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ENDP - Q2 2019 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 2Q19 total enterprise revenues of $700m, adjusted net income from continuing operations of $120m, and GAAP diluted loss per share from continuing operations of $0.43.

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PRESENTATION

Operator

Good day, ladies and gentlemen, welcome to the Second Quarter 2019 Endo International LTC Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's call, Laure Park, Senior Vice President, Investor Relations and Corporate Affairs. Please go ahead.

Laure E. Park - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you. Good morning, and thank you for joining us to discuss our second quarter 2019 financial results. Joining me on today's call are Paul Campanelli, President and CEO of Endo; Blaise Coleman, Executive Vice President and CFO; and Pat Barry, Executive Vice President and Chief Commercial Officer of our Branded business. We have prepared a slide presentation to accompany today's webcast, and that presentation as well as the other materials are posted online in the Investors section at 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 yesterday's press release 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 yesterday for Endo's reasons for including those non-GAAP financial measures in our earnings release and today's presentation. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measure is contained in our earnings press release issued yesterday unless otherwise noted therein.

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

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

Thank you, Laurie. Good morning, and thank you for joining us for today's call. I hope you've had a chance to review the company's earnings release issued yesterday. Let's turn our attention to the second quarter 2019 earnings presentation. Beginning on Slide 2, here's a brief agenda for today's call.

Moving to Slide 3. Endo's pleased to report another solid quarter of adjusted operating results, reflecting the continued execution of our multiyear strategic plan. Led by XIAFLEX, VASOSTRICT and ADRENALIN, revenues for both the Specialty Products portfolio of our Branded Pharmaceuticals segment and the Sterile Injectable segment continued their double-digit growth momentum. We reported second quarter 2019 total enterprise revenues of $700 million and adjusted EBITDA of $307 million, which were both in line with our expectations. We are reaffirming our previously provided full year 2019 revenue, adjusted EBITDA and adjusted EPS guidance. Blaise will walk you through our financial performance later in our presentation.

Moving to Slide 4. You will see a snapshot of our segment revenues and our consolidated adjusted EBITDA for the second quarter.

Now moving to Slide 5. While our overall Branded Pharmaceuticals segment revenue declined by 2% year-over-year, the Specialty Products portfolio of our Branded Pharmaceuticals segment continued to advance in the second quarter, with year-over-year growth of 17%. This performance was driven by strong execution across all products within our Specialty Products portfolio. Starting with our XIAFLEX franchise. We had another outstanding quarter of growth. Our XIAFLEX franchise grew 18% in the second quarter compared to the second quarter of 2018 and 9% compared to the first quarter of 2019. This year-on-year and quarterly sequential growth reflects strong demand growth driven by both the Peyronie's disease and Dupuytren's contracture indications due to the continued investment and promotional efforts behind XIAFLEX.

Additionally, we are pleased with the performance of the other Specialty Products. SUPPRELIN LA, Aveed and NASCOBAL grew by 19%, 26% and 8%, respectively, in the second quarter compared to the prior year primarily driven by volume. Offsetting the growth is ongoing generic competition in the Established Products portfolio of our Branded Pharmaceuticals segment. Across our specialty business, I am proud of the commercial capabilities that we've built. These capabilities are driving growth today and provide a framework for the expected launch of CCH for cellulite as well as other opportunities. This includes strong channel capabilities that provide exceptional access for physicians and their patients, innovative unbranded media and PR campaigns, coupled with branded digital consumer tactics, that are engaging targeted populations and encouraging them to take action as well as exceptional execution by our sales and field reimbursement teams.

Additionally, I'm pleased with our campaigns and I'm especially proud of feedback from physicians that we are improving the quality of lives for their patients. Based on the continued strong underlying growth in our Specialty Products portfolio, we are reaffirming our full year 2019 revenue growth guidance in the low double-digit percentage range and our full year 2019 XIAFLEX revenue guidance of growth in the mid- to high teens percentage range.

Moving to our CCH development program for assessing the treatment of cellulite. We continue to prepare on both the commercial and regulatory front. We remain on track for a second half 2019 BLA submission, with the market launch targeted for the second half of 2020, subject to FDA approval. On the commercial front, we are continuing to build out our marketing team and plan to add sales leaderships later this year. As part of our plan to introduce Endo Aesthetics to the physician community, we've attended 16 congresses and medical meetings through July. We had the opportunity to engage with hundreds of aesthetics HCPs, including approximately 170 KOL meetings. Additionally, our Phase III data was recently presented during the Premier Global Hot Topics session by clinical investigator Dr. Lawrence Bass at the American Society for Aesthetic Plastic Surgery meeting and by multiple physicians, including clinical investigator Dr. Michael Gold at the Vegas Cosmetic Surgery meeting, which is the premier multi-specialty meeting within Medical Aesthetics.

