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EDITED TRANSCRIPT

ENDP - Q1 2017 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 1Q17 GAAP net loss from continuing operations of \$165m and GAAP diluted loss per share of \$0.74. Expects 2017 revenues to be approx. \$3.45-3.60b, reported diluted GAAP loss per share from continuing operations to be between \$0.80 and \$0.50, and adjusted diluted EPS from continuing operations to be \$3.45-3.75.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

CORPORATE PARTICIPANTS

Blaise Coleman *Endo International plc - CFO and EVP*

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

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

CONFERENCE CALL PARTICIPANTS

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

Dana Carver Flanders *JP Morgan Chase & Co, Research Division - Analyst*

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

Esther Hong *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

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

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

Nicole Germino *BMO Capital Markets Equity Research - Associate*

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

Yih-Jiunn Chiu *Morgan Stanley, Research Division - VP and Research Associate*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International plc Q1 2017 Earnings Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded. I would now like to turn the conference over to Senior Vice President of Investor Relations and Corporate Affairs, Stephen Mock. You may begin.

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

Thank you. Good morning, and thank you for joining us to discuss our first 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.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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've had a chance to review the company's earnings release that we issued earlier this morning.

Let me now turn to our first quarter 2017 earnings presentation. Beginning on Slide 2, here's a brief agenda for today's call.

Moving to Slide 3. Endo's very pleased to report a strong first quarter. This performance illustrates our new formula for success focused on operational execution is beginning to take shape. Solid revenue growth driven by Generic Pharmaceuticals and our Branded specialty products, coupled with cost savings from previously announced restructurings, drove significant growth in our adjusted EBITDA. We are off to a solid start this year and are reaffirming full year 2017 revenue, adjusted EBITDA and adjusted EPS guidance. Blaise will discuss our financial guidance in greater detail later in our presentation.

Moving to Slide 4. You'll see a snapshot of our segment revenues for the first quarter. Strong growth in our U.S. Generics segment offset the expected sales decline in U.S. Branded and International Pharmaceuticals. Total company sales slightly outperformed our preliminary preannounced first quarter range as we achieved 8% year-over-year growth.

Now moving to Slide 5. As I just mentioned, our generics business delivered a very strong performance in the first quarter, driven by quetiapine ER and ezetimibe, the first-to-file products launched in fourth quarter 2016 as well as our sterile injectables portfolio.

Speaking of sterile injectables, VASOSTRICT's momentum continued with first quarter sales of \$99 million, up 24% versus prior year. Based on our strong first quarter performance, we now project full year sterile injectables revenue growth in the mid to high teens percentage range. The strong performance of new launches and alternative dosages was driven primarily by the 2 fourth quarter product launches I just discussed in addition to continued uptake of potassium chloride powder. However, revenue for ezetimibe and quetiapine ER are meaningfully below previously communicated expectations due to lower generic conversion and net price. That said, for full year 2017, we expect new launches and alternative dosages to grow in the low single-digit percentage range.

Our Base generics business declined approximately 32% compared to first quarter 2016, which is in line with the guidance we provided in February. The decline in the first quarter was driven in part by the annualization of 2016 competitive events as well as product discontinuations. From a price perspective, first quarter price erosion was in line with our expectations. Looking forward, we continue to expect below 30% range decline in our 2017 Base business as guided during our February 2017 earnings call.

As previously communicated, our total Generics segment is expected to decline in the high single to low double-digit percentage range in 2017 versus 2016 due to Base business sales decline, partially offset by revenue growth in sterile injectables and new launch in alternative dosages. As we continue to have a shift in product mix, we expect adjusted gross margin improvement versus prior year with our Generics adjusted gross margin in the high 50% range.

Turning to Slide 6. Par launched 8 new products year-to-date with 4 products launched in the first quarter. We made 6 regulatory submissions year-to-date and continue to expect approximately 20 ANDA filings in 2017.

In addition to these milestones, we've had success on the patent litigation front in 2017, serving to help secure our future in new product pipeline. We settled several patent cases with 8 certain launches with a few disclosed on the slide. In addition, we received a favorable decision on ZORTRESS with the District Court finding the compound patent invalid.

