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ENDP - Endo International PLC at Bank of America Merrill Lynch
Leveraged Finance Conference

EVENT DATE/TIME: NOVEMBER 29, 2017 / 2:30PM GMT



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

CORPORATE PARTICIPANTS

Blaise Coleman *Endo International plc - CFO and EVP*

PRESENTATION

Unidentified Analyst

Thank you, everyone, for joining us for our next presentation. I was a little busy there on the transition. But I want to thank the team from Endo International for joining us, particularly Blaise and (inaudible) who's with us as well. I'm going to go ahead and turn it over to Blaise, and for the presentation and then we'll follow up with Q&A.

We're going to go straight -- okay. You don't want it? Okay. Just do a straight discussion. Okay. We're going to do just straight dialogue. I don't know if you want to just go ahead and open it up with Q&A.

QUESTIONS AND ANSWERS

Unidentified Analyst

I know -- let me just talk about, I thought for starters, kind of just your overall, where you are from a strategic perspective. Right now, you have -- there's a lot of, I'll call it, moving parts that I know a number of people here want to discuss, just where your direction is at right now, what your thought processes are in terms of positioning your products and so forth, and just give us a backdrop just for starters.

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

Sure. Yes, and maybe -- well, first, Larry, thank you for having us here today. We appreciate the opportunity, and we appreciate everyone's interest here in attendance today listening with regards to Endo. Maybe a good place to start, Larry is with the third quarter, and the reason I bring it up is because we feel good about the results that we had in third quarter financially, but more importantly, what it reflects in terms of where we are in terms of moving with our strategic priorities. When we started the year, we laid out, really, 3 key strategic priorities as part of our multiyear turnaround plan, and the first priority was around reshaping our organization for success. And that initiative and that priority was really around simplifying and rightsizing our company as we move forward. And in the beginning of the year, we launched a number of initiatives on that front, and the execution of those initiatives, we feel really good about. And in fact, when we look at our adjusted EBITDA and adjusted EPS for the third quarter of '17, the better-than-expected performance, a component of that is really us realizing some of those savings, particularly around operating expense, faster than we had anticipated. So really good execution around those initiatives and around that important priority. The second part that we set out for ourselves was around building the capabilities and portfolio we need for the future, and this by far is our most important priority for us, as we think about the environment we're in and the challenges we face as an industry. And an aspect of that priority was around making sure we're highly focused on those core assets that we believe we can grow and make sense for us to have in the future and divesting non-core assets. And on that latter piece, we saw the -- we announced the divestiture of our Mexican subsidiary, Somar, during the quarter, which is an important milestone in terms of our divestitures. In terms of our new product portfolio, and particularly in our generic space, we saw the successful launch of vigabatrin for oral solution, which is the branded -- sorry, the generic version of the branded product SABRIL. And we'll talk a little bit more about that, that product, as we move along here. In terms of our on-market portfolio and the progress we've seen on that front, we saw really good growth in our core areas of focus both in our generics and branded business. In particular, in our Sterile Injectables business, for the quarter, we saw 28% growth year-over-year, really driven by continued growth in VASOSTRICT and ADRENALIN. In our branded specialty business, we saw top line growth year-over-year around 11%, and that was really driven by our XIAFLEX franchise, which is really the cornerstone of our branded specialty business. So again, good progress from that standpoint. The third priority we had we've set for ourselves that's important is around the concept of driving margin expansion and delevering. And in terms of margin expansion, in the third quarter, we saw our gross margin year-over-year expand by about 220 basis points. And from an adjusted EBITDA perspective, we saw our margin grow about 600 basis points. So you're starting to see some of the initiatives we've taken play through in terms of the margin expansion. But what we are also seeing is the mix of product playing through, where we're seeing favorable product mix, and that's really reflective of making sure -- and our focus on making sure we're investing and



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

developing products that are in the higher-margin space than we have previously been in. So a long answer to your question, but I think an important one, that not only do we feel good about the financial results of the quarter, but more importantly, the progress for making these our strategic priorities.

Unidentified Analyst

In the Sterile Injectables, the vigabatrin, can you just talk about the opportunity? How much and where that end market is and how opportunistic it is from a commercial perspective?

