, we just -- we are not going to be able to opine now. That said, what we do -- what we have communicated is there's just slightly under 1,300 cases as of July 2017. That's currently pending against us, so this -- at this point in time, it's something that we think we can navigate through, but I think this is a very different type of case, and we're not going to be able to opine. Regarding ClarusONE, again, there's not much more that I can add, we forecasted, we communicated, when we said that our base erosion was going to be in the low 30% range, the component of the impact of the ClarusONE bid is part of that. We built that into our forecast. And I would say that we are, as we forecasted. Blaise, I'll turn it to you, if there's anything -- any color that you want to add, but I think it was pretty in line with what we forecast.

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

Yes. So Andrew, just to remind you, we had talked about, as part of that overall base erosion that Paul mentioned, low 30s, an element of that is normal-course annual pricing erosion. So when you strip out the product discontinuations and the prior year competitive events and we had said somewhere in the high single digits for price erosion. We continue to see that in terms of where we're tracking towards. And an element of that, we said sort of in the low to mid-single digits was related to the ClarusONE impact, and we don't have a change from that as we stand here today.

Operator

Our next question comes from Annabel Samimy from Stifel.

Andrew Abriol Santos Ang - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Andrew in for Annabel. Just a couple of questions. So can you talk about cash flow generation at this point with the settlement? And to what extent will you have any remaining flexibility to address balance sheet issues or pursue further investments in your own franchises? And second, can you provide us any update on your -- any other 505(b)(2) programs we might expect in the coming year? It looks like this is a big driver for generics franchise? And if I can sneak actually just one more in, do you need to consider strategic initiatives for brands at this time?

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

Okay. So I'll take the last 2. So again, on 505(b)(2) initiatives, we are always very cautious in what we communicate, right? So we don't want to place ourselves at a competitive disadvantage. But as part of our ongoing R&D development, we always have strategies whereby we can hopefully bring more 505(b)(2)s in place. And of course, some of these include intellectual properties and some don't. And I've repeatedly tried to differentiate these 2 that -- to talk about the difference between 505(b)(2)s that have intellectual property and don't. So I think right now, we're focused on our continued execution and protection of our ADRENALIN. And our VASOSTRICT, we always have a series of additional 505(b)(2)s that we work on, but we don't disclose because, as I said, we don't want to place ourselves at a competitive disadvantage. So as we progress and we have more that we can speak about, we'll be happy to do so. In terms of strategic initiatives, on the branded side, we are very excited about our businesses with respect to our urology franchise and our cellulite clinical trials. So it's strategic initiatives, and our view is we are very excited about these areas. We are looking to grow these areas. And the way I would look at strategic initiatives, if there was a mindful, thoughtful approach whereby we could expand in these areas, this is something that our business and corporate development teams would look into. But right now, we're laser-focused on debt reduction in executing on the cellulite R&D plan. With that, I'll pass it over to Blaise to talk about our cash flow.

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

Yes. So just in terms of cash flow, you can see from our guidance that we did increase cash flow prior to debt payment for the full year. If you were to use that and roll forward our cash, we're going to end somewhere, and take the midpoint of our cash flow guidance. We were going to add somewhere around $800 million of -- with unrestricted cash at the end of the year. And if you look at our mesh payments that we now have projected for 2018 and 2019, and you take the midpoint, it's somewhere around $760 million. So we'll be able to fund the mesh payments that are going to be coming due in '18 and '19 from cash on the balance sheet. That's our expectation. We're not going to provide any further guidance right now beyond 2017 in terms of future cash flow, but we'll obviously provide that update for 2018 when we give 2018 guidance.

Operator

Our next question comes from Marc Goodman from UBS.

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

Marc, are you there? Are you on mute, Marc?

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

Why don't we move on to the next question, Jimmy?

Operator

Next question comes from Randall Stanicky from RBC Capital Markets.