Par recently received the first ANDA approval for vigabatrin for oral solution, the generic version of SABRIL. Vigabatrin is a product with significant regulatory requirements that include a comprehensive shared REMS program. We look forward to launching the product in the coming months. Additionally, we're the first generic company sued for the filing of Paragraph IV on teduglutide recombinant powder for injection, the generic version of GATTEX. Par believes it is a first file for teduglutide, which also represents Par's first ANDA filing for a polypeptide.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

We believe all these pipeline candidates represent first-to-file or first-to-market opportunities. As you know, sterile injectables is a strategic area of focus for us. Year-to-date, we have 3 sterile injectables including the February launch of ephedrine sulfate and we recently received approval for neostigmine methylsulfate injection. We are extremely excited about our Generics portfolio and how it's starting to take shape.

Turning to our U.S. Branded Pharmaceuticals on Slide 7. Specialty products grew double digit driven by XIAFLEX up 12% and SUPPRELIN LA, up 11%. However, first quarter order performance was more than offset by the previously communicated year-over-year impact of the loss of exclusivity for Voltaren Gel and FROVA in the first quarter of 2016, the third quarter 2016 divestiture of STENDRA and the continued erosion of established products including pain. The decline reflects a transitioning portfolio and shift of focus to specialty products. We now expect our Branded specialty products revenue to grow in this high single to low double-digit range and continue to expect XIAFLEX to grow in the high single to low double-digit percent range.

In terms of overall Branded revenue, we expect it to decline in the low to mid-teens percentage range year-over-year based on the reasons discussed earlier. Adjusted gross margins for the Branded segment are expected to remain in the high 70s percent range.

You should take note that following the return of BELBUCA to BDSI and the decision to no longer promote our mature pain products, we have reclassified the way we report our U.S. Branded Pharmaceuticals segment to focus on our specialty products. In doing so, we now include our legacy pain products with established products. For modeling purposes, specialty products include XIAFLEX, SUPPRELIN LA and other specialty including TESTOPEL, NASCOBAL Nasal Spray and AVEED. Other established products include products that we previously disclosed in the pain and other established products category.

On Slide 8, let's discuss the exciting Phase IIb data on XIAFLEX in cellulite. In late February and early March, the highly statistically significant data was presented and was well received at 2 medical conferences, the American Society of Plastic Surgeons Aesthetica Super Symposium and the American Academy of Dermatology. 189 patients were randomized to receive XIAFLEX where collagenase clostridium histolyticum 84 micrograms and 186 to receive placebo. The subjects received 3 treatment sessions separated by approximately 21 days. The primary analysis population was the intent-to-treat subjects defined as those that received at least 1 injection. The primary endpoint was the percentage of patients who, at day 71, had a greater than or equal to 2-point improvement from baseline in both the clinician reported and patient reported Photonumeric Cellulite Severity Scale or PCSS. In other words, both the investigator and the patient independently had to observe at least a 2-level improvement in severity of the cellulite for that subject to be considered a responder.

On the primary endpoint, the graph at the left shows that a highly statistically significant greater percentage of patients receiving XIAFLEX had a 2-point or better improvement in both clinician- and patient-reported PCSS score at day 71 compared with placebo. Similarly, on one secondary endpoint, a statistically significant greater percentage of patients who received XIAFLEX had a 1-point or better improvement in both clinician- and patient-reported PCSS score at day 71 compared with placebo. The photos on the right show XIAFLEX-treated cellulite area of a 2-point responder and a 1-point responder comparing appearance pretreatment at day 1 to posttreatment at day 71.

Moving back to the graph at the left for a moment. Another key secondary endpoint shows that 73.1% of XIAFLEX-treated subjects saw a global aesthetic improvement in the area treated that they considered improved, very improved or very much improved. This represented a highly statistically significant difference from the placebo-treated subjects. This Global Aesthetic Improvement Scale is recognized as a very important reflection of the patient's overall global aesthetic impression of the treatment efficacy in the area. While not shown on the slide, but presented at the 2 conferences, 4 additional cellulite efficacy measurements included as secondary endpoints demonstrated highly statistically significant improvement in the XIAFLEX-treated subjects compared to placebo.