Blaise Coleman - Endo International plc - CFO and EVP

Yes. So probably the place I'd focus to on Sterile Injectables would be around ADRENALIN, and that's a product we recently launched this year. And the ADRENALIN product, we had about \$25 million of revenue in the quarter with about 65% market share, and we see good continued growth with that product as we move forward. In terms of the sort of the competitive landscape for ADRENALIN, right now, there's only one other company that's on the market that has a non-vial presentation of one of the dosage categories that we compete in, so there's limited competition right now in terms of on market. From a potential future competition standpoint, we are aware in Q2 of '17, we were notified of a Paragraph IV filing by a company, and we -- that triggered us to file a suit and triggered a 30-month stay through December of 2019. The only other point to make in terms of potential future competition, particularly with that product, is that we are aware that prior to Endo receiving the patent listing for Endo's patent in the Orange Book for ADRENALIN, there was a filing an, NDA filing, with the FDA. So there was a company that filed with the FDA prior to the listing of our Orange Book patent. When and if they get approved and come to market, it is unclear, but that's sort of the competitive landscape. All that said, we feel really good about Sterile Injectables, in particular, ADRENALIN, what we're seeing there, and then that will be a meaningful contribution to our Sterile Injectables business as we continue to move forward.

Unidentified Analyst

Does the -- I call it the -- I'll call them commodity, the legacy kind of Qualitest business obviously the pressures it's under. It's substantially a smaller portion of your revenue today, certainly, than it was, call it, 12, 18 months ago. I mean, do you expect the types of pressures that we've heard in the markets? I know Paul has been talking about how you continue to expect pressure. Is that what you expect, going forward? Do you expect the same material kind of erosion in that business as you've seen in the past?

Blaise Coleman - Endo International plc - CFO and EVP

Yes. So you're referring to what we call our base business, and a portion of that would be legacy Qualitest. A portion of that would be legacy Par. And maybe to speak more generally about -- and that's where we really see the pricing, the challenges, and I think it's been very well documented, the pricing challenges we're seeing as an industry, and we're absolutely not immune to that obviously. And the 3 drivers that we see are really around customer consolidation, obviously, being a key driver, the number of me-too approvals that are coming out, as well as the accelerated rate of approvals we see coming out of the FDA. When we think about those drivers and we say, "Okay, well what's going to happen in the future, if we start with the first one, which is around customer consolidation." The most recent consolidation was really around (inaudible). We're going to have to see how that plays out as we move into 2018, and we would suspect and anticipate that, that will create pressure moving into '18. Now beyond that, we don't see at this point meaningful opportunities for further consolidation in the customer space, so that could start to stabilize a bit, which I think would be very good for the industry, and certainly, for the manufacturers. In terms of the other 2 drivers, which is around the level of me-too approvals and also the rate at which the FDA is accelerating ANDAs, our view on that is that we're going to continue to see a relatively high level of me-too filings and approval as we continue into the future. And I think it's been clear from the FDA that their objective is to continue to increase the rate at which they're accelerating NDA approvals. So from that standpoint, the priority I mentioned upfront, which I said was the most important, which is building the portfolio and keeping (inaudible) through the future is absolutely critical because to create value in the space, you are going to need differentiation. And that's, as we think about our new product pipeline, that's what we're really focused on, is how do we find those harder to make technologies that will give us some differentiation as we move into the future.



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

Unidentified Analyst

Okay. Why don't we go ahead and open up to the audience since we have questions from the audience? Go ahead. Andrew?

Unidentified Analyst

(inaudible) bank agreement and is that part of your deleveraging process?

Blaise Coleman - Endo International plc - CFO and EVP

So can you just repeat the question? I missed it...

Unidentified Analyst

Can you talk about what availability you have to buy back bonds under your bank indenture? And is that part of your deleveraging process?

Blaise Coleman - Endo International plc - CFO and EVP

Sure. Yes. So I'll take the second part first, which is when we think about delevering, we've been clear that, that is going to take some time for us to do, and it has to do with just some of the uncertainties we have in front of us. And those uncertainties are both risks that we have, but also opportunities, and depending on how those play out, will dictate our ability of -- to what level of delevering we can get under what time frame. In terms of the capability, there's no restrictions we have under our credit agreements in terms of the level of either secured or unsecured. In the case of the bonds, we could repurchase. And when we think about, okay well, what are the mechanisms to delever, there's 2 parts to that equation. One is to take down the absolute level of net debt, but also there's an element of EBITDA. And ultimately, we do want to drive growth in EBITDA. But again, when will we be able to do that, obviously, where we are today, will take a little bit of time for us to determine based on some of the uncertainties I just spoke about.