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

Paul, just a very basic, big-picture question. As generic approvals at the FDA continue to ramp, the consortiums are going to have more options to come back and press on price. And so, what breaks that dynamic? Do we need to see more companies, like Natco in its call this morning, talking about pivoting away from the U.S.? Or do you think we need to see more broad-based consolidation? How do we get comfortable that as we move into 2018, things start to stabilize? And then I have a follow-up for Blaise.

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

Yes, so I'll answer your question. I mean, at the end of the day, when you're seeing more -- you are seeing a fair number of approvals coming through. The challenge is that you're not seeing first-time generics, right? So you're getting a lot of additional approvals coming on, products that are already in the market. So that's the challenge. So I think you're starting to see one of the ways in which we're addressing it, right? So we're making tough decisions on our manufacturing network. I think if you are a large volume player in a commodities business, that's the challenge, right? So when you are also backward integrated and your pulling API facilities on large drug product manufacturing sites, you've got to be very, very careful because that's the challenge. And next year, we all know, we're going to have 3 consortiums that's going to represent around 90% of the buying and purchasing powers. So the challenge, as we see it here is, I don't think offshore is the answer. I think what we're highly focused on -- again, we keep on talking about differentiating, so we are looking to focus in areas of injectables, alternative dosage forms, but you also got to focus on your plants. You got to look at making tough decisions on sites and people. It's a challenging time, but you've got to focus on efficiencies. And I think that's something that, if you wait for the consortiums, you've got to be very careful because that train can leave the tracks. You've got to get out in front of the consortiums to make those tough decisions. I think you'll see more change coming in 2018 as you look at Eikon just becoming part of WBAD consortium.

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

I mean, this may be a naive question, but is there a need for a -- like a -- kind of broad-based pruning of portfolios across most of the manufacturers? And is that even possible, given some of the pushback from the consortiums?

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

I don't think so, Randall. I think -- I mean there's always going to be a need to some degree. The balance is going to be those who choose to provide the high volume products to deal with that through plant absorption versus the products that are profitable, right? And that's something that you've got to distinguish between yourselves in the U.S. and the ex U.S. companies that have backward integration into APIs. But to turn out product for plant absorption, in my view, is not a future strategy, right? That's not what we're about. So that's maybe a nuance that some -- that maybe some of the larger producers consider when they make decisions to move into that area. But on a go-forward basis, the Endo-Par strategy is to be differentiated. It's the focus on Paragraph IVs where we've been historically successful. We're looking at other ways in which we can market our products and in being out in front of the consortiums and understanding that these initiatives change as time goes by, right? So focusing on alternative dosages and injectables, we say that, but other companies move into that area as well. We need to keep on moving forward and thinking through our strategy and how we can better position ourselves against the consortiums. That's the way we look at it, Randall.

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

That's helpful. And Blaise, just a quick follow-up on SEROQUEL and ZETIA, the contribution in 2Q. Can you provide that? I know you'd said $275 million to $280 million for the year. I think $200 million of that was in Q1. And so is there a way to back into the 2Q contribution?

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

Yes. Listen, we had about a little over $50 million in sales on a combined basis for those 2 products in the quarter.

Operator

Our next question comes from Elliot Wilbur from Raymond James.

Young Min Lee

This is Lucas Lee in for Elliot. So as a follow-up to the dialogue around resolution of mesh litigation claims, understand that this resolves the vast majority of known and potential cases. But assuming there could still be some emerging cases, could you help us frame what the cap on liability is -- potential liability is? We're just trying to get a sense of how many patients ultimately used the mesh product and then how many of those have turned into claims?

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

Yes. So no, Lucas, we're not going to be able to quantify that for you. What you have to understand is the 22,000 that we disclosed is virtually all known claims. Now moving forward, what we've done is we've talked about things that have occurred and what we put in place to deter and I mentioned this in my opening comments, right? What's in place to deter the assertion of weak or meritless case, right? The sheer nature of having the CMO in place, the case management order, at the NDL level, and also having a case management order in the state of Minnesota, whereby that is the home state of AMS, that, in itself, is going to deter, again, weak or meritless cases, right? So there is a process in order to move cases forward. They end -- the CMO in itself is a deterrent of having mass [court] cases coming forward. So that's one component. You've got to recall that we stopped shipping and selling the product in Q1 of 2016. So you have a timing issue. You also have the statute of limitations that ranges state by state in the range of 2 to 3 and up to 6 years. But the bottom line is, is you have a statute of limitations. When you look at all of these components, I think we have positioned ourselves in a good place to move forward and away from mesh. So I hope I answered your question, Lucas.