Importantly, XIAFLEX was well tolerated with side effects predominantly limited to local injection sites such as bruising, pain and swelling, which was mild to moderate in intensity and transient. There was a very low discontinuation rate of only 3.7% due to adverse events. These reactions have been seen in our previous cellulite trials and are consistent with the safety profile of our approved indications for XIAFLEX.

In conclusion, this Phase IIb study demonstrates the treatment with XIAFLEX significantly improved clinician and patient ratings of cellulite appearance versus placebo across a number of efficacy measurements. XIAFLEX treatment was generally well tolerated. Given these results, further



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

clinical evaluation of XIAFLEX for cellulite is certainly warranted. We remain excited about the prospects for XIAFLEX and cellulite and plan to initiate Phase III studies in the second half of 2017.

Now moving on to Slide 9. Let's address International Pharmaceuticals. First quarter International revenues of \$65 million declined 8% compared to the same period in the prior year. Paladin's first quarter of performance actually exceeded our expectations due to delayed competition on certain established products. The disappointing Phase III serelaxin results announced by our partner, Novartis, triggered noncash goodwill and intangible asset impairment charges, which impacted our GAAP results. The previously announced divestiture of Litha is still expected to close this quarter and due diligence on the potential sale of Somar is continuing to progress. In 2017, we now expect International revenues to decline in the high teens to low 20s percentage range as opposed to a mid to high 20s decline, reflecting better-than-expected Paladin results. This guidance assumes that Litha divestiture closes in the second quarter and a full year of Somar sales.

Now let me turn the call over to Blaise Coleman to further discuss the company's first 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 10, you will see a snapshot of the first 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 diluted loss per share of \$0.74 in the quarter versus diluted loss per share from continuing operations of \$0.40 in the first quarter of 2016. GAAP net loss from continuing operations in the first quarter of 2017 was \$165 million compared to GAAP net loss from continuing operations of \$89 million during the same period in 2016. This is primarily due to the after-tax impact of goodwill and intangible asset impairment charges related to Paladin and the U.S. Generic Pharmaceuticals segment during the first quarter of 2017 as compared to the same period last year.

On an adjusted basis, first quarter results were strong. Adjusted operating income of \$437 million and adjusted diluted earnings per share from continuing operations of \$1.23 increased 22% and 14% versus first quarter 2016, respectively, primarily due to higher revenues, improved adjusted gross margin and lower adjusted operating expenses.

Turning to Slide 11, let's discuss our recent debt refinancing. On April 27, we completed our debt refinancing. As part of the refinancing, we repaid our Term Loan A due in early 2019 and Term Loan B due in 2022 by issuing a new 7-year covenant-lite Term Loan B and senior secured notes both due in 2024. In conjunction with these transactions, the revolver maturing in early 2019 has been replaced with a new 5-year revolver maturing in 2022. As a result of this refinancing, we have significantly enhanced the company's operational flexibility over the medium and long term including the extension of our debt maturity schedule.

This brings us to our guidance on Slide 12. We are reaffirming our 2017 full year revenue, adjusted EBITDA and adjusted diluted earnings per share financial guidance. We continue to expect revenues to be approximately \$3.45 billion to \$3.6 billion, a low double-digit decline versus 2016 primarily reflective of the pressures in our Base generics and Branded established products categories. Reported diluted GAAP loss per share from continuing operations are projected to be between \$0.80 and \$0.50, reflecting impairment and restructuring charges. We continue to expect adjusted diluted earnings per share from continuing operations to range between \$3.45 and \$3.75, reflecting higher interest expense assumptions following our refinancing, offset by the benefit of higher expected adjusted gross margin. More importantly, we continue to expect adjusted EBITDA from continuing operations to be between \$1.5 billion to \$1.58 billion, representing a significant increase in adjusted EBITDA margin year-over-year. The company's financial guidance is based on the assumptions noted on the slide.

From a P&L phasing perspective, we now expect approximately 52% of our total enterprise full year revenue and 53% of our adjusted earnings per share to be realized in the first half of the year primarily due to the exclusivity periods of quetiapine extended-release and ezetimibe. Additionally, we are currently forecasting \$15 million in net cash tax receipts in 2017 with federal and state tax refunds expected to exceed global income tax payments.

MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

Lastly, in terms of projected cash flow on Slide 13, we had \$137 million in cash flow prior to debt payment in first quarter 2017 and continue to expect full year 2017 cash flow prior to debt payment in the range of approximately \$200 million to \$280 million and estimate ending net debt-to-adjusted EBITDA leverage ratio to be in the high 4x range.

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

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

Thank you, Blaise. This was a strong first quarter for Endo. To reiterate, this performance illustrates how our new formula for success, focusing on exceptional operational execution, is beginning to take shape. We are committed to execute on key priorities we set forth at the end of February. I want to thank the entire Endo organization for their commitment and contributions to the company as we strive to build a new and unified Endo.

That concludes our prepared remarks. 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) Operator, may we have the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from David Amsellem with Piper Jaffray.

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

Wanted to drill down on XIAFLEX and particularly the sales guidance on the product. So now in Peyronie's disease, I guess your predecessor had cited what is ostensibly a significant market opportunity, but doesn't look like you're getting much traction there. So maybe elaborate on what's happening there. Is it just too promotion-sensitive? Is it a question of reimbursement? And then, secondly, just given what looks like some challenging dynamics, why such significant investments in these label expansions, which are really for a product that is a brand that's outside of your generics wheelhouse? Why not explore potential divestiture of the asset, try to monetize that and delever? I just want to get your thought process there.

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

Okay. Well, a lot going on there. I think the answer, first, in the Peyronie's indication, we would tell you that we're seeing mid-teens growth. So not exactly sure what you're referring to, but we're pretty solid in Peyronie's mid-teens. In Dupuytren's contracture, we're saying that we're in low single-digit growth. But when we look at how we invested in the marketing efforts in those 2 indications over the history, keep in mind that we had a much larger sales force detailing the pain. We're laser-focused into XIAFLEX in these 2 indications. We're putting the additional marketing resources behind these 2 indications. We actually think that they have both the ability to have some modest growth. And we'll be able to kind of elaborate a little bit more in the back half of this year, but we are putting some marketing dollars specifically, direct-to-consumer funding into Dupuytren's contracture. So more to follow, but we feel pretty good about the growth specifically in Peyronie's disease. In terms of -- your question was really about our wheelhouse, we really view XIAFLEX as a core asset. We've got a very skilled and talented sales team that is laser-focused on specialty. We are excited about the prospects of our Phase III clinical trial later in this year and typically these trials take 18 to 24 months. So we've got a good runway to really gear up and prepare for success in cellulite. So we view this as a core asset and we're pretty excited about it.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

Operator

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

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

I was hoping you could address how launches stand relative to guidance for the year. We have a couple of recent approvals, but the timing on availability is a bit uncertain and how that plays into what guidance implies for EBITDA in the back half of the year post SEROQUEL and ZETIA. As you've noted, the contribution from those has been less than expected and the guidance is unchanged.

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

Yes, so it's all harder to give a lot of visibility in terms of product specifics. What I would tell you here is that we've committed that we're going to launch at least 20 products. We feel that we're on track. We've done a great job so far year-to-date where we've had recent approvals and you can see where products like vigabatrin and neostigmine recently have been approved. The reason it's hard to provide clarity, a lot of the products in the back half are not Paragraph IV, so we're just trying not to put ourselves at a competitive disadvantage. What I can say is that we are tracked to what we've committed to, both from the number of applications that we think will be approved as well as the value that we believe that these products are going to drive for Endo. So we feel pretty good about our portfolio and our pipeline right now.

Operator

Your next question comes from Annabel Samimy with Stifel.

Esther Hong - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Esther Hong in for Annabel just to drill down on the previous question. So within guidance, the launches that are certain are included and -- in guidance or I guess I'm trying to get a better sense of what's included.

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

Okay. So when we say certain -- I want to make sure that we're not mixing apples and oranges. Typically, what we will refer to [is take] certain on Paragraph IV. That's not what we're talking about here. We have a host of products that are not subject to Paragraph IV that we typically just don't give visibility to because we're trying not to alert our competition. What we're saying is that these could be either Paragraph IIs, Paragraph IIIs and we're just -- we could be one of several companies. We're just trying not to provide our competition or trade partners advanced notice. What we are saying is that when you look at what we've done year-to-date, we've executed on what we said we have. The values that we had indicated are unblind, so we're feeling pretty good. So apologize for the vagueness, but we just cannot put ourselves at a competitive disadvantage.