Unidentified Analyst

You mentioned (inaudible) the third quarter reflects from your perspective -- the third quarter reflects where that program is and its maturity? Or is there still some additional cost reduction to go? And then a follow-up on you also mentioned you are investing into some of the additional harder to manufacture products, does that require some additional investment from what you've been spending? Or do you already have that kind of capability built into the infrastructure? Just the kind of puts and takes to figure out how we should look at expenses.

Blaise Coleman - Endo International plc - CFO and EVP

Yes, thanks for that. So in the first part, in terms of does the third quarter reflect it? It's reflective of the initiatives that we've undertaken to date. In terms of opportunities in the future. As I mentioned, one of our priorities is to drive margin expansion, so this is a big area of focus for us. We do see future opportunities to drive further margin expansion and to -- and for more opportunities on that front. But the how and the when of those opportunities is I won't be providing -- predicting when that will be today, but it's a clear area of focus for us as a management team as we move forward. In terms of other initiatives, going forward, we just think part of and levels of investment. For us, part of running a generics company is regardless of pricing environment, regardless of the challenges we face. It's just best practice to constantly be reviewing your own market products, your product development, the products you have in your portfolio that are under development, your manufacturing and your development capabilities and if you're proactively making changes that you need to be competitive in the future. The one thing we've talked a lot about here is cost rationalization, and part of that was taking products out of our portfolio to drive some of these benefits, but the piece that I didn't mention and we haven't talked about is reinvestment. So our goal here is not to cut our way to the future. Our goal is to reduce where we see either excess



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

capacity or places that are not core to us, and then reinvest where it makes sense. So there is a part of reinvestment that you will see in the future with some of those savings being reinvested back into the business because the only way for us to achieve our ultimate goal is, as I just mentioned, is to grow again, and that's -- and the way we're going to do it is by making sure we're ready for the future both in terms of portfolio we have and the capabilities that will enable us to deliver on that portfolio.

Unidentified Analyst

Can you tell me what other non-core businesses you're looking to sell kind of. And also, can you put a number on anything like that?

Blaise Coleman - Endo International plc - CFO and EVP

Yes, so we haven't spoken to any other pieces of our business at this point that are non-core. We've been pretty clear that the 2 big areas for us where within our international business that was our Litha business in South Africa that we've divested and the Mexican subsidiary, Somar, that I mentioned a minute ago. So there's nothing specific that we've mentioned further than that. What I will tell you is, as it complements the answer I just gave, which is as part of our ongoing process, we're constantly looking at our portfolio and determining where we should be competing in the future and maybe where we shouldn't be. As we work through that, there may be opportunities we identify that will be noncore in different parts of our business that we would look to potentially divest.

Unidentified Analyst

Assuming everything goes well, what's a reasonable time line for XIAFLEX for cellulite to launch?

Blaise Coleman - Endo International plc - CFO and EVP

Yes. So thanks for that question. And maybe I'll just take a minute to tell you that we are really excited about the opportunity to move forward into Phase III in cellulite based on the Phase IIb trial results we saw, and we expect to start that trial in the coming months. And assuming that that's how it plays out, we would anticipate somewhere in late 2018, early 2019 of getting the results of the Phase III trial. And then from there, it will be based upon the regulatory time line, which should be normal course. So if you play that out, you're probably into early mid-2020, somewhere in that time frame.

Unidentified Analyst

Blaise, just as a follow-on to Brian's question really quick, on the XIAFLEX trial, I know Paul said on the most recent call, you kind of produced the resources or the commitment to the Phase III trial akin to kind of paralleling with -- what was on the Phase II. Can you just talk about what kind of dynamics around that trial and capacity?

Blaise Coleman - Endo International plc - CFO and EVP

So and to -- when we think about the Phase III trial, I think what we were saying is that the way we have it designed now will be similar to how we have the Phase IIb designed. In terms of resourcing, we really haven't talked about the level of investment that we're going to be making to that Phase III. What we will do though is part of our 2018 guidance that we'll give at the end of the year, we would anticipate giving how much of R&D investment relates to the Phase III trial.