Operator

Our next question comes from David Amsellem from Piper Jaffray.

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

David, you there? Okay. Can we have the next question please?

Operator

The next question comes from Louise Chen of Cantor Fitzgerald.

Brandon Richard Folkes - *Cantor Fitzgerald & Co., Research Division - Analyst*

It's Brandon Folkes on for Louise. On XIAFLEX, could you detail your plans to further accelerate this franchise? And what are you doing to optimize reimbursement here?

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

So we're planning for success. At the end of day, I don't think there's any surprises. Starting point, we'll talk about the on-market indications. We're very pleased with the growth that we've communicated. We are reinvesting. We've made tough decisions on our pain portfolio, but we're taking in and reinvesting into XIAFLEX for Peyronie's and for Dupuytren's. So more to follow. We've got a direct-to-consumer advertising campaign that we're hoping will show growth in the category towards the end of this year to certainly into early 2018. So from that standpoint, we're investing in the on-market indications. I think my comments with respect to cellulite is obvious. We are planning for success. We're excited about moving to Phase III clinical trials. So it's a clinical trial. And, as in any R&D program, there's always a degree of risk, but we had favorable results in Phase IIb. We had great interactions with the FDA, and we're continuing to move forward to Phase III towards the end of 2017. Regarding your question about reimbursement, I'm not going to disclose our strategy of pricing at this point in time. We are well aware of potential issues regarding the differences between prescription product and cash products. We're addressing that in due course and I think in the future, as we have solidified our plan, we'll come out and we'll communicate more, but we're planning for success on the R&D side.

Operator

Our next question comes from Gary Nachman from Bank of Montréal.

Ann-Hunter Van Kirk - *BMO Capital Markets Equity Research - Associate*

This is Ann-Hunter Van Kirk on for Gary. What are your expectations for leverage over the next couple of years in light of the mesh payment? And are you considering any additional cost cuts to help pay down debt?

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

So Blaise, you'll take this one?.

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

Thanks, Ann, for the question. I think, as we told you, for 2017, we expect to be in the high 4x range from a leverage perspective. And as we've previously communicated, we do continue to aspire to leverage down over time back into the 3 to 4x range. In terms of timing, of when we'll be able to achieve that leverage goal, although today's announcement around mesh removes one of the near-term uncertainties we've been facing in terms of developing a path and time frame in order to achieve that goal, we're just not going to be able to provide any specific time line today as there continues to be a number of key uncertainties both in the near term and midterm that could impact the timing of delevering. But again, we will -- as we talked about, when we come to 2018 guidance, we'll certainly provide what our expectations are both from a cash flow perspective and from a leverage perspective for '18.

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

On the cost-cutting side, Ann, I think you've seen that we made some very difficult decisions over the last 10 months. Right now, as we look at our manufacturing requirements, I think we've done a good job of making tough decisions, but our current manufacturing footprint provides us flexibility in order to be nimble in the generic world right now. So I don't anticipate major future cost initiatives. Of course, as part of our normal course, we're always going to be looking at ways to become more efficient. But I think as we sit here today, we are well positioned to meet our manufacturing capacities.

Operator

Our next question comes from David Amsellem from Piper Jaffray.

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

I had a couple of product-specific questions. Just wanted to get your views on 2018 and the competitive landscape or expectations for competitive -- more competition on CORPHEDRA and also ADRENALIN. If you expect to see other approved products come into the market. And I guess also same question for the potassium products. Just maybe help us understand what the competitive dynamics may look like next year.