Esther Hong - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay, understood. So different question. So one of the key strategies was to move away from more commoditized products to alternative dosage forms and injectables. It seems like a lot of companies have this strategy to move to these high-barrier, high-margin products. So how do you see the competitive landscape shifting for these types of generics? And do you think we'll find ourselves in the same commoditized environment for these products in a year or two? And how do you manage this natural trend?



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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

It's a great question. I mean, typically, we communicate a lot about this operational execution where we're just laser focused, this has been a historical part of what we've done at Par, now Endo. I think one of the things that we're -- I think differentiates ourselves, on the sterile side, I think it's a very good time, I said this time and time again, to have a sterile facility on U.S. soil. I believe that does give us an advantage. It's a highly compliant facility, incredibly efficient. We're investing in it from a CapEx standpoint. We're putting new technologies into that facility. So as you look at your product opportunities, you've got to consistently expand your reach, right, in products that you pick. We just recently filed a Paragraph IV on teduglutide. As I said, that is the first time that we filed on a polypeptide. That would be an example that we -- as the opportunities are moving with brand companies with new technologies, we have to kind of be at the forefront here and I think that's something that we have done and we've proven that out recently with the teduglutide. So as new technologies are being launched by branded companies, it's incumbent upon us to invest in CapEx and put those technologies into our company and I think we've done a pretty good job so far.

Esther Hong - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay, great. Can I just squeeze in one last question? So you said in the past that major mesh liabilities would be paid out by 3Q '17, but with the increasing number of claims, what comfort do you have in that timing now?

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

Yes. So just in terms of mesh, just to refresh everyone. So our liability at the end of March now stands at \$714 million and there's approximately \$272 million that's already funded in the Qualified Settlement Fund. So that leaves about \$442 million of the accrual to be paid the rest of 2017. So we're still on track to pay that as we previously guided. With respect to your question on additional claims, the additional claims that we disclosed in the previous 8-K and will be in our 10-Q that we file later today, those are claims that we do not have accrued for. So they're unaccrued claims that we've disclosed.

Operator

Your next question comes from Liav Abraham with Citi.

Unidentified Analyst

This is Eugene on behalf of Liav. Firstly, can you provide more color around the updated gross margin guidance for the year? I just wanted to see if this has anything to do with the delay in the McKesson and Walmart mid-cycle? And secondly, can you actually break down exact contribution from generic SEROQUEL and ZETIA this quarter?

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

Okay. So Blaise will take the first one.

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

Yes, from a gross margin standpoint, as we talked about, we did update our guidance by about 50 basis points in terms of the increase that we had at the beginning of the year. And what we're seeing really is just the underlying strength of some very key areas of our business, both our specialty branded business and our sterile injectables business. We see those performing better than we anticipated. And then we also, as Paul talked about, we're going to see lower quetiapine and ezetimibe sales than we forecasted. And that combination actually is a very -- has a positive impact from a gross margin perspective and that's what's reflected in the revised guidance.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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

What was the -- Eugene, you had other questions?

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

I'm sorry, Eugene, what was your second question?

Unidentified Analyst

What's the breakdown of contribution from generics SEROQUEL and ZETIA for the quarter?

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

Are we getting that?

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

Yes, so for first quarter, we had about \$200 million in revenue for quetiapine and ezetimibe combined.

Operator

Your next question comes from Chris Schott with JPMorgan.

Dana Carver Flanders - *JP Morgan Chase & Co, Research Division - Analyst*

This is Dana Flanders on for Chris. Just my first question, you talked about the FDA removing unapproved ADRENALIN products by the second half of the year. Can you just help frame that potential revenue opportunity into the back half and 2018? And then just another follow-up on the injectables portfolio. VASOSTRICT, good growth into Q1, still growing. Just can you talk about what's driving that underlying growth and if you would expect that to continue over time absent competition?