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

Unidentified Analyst

In terms of your secured debt capacity, we think it's probably going to go down a bit over the next few quarters. How do you think about using that now to capture market discount based upon where your unsecured bonds are trading. Are you going to repurchase them versus saving potentially a smaller amount of secured debt in the future for sort of emergency type need?

Blaise Coleman - Endo International plc - CFO and EVP

Yes. So we feel really good about where our secured capacity is today, and it is to us an important asset as we think about, as we move forward into the future for the reasons you just mentioned, which is we do have some uncertainties out there. Again, those uncertainties are both risk and opportunities, but there are some risks out there that we need to be mindful of as we do our planning. The question you're asking is something that we are constantly looking at. And ultimately, what we're trying to do is say, "Hey, what puts us in the best position to create value as we move forward for our investors and also positions us to be able to make sure that under different scenarios, we're in the best possible position we are to be competitive as a company." So I don't have anything specific to tell you other than we are constantly evaluating that, and that's something, as we think about our capital allocation and part of delevering and how we're going to get our net debt down. We'll look at different ways. Is it secured or unsecured debt? There will be decisions we need to make at and when we're ready to do that.

Unidentified Analyst

I got a 2 parter on testosterone litigation. So could you compare and contrast your litigation strategy, mesh versus testosterone? And the second part, I understand it's early in the process, but if you were to take any charges, would they be coming based on your experience a year from now, 2 years from now, 6 months from now? Any thoughts on that?

Blaise Coleman - Endo International plc - CFO and EVP

Sure. Let me just give an update on TRT litigation and I'll address your questions as part of that, which is the TRT litigation, the first federal MDL trial for Testim occurred in early mid-November and concluded November 16. And in that trial, the jury found on all counts in favor of the defense. As we move forward, we'll see another MDL trial in April of '16 -- or April of '18, excuse me, is currently scheduled. And at the state level, there's trials in January of '18 that are scheduled in Pennsylvania. So that's sort of the cadence of what we're going to see. I'm not going to speculate in terms of anything from a financial exposure standpoint. In terms of the criteria when and if we were ever to take a charge on any litigation matter regardless of CRT or any other matter, it's when it's estimate-able and probable. And it's really that probable piece when something comes probable, that would trigger us. And that's really based on a legal opinion of what the likelihood is, is that a company could have a likelihood of a payment. So I say that because even in a case -- again, any case generically, where you have a verdict that may go against a defendant, that doesn't automatically mean that you take a charge at that point in time because the probability could be that based on appeal or other mechanisms, that it's not probable that there will be a charge or the charge would be different than whatever the finding was or the award was in that original trial. But anyway, from a TRT perspective, as I mentioned today, the next key date coming up is the trial in the state court in January, and then the federal MDL trial in April.

Unidentified Analyst

Questions in the audience? Just to walk-through kind of going forward, your pipeline around kind of within the sterile business model, if you will, can you just speak of what you're thinking in terms of what's in place today, outlook for 2018?

Blaise Coleman - Endo International plc - CFO and EVP

Yes. I'm not going to get into any specific products for competitive reasons. I think that will be pretty obvious. But overall, from a generics pipeline perspective, we feel good about our pipeline in terms of where it is. There's always an issue of timing in terms of is something going to be in 2018 or '19 or '20 as you work through. That's just the nature of the business. But in particular, Sterile Injectables is a place we feel good about. As we



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

think about our pipeline, and we didn't talk about this yet, is one of the areas that we're also focused in on in terms of having that right portfolio is around business development. So as we think about business development front, it's product specific. It's portfolio specific. We're not talking about transformational business development. We're talking about complementary business development that really, we think, could help boost -- or bolster, sorry, our Sterile Injectables business, as well as some other parts of our business. So we're active on both the internal front in terms of what we're bringing through development, and we're very active on the external front in terms of what we're looking from this development standpoint.

Unidentified Analyst

Is there any particular areas in the business development side you're targeting?

Blaise Coleman - Endo International plc - CFO and EVP

Well, yes, and it would be areas that are core to us. So Sterile Injectables, as we just mentioned, sort of other hard-to-make type technologies in the generic space. And then on the branded side, we're also looking at potential opportunities that make sense, given our platform as a specialty pharma company, and particularly, our XIAFLEX platform. Are there potentially some complementary assets that could make sense for us on that space?