Turning to Slide 6. Our Sterile Injectables segment continues to deliver with net sales growth of 12% in the second quarter 2019 versus the second quarter of 2018. This performance was driven by ertepenem for injection, the Authorized Generic of INVANZ, which was launched in the third quarter 2018, with net sales up $26 million. Also contributing to the revenue growth were VASOSTRICT, with net sales of $116 million, a 9% increase

versus the same period in 2018 driven by price and business mix and ADRENALIN with sales -- with net sales of $46 million in the quarter, up 25% compared to last year driven by price and volume. The performance of our key Sterile Injectable products was partially offset by the impact of competition on other products within our Sterile Injectables portfolio. As anticipated, second quarter 2019 Sterile Injectable net sales declined versus the first quarter 2019, primarily as a result of a non-recurrence of the first quarter stocking benefit and the expected destocking in the second quarter. Transitioning to compounding by outsourcing facilities. We are extremely pleased with the U.S. District Court for the District Court of Columbia's recent decision supporting the FDA's determination that vasopressin cannot be used for bulk compounding by outsourcing facilities. In granting summary judgment, the court specifically upheld the FDA's decision that there is no clinical need for such compounding under the Drug Quality Securities Act. That said, while Athenex, a compounding outsourcing facility filed a motion for stay or an injunction of a court's ruling and has announced its plan to appeal, it is required to cease selling its compounded vasopressin product, unless and until a stay or an injunction is granted. We, along with the FDA, will oppose Athenex' motion. Looking forward, we reaffirm our guidance of 2019 Sterile Injectables revenue growth in the high single to low double-digit percentage range, with VASOSTRICT revenues expected to grow by a low double-digit percentage.

Turning to our Generic Pharmaceuticals segment on Slide 7. The decrease in revenue for this segment during the second quarter versus the same period last year primarily reflects the impact of anticipated competitive pressures on certain generic products. This decrease was partially offset by the benefit of product launches, including colchicine tablets, the Authorized Generic of COLCRYS, a Paragraph IV settlement. Now over the past several weeks, we have experienced an increase in questions related to the generic market. As we've noted before, while we are seeing a normalization in the landscape, the environment remains active and dynamic, reflecting a high level of competition primarily driven by new market entrants. With that said, we are reaffirming our guidance for full year 2019 generics revenue to decline in the mid- to high teens percentage range.

Moving to Slide 8. As expected, our International Pharmaceutical segment performance reflects, amongst other things, the impact of ongoing generic competition on our ex U.S. businesses, including our Canadian business. For the full year 2019, we reaffirm our guidance of International Pharmaceutical's revenue declines of approximately 20% compared to full year 2018.

Turning to Slide 9. We shift focus to our diverse pipeline. As referenced earlier, we continued to progress through our regulatory and pre-commercialization activities for CCH for cellulite and remain on track for our planned commercial launch in the second half of 2020. As part of our data generation plan, we have several real-world CCH studies in development focused on dosing, injection technique and responses in target patient populations as well as rollover studies on durability. Also, we continue to have optionality with CCH to develop new indications. We remain on track to launch approximately 50 new products in 2019 across our Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals segments and have launched 6 products year-to-date. Our Sterile Injectables pipeline is supplemented by strategic relationships with third-parties, such as Nevakar, which will potentially provide 5 differentiated 505(b)(2) hospital and critical care base products. We continue to expect to launch the first product from our Nevakar agreement in late 2020. As part of the normal course, we actively review and manage our portfolio where there are no guarantees of success. The projects we choose to commercialize are those we believe will provide the highest profitability, durability and then have an appropriate return on investment. In that context, we called our portfolio, focusing our attention on approximately 65 products on file with the FDA and approximately 55 projects in development that are anticipated as high-value endurable opportunities. Our R&D portfolio is now more heavily focused on sterile and related products along with branded specialty and CCH. After these actions, our pipeline is increasingly reflective of our core growth strategy. The table on the bottom of Slide 9 shows some of our key disclosed future first-to-file or first-to-market opportunities.