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

Yes. So Dana, sure, this is Paul. On the VASOSTRICT question, right now, we think the -- as it has been for several quarters, the entire vasopressin, VASOSTRICT market has converted. So any growth would be just, again, taking very modest pricing increases as you would with any branded type of product. So I think we've maximized that potential opportunity there with VASOSTRICT. Again, it would just be normal course, very modest type of price increases there. On the ADRENALIN side, I think the way that we would characterize it is that you'd really need to look at the number of units and we're seeing here, I'll give you a little guidance here. On the 1 ml, there's around 6.5 million units for the 1 ml and there's around 700,000 units for the 30 ml. I think you should start looking at this as a potential benefit to Endo towards the second half of 2017, right? So the FDA, my understanding, has communicated to the unapproved sources both for the 1 and the 30 ml that they do need to vacate the market, but you won't really see that benefit until the second half. So you can take those units, I kind of like to refer to it as kind of exclusive generic pricing, the way I would look at it, and then you could probably figure out what the value is. Right now we're really only holding about 20% share for those current units. So that should give you enough visibility to run some math.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

Operator

Your next question comes from Greg Fraser with Deutsche Bank.

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

This is Greg Fraser on for Gregg Gilbert. On cash flow, how should we think about quarterly trends for the rest of the year? You're targeting \$105 million to \$185 million for the year and you just reported \$168 million in the first quarter. And then my second question is just on mesh and where does the count of potential cases stand for which you haven't accrued? And how should we think about the path forward for those cases in terms of when we could have greater visibility on liability that could lead to accruals?

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

Yes, so Greg your question on cash flow, we did have \$137 million in cash flow prior to debt payments in Q1. And as we project out to the \$200 million to \$280 million we guided to on a full year, there was really 2 primary drivers in terms of why the rest of the year levels is going to be lower than what we had in Q1 and part of that's going to be we're going to have lower EBITDA Q2 and beyond just due to the quetiapine and ezetimibe loss of exclusivity. So that is driver as we exit Q1. The other thing that I would remind you about is in terms of the changes we saw in our assets and liabilities and specifically in our working capital, we had a significant benefit in Q1 of '17 related to the collection of the AR on the November and December sales for quetiapine and ezetimibe that we collected in Q1. So that's where you're seeing play through from a phasing standpoint.

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

On the mesh question, Greg, I think what we're saying we have a master service agreement in place and we've talked about that. What we do know and I think we've communicated is that these claims are really unsubstantiated. We just don't know if they're valid or not. What we did see was an increase of around 800 cases that took us from around 9,700 to about 10,500. That's where we are right now. Again, they're unsubstantiated. They're not accrued for. And as we know more, we'll communicate more, but right now, frankly, we just don't know, but that should give you an indication that the MSA increase by about 800 individuals.

Operator

And your next question comes from Randall Stanicky with RBC Capital Markets.

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

I want to go back to a couple of the prior questions. Just first on ZETIA and SEROQUEL, can you just confirm that \$200 million is against the additional \$360 million that you had called out before? And if so, how much of that falls post 1Q? Should we assume that the contribution is minimal? And then can you help us quantify the margin differential? I don't necessarily need the exact gross margin. I'm just trying to understand the difference in margin given that those products are partnered versus the remainder of the Generics business so that we could understand the margin lift for the remainder of the year.

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

Right. So let me -- maybe we can tag team this thing between Blaise and myself. In terms of the worth -- the value for these products, both these products are going to have significant competitors and we see that already with quetiapine. So the value of the sales are clearly being generated in Q1, so both quetiapine and ZETIA having their fair share of competitors. We feel good about staying in both products, specifically in quetiapine. We still have reasonable share. But the pricing on that product, we've seen some -- we've seen lower-than-anticipated pricing right out of the race here for day 1 (inaudible) so that's part of the challenge. And then maybe Blaise can...



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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

Yes, and just to build off of that for a second, Randall, just to make sure we clarify for you is that the \$200 million that we mentioned is Q1 sales for quetiapine and ezetimibe. And from a full year guidance perspective, we've previously said about \$360 million for full year quetiapine and ezetimibe sales. We're seeing that's going to be lower and we're more probably in the \$275 million to \$280 million range from a full year perspective. From a gross margin standpoint, Paul talked about that those are partnered products and we do have a significantly higher margin when we look at our sterile injectables business as well as our alternative dosage and new launches. So that's what's playing to that mix.