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

Okay. So the starting point is -- I mean, let me take that potassium question first. So as I've said over the past several quarters, when I look at these 505(b)(2)s, they're broke into categories where you have intellectual property and those in which you don't. In the case of potassium liquid, in the case of potassium powder, there is no intellectual property. So there's no barrier to entry. So I kind of always viewed these as exclusive generics, right? So there's going to be a period of time whereby we should expect generic competition. So I think we've said that we felt good on both of these products through 2017. And I think that's the way you should look at both of the potassiums. With respect to ephedrine, again there are also no patent barrier with respect to ephedrine. Anyone that wants to get into this category, that said, has to file an ANDA. So that in itself will take some period of time. Right now, there are 3 players in the market. We have a fair share of the ADRENALIN market -- I'm sorry, the CORPHEDRA market. But there's no barrier to entry with respect to that. So we feel good about 2017, but you should be looking at it as the potential for entrants to come in as you would typically forecast out in the future. And then regarding ADRENALIN, ADRENALIN is a little bit of a different story. We have intellectual property. There was a Paragraph IV that was filed. There is the potential that, that one company could come to market. However, we have yet to see them, and we have not seen them produce the unapproved version for about 5 years. So stay tuned with respect to generic competition there. Anyone else filing an application, an ANDA rather on ADRENALIN on a go-forward basis would have to file a Paragraph IV and be subject to a 30-month stay. So that takes care of ADRENALIN, and I think we've answered your question.

Operator

The next question comes from Ken Cacciatore from Cowen.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Guys, quick question back to testosterone. Just trying to understand, when do you technically have to consider taking reserves? And can you just give us a sense on when your litigation that's going -- where that -- where it stands -- where those -- I think it was 1,300 cases stand?

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

Yes. So Ken, I'll take the time, and I'll let Blaise answer your reserve question. So right now, the way we've communicated, we've got less than that 1,300 cases, and that was as of July 31. That's currently pending against us. The first MDL trial against Auxilium, involving Testim, that's set to begin, I believe, in November 2017. So that's the first timing. Then there's a trial against Auxilium in the Court of Common. I guess, it's actually the commonwealth of Philadelphia County. That's going to start in January of 2018. And then the third is the first MDL trial against Endo. And that's involving FORTESTA. That's going to begin in the September 2018 time frame. And then Blaise, on the reserve?

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

Yes. I mean, Ken, just in general, the guidance is that you take a reserve when it's probable and estimate-able, and given our strategy, to fiercely defend against these claims right now, that criteria is not that.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Great. And then also, I just wanted to ask on cellulite, a new area for the company. Let's talk about maybe some of the personnel or the things that you are doing both internally and externally as you try to get into the good trial design and the opportunity, kind of that -- seems like a real massive opportunity for the company. So just trying to understand internally the steps that you're taking to maximize it.

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

So Ken, at this point in time, we're not going to quantify the potential value for cellulite. When we get a little bit further through our assessments, we will communicate, when appropriate. In terms of -- I'll start with planning for success in the R&D side. From that standpoint, I think we're well equipped. We've got a very strong R&D team and a technical team that can help not only in the clinical trial design side, but also on the manufacturing scale-up side. And I would say it's a very complicated manufacturing process. I think we feel good about not only our drug substance production. We feel real good about our drug product production. So from a technology standpoint, we feel good. And the R&D team is in discussions with the FDA. As I said, we're planning for success on -- in the clinical trial Phase III to start in late 2017. Regarding the commercial team, they're planning for success as well. Every day, the team is getting stronger. I'm incredibly proud of the leadership that we have with Pat Barry, and we are building our team as appropriate. And as we get closer to our launch date, we plan on having the sales and marketing team in place in order to maximize the value of cellulite. So stay tuned, but we are very excited about the potential growth for cellulite.

Operator

Our next question comes from Kevin Kedra from Gabelli.