Unidentified Analyst

One other, I think, question that probably you hear a lot quite a bit from investors, and obviously, the trends in the core generic business (inaudible) about your -- kind of your base business. Obviously, the trajectory in the past couple of years has been pretty challenging. Paul made reference, I think, on the call, talking about he thought that he was seeing signs, a bit of bottoming, if you will. Can you just speak to what he was referencing? You maybe seeing and kind of drives -- it kind of gets back to original 3 points in your drivers, but can you just frame what your (inaudible)

Blaise Coleman - Endo International plc - CFO and EVP

No, I appreciate that question, Larry, because I think there's a bit of a misunderstanding in terms of how some folks are interpreting that response. So first, let me clarify what our view is around generic pricing going forward. And as I mentioned earlier, our view is for those reasons that I mentioned, those 3 drivers, there's been structural changes here, and we would expect, as we move forward, to continue to see headwinds at least in the near term from a generics pricing standpoint as an industry. The comment Paul was making was very much in particular to our company and really certain areas of our portfolio. So to be more specific, when you look at certain areas of our base business, we're basically saying that there are limits at which we're going to be able to go to from a pricing standpoint. And the simple point is that there are certain parts of our business today where the headroom left to go, there's not a lot of headroom before us, and Paul's simple point was is that we're essentially, for those areas, reaching close to the bottom.

Unidentified Analyst

All right. So you just made -- making a call on more your profile rather than necessarily the market profile.

Blaise Coleman - Endo International plc - CFO and EVP

And only in particular areas of our base business, not the entire base business. And we'll always be smart about these decisions in terms of when and we do or don't concede to a price concession. It's -- there's a lot of things that we take into consideration, but the basic point was there are limits to how far we would go in certain areas.



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

Unidentified Analyst

And to that end, could you just speak to -- I know you had also touched on it. It seems that the behavior of the FDA is certainly different today than it was, let's say, a couple of years ago. Can you just speak to those drivers and the thought process, the FDA obviously are trying to do introduce more competition? Is that's something that you see coming to an end as well? Or is that just something that we're kind of in the early innings, if you will?

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

Yes, so our view is that based on all of our interactions with the FDA, and then all the public comments by the FDA and the actions they're taking that they're very committed to accelerating the rate of generic products to the market. And I see that as a fundamental meaningful way of creating more access to drugs and drugs at lower prices. So I think there's an absolute commitment to doing that, and so we will -- I think we'll continue to see them trying to make progress on accelerating ANDAs.

Unidentified Analyst

Right. So you don't see foresee that changing anytime soon?

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

I don't foresee it changing. At what rate it continues to increase at and to the extent that they're able to make progress, especially when it comes to complex generics and finding ways to get some of those approved, which are different than sort of your normal generics, I think, is a wait-and-see. But I think, clearly, if we take them at their word, they're committed to doing that.

Unidentified Analyst

Right, okay. We have another question on the left side.

Unidentified Analyst

(inaudible) base business (inaudible). You better give us something.

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

Yes, sorry. So our base business, I want to clarify the point. We're not saying that it's -- the base business revenue is bottoming out. We were just saying there's portions of it is bottoming out. Our base business revenue is about 35% of our revenue, generics revenue.

Unidentified Analyst

What percentage of the base business is (inaudible)?

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

I'm not going to qualify that today, but there's an aspect of it that's at the bottom.



NOVEMBER 29, 2017 / 2:30PM, ENDP - Endo International PLC at Bank of America Merrill Lynch Leveraged Finance Conference

Unidentified Analyst

Any other questions in the audience? Okay. Just -- one last question for me. On mesh litigation, obviously, it's set aside. The cash flow, you've been very forthright about. The incremental dollars set aside, I believe there's 22,000 cases or hereabouts. Is that, without asking specifics, is that playing out from as you anticipated in terms of from where you were, call it, 6 months ago to today?

Blaise Coleman - Endo International plc - CFO and EVP

Yes, so we did take a charge in Q2 to cover all known mesh liabilities at that time, and we also provided guidance in terms of what the cash cadence call would be in terms of our mesh settlement payments in the second half of '17 as well as 2018 and 2019, and there's really no updates. That's all playing out exactly as we thought it would.

Unidentified Analyst

Yes, okay, yes. Okay, great. Okay. Well, Thank you, Blaise.

Blaise Coleman - Endo International plc - CFO and EVP

Larry, thank you for having us.

Unidentified Analyst

Thank you very much. Thank you

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