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

Okay. And Paul, one question that we talked about before, obviously, ClarusONE didn't come online April 1. Where are we with that? And do you have visibility into how much impact or lack of impact that you may see from that, thanks.

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

So most recently we're in negotiations with them in late April. So we're -- obviously, it's top of mind. I think where this is going is that we certainly are still going through terms and conditions with ClarusONE. I would say that the intent for ClarusONE is to bring the contracts on as quickly as possible. Right now, it's a little bit business as usual. We're operating without a ClarusONE contract, I would say. It's probably being governed on the historical one-stock contract, but we also are still selling into Walmart via the ClarusONE personnel. So it's a little bit of stay tuned. We're -- the contract is technically not in place, we're still negotiating it. I would venture to guess that this will be probably more of a June-July impact for Endo. And I'm sorry, Randall, what was your other -- the other question you had?

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

Well, you talked about 3% to 4% erosion built in the full year last quarter. Now obviously, this has been delayed. But as you think about an annualized impact, is there any change to how you're thinking about that?

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

Yes, yes. I think Randall right now, we feel pretty good about that 3% even though there might appear to be a bit of a delay in ClarusONE. They're still -- we still have our fair share of [ropers] that are going on, so we feel that 3% is pretty much a good number and I call that normal course. I won't change that.

Operator

Your next question comes from David Risinger with Morgan Stanley.

Yih-Jiunn Chiu - *Morgan Stanley, Research Division - VP and Research Associate*

I'm Chiu Jiunn calling on behalf of David Risinger. I just have a quick question, which is how do you see the rate of change in generic pricing trending in 2018 relative to 2017?



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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

Okay. So again, we're not going to get too deep into 2018 with guidance. What I have historically said in terms of the way I look at pricing pressures, when we see these big swings in base erosion and pressures, it typically -- it's typically because, I believe, of a material change within one of these 4 consortiums. So absent of that, that I think, I hope that we can go back to what I'm referring to like normal course. And for normal course for Par, it might be low to mid-double digits. But at this point in time, we're really not prepared to go into too much visibility in 2018.

Operator

Your next question comes from Gary Nachman with BMO.

Nicole Germino - *BMO Capital Markets Equity Research - Associate*

This is Nicole on for Gary. Could you just quantify the contribution from ephedrine, VASOSTRICT and ADRENALIN? And also for XIAFLEX, how should we think about the revenue split between Dupuytren's and Peyronie's?

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

I will. So for XIAFLEX, I would tell you the split in revenue between Dupuytren's and Peyronie's, it's about 55% for Peyronie's and around 45% for Dupuytren's. And then, I'm sorry, you had a couple of questions on ephedrine contribution?

Nicole Germino - *BMO Capital Markets Equity Research - Associate*

Yes, ephedrine, VASOSTRICT and ADRENALIN.

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

Okay. I think in ephedrine, what we're saying is it's a bit early. So we've launched that product back about 1.5 months ago. So I think you're just going to have to be a little patient with respect to ephedrine. We know that there's 3 players, we're one of 3. Our goal is to get a fair share of a 3-player market, so I think you've got to look at the units and you've got to look at -- it's Par and it's Eclat and it's Akorn, and I think our goal is to get our fair share. We worked very hard for this particular product, but it's going to take some period of time to ramp up. So I think you could start to anticipate, hopefully, that we would be in that range towards the second part of 2017. ADRENALIN, what we can say we've disclosed the sales for Q4 at the last earnings call. We can tell you for Q1 of this year, ADRENALIN, we generated around \$6 million of revenue. As I indicated before, we've got only about 20% share. So with the anticipation of the unapproved sources coming off the market, you should see a ramp-up. But again, that ramp-up will not take place until second half of 2017. And I think your last question for VASOSTRICT, I think, as I said in the introductory remarks, we generated \$99 million of revenue for Q1.

Nicole Germino - *BMO Capital Markets Equity Research - Associate*

Okay, great. And so just one quick follow-up on SG&A. It came in very light this quarter. How should we think about this trend going forward?