Now let me turn the call over to Blaise to further discuss the company's second quarter financial performance and full year 2019 financial guidance. Blaise?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Thank you, Paul, and good morning, everyone. First, on Slide 10, you'll see a snapshot of the second quarter GAAP and non-GAAP financial results. Paul covered the company and segment revenues earlier, so I will not review that again. On a GAAP basis, we had a diluted loss per share of $0.43 from continuing operations in the quarter versus a loss of $0.23 per share in the second quarter of 2018. GAAP operating income in the second quarter 2019 was $40 million compared to GAAP operating income of $55 million during the same period in 2018. On an adjusted basis, second quarter adjusted net income from continuing operations of $120 million was lower than the previous year, primarily driven by lower adjusted gross

margin in our Generic Pharmaceuticals segment due to a decline in revenue and an unfavorable change in product mix. Adjusted diluted income per share from continuing operations in the second quarter 2019 was $0.52 compared to $0.76 in second quarter 2018.

Slide 11 provides a summary of Endo's 2019 full year financial guidance. We are reaffirming our financial guidance for the year, and the financial guidance assumptions are unchanged. These assumptions are presented at the bottom of Slide 11.

Moving to Slide 12. This is a summary of the segment and product-specific guidance previously discussed.

Advancing to Slide 13 and wrapping up the financial discussion. In June 2019, we borrowed $300 million under our $1 billion revolving credit facility and expect to use the proceeds from this borrowing for purposes consistent with our previously stated capital allocation priorities. For the first 6 months of 2019, we had unrestricted cash flow prior to debt payment of $334 million and we ended the second quarter of 2019 with approximately $1.4 billion of unrestricted cash and a net debt-to-adjusted EBITDA leverage ratio of approximately 5.3x. We are updating our 2019 guidance for expected unrestricted cash flow prior to debt payment to be in the range of approximately $100 million to $200 million compared to expected use of unrestricted cash prior to debt payment of $100 million to $200 million previously. This change reflects the impact of the revolver drawdown we executed in June 2019.

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

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

Thank you, Blaise. Moving to Slide 14 and concluding today's presentation. We are very proud of the many achievements to date and the steadfast focus of our teams to execute on all levels. We've taken and we will continue to take the actions needed to achieve our longer-term objectives. We believe that our focus on enhancing our capabilities in Sterile Injectables and our Branded Specialty Products portfolio, including Medical Aesthetics and strengthening our generics portfolio profile, position us well for the future. I am grateful to all of our Endo team members for their commitment and their hard work.

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

Laure E. Park - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Paul. In the interest of time, if you could limit your initial questions to allow us to get in as many as possible, we would appreciate it. Operator, may we have the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) First question comes from Greg Gilbert from SunTrust.

Gregory B. Gilbert - *SunTrust Robinson Humphrey, Inc., Research Division - Analyst*

Just one two-parter. Paul, it seems like most agree that a settlement that puts the opioid issue to bed is unlikely anytime soon and I wanted to know if you agree with that? And if so, can you speak to the importance, or lack of, on the imminent Oklahoma ruling and let us know what's been going on with the MDL actions leading up to the trial.

And the second question is about your injectable strategy. Can you update us on your strategy to expand your injectables portfolio and maybe you could touch on that from both an internal capability standpoint and this debt standpoint?

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

Sure. Thanks, Greg. So I think as we've said in terms of opioids, the focus has been and always will be on a global settlement. The teams are always working hard, we're never going to take anything off the table. If something was appropriate, would we consider it? Of course. But absent of something material, we need to be focused for a potential MDL trial, which we don't know if we're in or not, but that time frame, as everybody knows, is October. So there's really no material update with respect to the MDL or really Oklahoma.

With respect to J&J, I can't speculate with respect to a decision one way or another. At the end of the day, we have to focus on our business from an execution standpoint and that's really what this is about here at Endo. The internal and external attorneys have the opioid situation obviously high focus and we're doing what we can do with respect to our Sterile Injectables strategy. We're actually real proud of some of the decisions that we've made to expand our portfolio. We've got a incredible facility in Rochester, Michigan, that we're proud of. We're also looking to expand injectable capabilities in indoor. We've got construction going on as we speak. We're hoping to have opportunities to launch products in the 2020, 2021 time frame. So that will be a big part of Endo in Scarsdale as we move forward. The strategy is going to be focused on hard-to-make injectables. I know that a lot of people say that but this is our focus, I think it's something that we've proven on polypeptides capabilities and really a strong focus to RT, ready-to-use formulations, and really get it into the hands of caregivers from a critical care standpoint. So that's where we're headed as a sterile company.