Kevin Kedra - *G. Research, LLC - Research Analyst*

First, I wanted to ask, given the FDA's decision to expand the class-wide REMS to immediate-release opioids. Just wondering if that has any impact on your business on the generic side or PERCOCET? And then secondly, Paladin. Is that a core asset for you guys at this point? And if not, are you considering anything to do with that business?

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

So let's start with Paladin. So yes, Paladin is a core asset. We're very excited about the prospects. Again, we believe that it can help augment some of our EBITDA strategies, and we have a pipeline that can help build Paladin through some of the efforts on the generic team both on the solid oral dosage and the injectable side. So that's an area that, now that we are a centralized operating company, we have better access to visibility. And you should expect to see a basket of products eventually flow towards ANDSs in Canada. And your other question, I'm sorry, was the...

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

The opioid REMS.

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

The opioid REMS, again, I think the REMS is -- I think from that standpoint, any barriers in -- as a REMS being put in place, I think that's all factored into our assumptions. From a generic point of view, we certainly have talked about the erosion factor. And obviously, OPANA coming off of the market, it's no longer a strategic focus on the branded side. But on generics, any of the impact has been built into our normal base erosion, and that's really where we are with respect to opioids. So I hope I have answered your question, Kevin.

Operator

Our next question comes from Douglas Tsao from Barclays.

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

Just to clarify, I think I heard you say that the contribution in the quarter was about $50 million for ZETIA and SEROQUEL. My presumption is that -- was that largely, ZETIA given sort of the loss of exclusivity or [hundred-day] exclusivity on SEROQUEL. And then what -- just given what you've seen in the market for those 2 products today, how should we think about their contribution in second half of the year? And then also, Paul, I think you sort of got to my question. But within that sort of base erosion rate of 34%, was there sort of a skew between sort of the controlled substances generics business or some of the other components of it was one a little stronger than the other? Or sort of relative strength of -- perspective there would be helpful.

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

Doug, quickly on the contribution from ZETIA and quetiapine, the $50 million is net sales, just so we're clear. And then, yes, the majority of that would be related to ZETIA. And then in terms of the contribution going forward, it won't be a very meaningful contribution starting in the second half of '17. And I'll let Paul talk about maybe the base.

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

Again, Doug, on the base erosion in controlled substances, at this point in time, as we have disclosed a couple of quarters ago, controlled substances are just normal course part of the overall base. We don't call it out any longer. We don't see controlled substances as being any -- having any technological barrier. I think when the consortiums allowed players to come into the market it kind of eliminated that barrier. So it's just part of the -- when we talk about the low 30s, 34%, it's everything in there and it includes controlled substances.

Operator

Our last question comes from Tim Lugo from William Blair.

Ashiq Mubarack

This is Ashiq Mubarack on for Tim. Just one quick one. I was just wondering about your appetite for M&A maybe moving forward, once you've had the chance to take some debt off the balance sheet. Is that something you're remotely interested in maybe next year in an effort to seek some new growth? Or is the macro environment a gating factor for that? Any thoughts?

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

So again, as I said, we are laser-focused on leverage and reducing debt. So that is our primary, primary focus. Now, the use of the word M&A, it's broad, right? So if we were to find thoughtful, mindful product acquisitions, of course, our business development team is going to be out there looking for those. That's going to be normal course. I think having mesh behind us allows us to look a little bit deeper. In terms of the broad, broad question about a large M&A-type of deal, I think, at this point in time, we're one day past mesh. We're going to stay focused on delevering. But if something came forward that was exceptional, of course, we would have a fiduciary responsibility to look at it. But I want to leave you with the impression we are laser-focused on reducing debt. So that's where we stand. So thank you for that.

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

Okay. All right. I guess that closes out the Q&A.

Operator

Yes, sir, it does. I see no further questions at this time.

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

Okay. Thank you, Jimmy.

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

So this is Paul Campanelli again. And I just want to say we do appreciate your continued interest and support of the company. We do look forward to providing you all with updates as we move forward. And I want to thank you all for joining us this morning. Again, many thanks and have a great day.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes the program. You may now disconnect. Everyone, have a great day.