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

Yes. So from an OpEx perspective, it was lower than we had originally anticipated and it was really driven by timing of spend and we also had some onetime favorable items related to some change in estimates that came through as well, so that was impacting the quarter in a favorable way. In terms of how you should think about it, we expect to step up spend in Q2 and that's reflected in our phasing guidance what we gave you on EPS.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

And as you saw, we have not changed our percent to sales guidance for the full year. So we're still planning to get back on track. We just had a lighter Q1 spend than we anticipated.

Operator

Your next question comes from Kevin Kedra with Gabelli.

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

Wanted to know if you've had any interaction with the FDA since -- on OPANA since the Advisory Committee and the vote there. And then, secondly, want to ask about -- beyond the processes for Litha and Somar, how much of a priority is it to pursue alternative or even divestitures of some of the noncore assets given that you recently refinanced your debt? Does that change your thinking at all about what to do with those assets?

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

So I think to start out with the OPANA question, obviously we're laser focused with the FDA. While they're-- we are waiting for eventual meeting with the FDA. We clearly are in preparation on concepts and ideas that we would like to communicate and have that conversation with the FDA. But at this point in time, it's a bit premature. That has not been established. The way I kind of characterize OPANA today, it's really business as usual, right? So we're ongoing and there hasn't been any formal discussions or meetings with the FDA. Regarding noncore assets in Litha and Somar, I think really what we had said in the past is these are markets that are not where we have expertise. We are laser focused on, for the most part, the U.S. with some contribution coming from small parts of Europe and obviously Canada. So we're focused on regulated market areas that we need to put our noncore assets into hands of people that understand emerging markets. So this is not an area that is going to be a core focus to Endo, just clearly focused on regulated markets. And I think that was really the big decision, that these are not large EBITDA drivers that you take up some resources. And we want to put these companies into hands of people that actually can maximize their capability. So that's really we're focused on U.S. and regulated markets.

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

Great, Paul. I was thinking more about kind of the legacy Branded business. Is that still something that you consider holding onto? Or are you willing to look at alternatives for that?

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

So as we said in JPMorgan, I mean, we will always consider optionality. I mean that's part of normal course. If something were to -- if somebody were to approach us and had a material interest in these mature assets, we would listen. But I would tell you, they are big drivers of EBITDA and cash flow and they're driving a lot of value for that. So absent of an exceptional offer, it's business as usual. So no, we are not out there aggressively pursuing a sale of our mature brands.

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

May I just squeeze one quick one. I'm not sure if I missed it, but did you give what the gross margin was for the Generic business this quarter?

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

It was 56%.



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

Operator

(Operator Instructions) Your next question comes from Tim Lugo with William Blair.

Unidentified Analyst

This is (inaudible) on for Tim. just following up quickly on an earlier SG&A question. Just your expectation for the slight increase to be more back half weighted or do you expect that it'll be shortly, right? And just following up on OPANA, do you have any more granular detail on the timing of the discussions on the evaluation with the FDA? And have they provided you any details on when they will complete their evaluation?

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

So I'll take the OPANA question quickly. I think it would be our hope and our anticipation that a conversation or a meeting could take place before the second half. So we're hoping that it'll be shortly, right? But I think as I said, we are being a little proactive in our views on things that we had pitched at the Ad Com and things that we would want to follow up with the FDA with respect to OPANA. But as I said before, right now, today, it's business as usual on OPANA. So I'll pass over to Blaise.

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

Yes. And then on the OpEx question, we would expect to see a meaningful step-up in Q2 from an OpEx standpoint. As I said, there were just some timing issues between Q1 and Q2. Again, that's reflected in the phasing guidance that we gave between first half, second half.

Operator

And I'm showing no further questions. I would now like to turn the call back to President and CEO, Paul Campanelli, for any further remarks.

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

Thank you very much. I just want to say that we do appreciate your continued interest and support of the company. We do look forward to providing you with updates as we move forward. I just want to thank everyone for joining us today. Have a great day. Thank you all. Goodbye.

Operator

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



MAY 09, 2017 / 12:30PM, ENDP - Q1 2017 Endo International PLC Earnings Call

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