Operator

Our 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, if you look bigger-picture, strategically there seem to be 2 avenues that companies are pursuing in the sector: Number one, consolidate, delever and diversify, although we've not seen much of that; or number 2, shift spend in business development to try to diversify away from retail generics over time. And if I'm hearing you correctly, that seems to be -- the latter seems to be Endo's strategy. So is that correct? And then is there a way to expedite that process? That's number one.

And then number two for Blaise. Can you just talk about the rationale behind the $300 million revolver drawdown from June, intended use there, given that it didn't seem like you needed the cash given the cash you had on the balance sheet existing?

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

Yes, Randall, so this is Paul. I think your instinct is correct. And we're -- first of all, we're not walking away from retail generics, we just need to be very smart about it. But what we're doing is we want to put more of an emphasis on our sterile side. I think complex injectable products is an area that we're starting to build a skill set, so you're going to see that shift with respect to Endo. We've made an announcement where we're being very mindful with respect to price that we bring to the market. I think size of a portfolio is not as important, it really gets down to the quality of the products within your portfolio. In generics right now, there's a lot of competition. If we're going to be in a retail product that we believe could have more than for place, we want to avoid that. With that in mind, you're going to start to see a even more mindful approach to products that we focus on the retail side. So there's going to be a heightened focus on sterile and a heightened focus on our specialty portion of our business with respect to products like XIAFLEX and our SUPPRELIN LA, our NASCOBAL product and -- as well as moving into CCH. So from Endo's point of view, you should see a strengthening of our sterile and our specialty portfolio.

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Sure. So Randall, just on your question regarding the drawdown of $300 million. Consistent with the financial guidance that we've provided for 2019, our secured borrowing capacity will likely be decreasing throughout the rest of 2019 based on our projected trailing 12-month covenant

EBITDA. And in that context, we made the decision to draw a portion of the revolver credit, $300 million, really to improve our financial flexibility by increasing our liquidity really through the time with use of the secured capacity that otherwise would be decreasing through the rest of 2019. So this was really about providing us additional financial flexibilities moving forward and really to deploy that against the previously stated capital allocation priorities that we set up for ourselves.

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

Makes sense. But there's no specific intended use, it was just more of an opportunistic drawdown?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes. Just to increase our financial flexibility, that's correct.

Operator

Next question comes from Chris Schott from JP Morgan.

Ekaterina V. Knyazkova - *JP Morgan Chase & Co, Research Division - Analyst*

This is Ekaterina on for Chris. And my first question is, you've touched upon this in your prepared remarks but maybe you could elaborate a little bit more, we've seen some companies say that the generic environment is stabilizing, others are citing accelerating competition by consortium pressure. So what are you seeing on the ground? Are we in a better place than we were a year ago or 2 quarters ago? And then kind of on the topic of generics, can you provide some additional color on the launches that you're expecting in the second half? Are these date certain or are these approved or these -- some pending approvals there as well? And just in terms of the quarterly progression, are these more 4 quarter -- the fourth-quarter heavy or three-quarter heavy?

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

Okay. Yes, thank you, Ekaterina. I think with respect to the portfolio, I'll take that one first. I mean I just -- I would just go back to the presentation. Unfortunately, we can't place an enormous amount of color on it. There are -- some of these products are part of settlement agreements which we are unable to disclose exactly the launch date. That's just normal course, that's just part of our settlement negotiations. Products that are not part of settlements, frankly we don't want to put ourselves at a competitive disadvantage either, so we'd just ask you to be patient. The important thing is when you look at that portfolio, the products that we disclose are technically challenging, hard to make. There are clinical trial requirements, difficult molecules, extended release, things that we hope and we anticipate will have durability.

With respect to the generic market, I mean, there's been a lot of use of words, stable, normalization, I think what with every company needs to look at is their own particular portfolio. These are words based upon a point in time. So if you want to start comparing to pre-2015, that's not where we are, right? And I think we need to get off of that mindset. We are in a hypercompetitive environment with the consortiums and it's driven by new market entrants, right? At the end of the day, that's the way we're looking at it. So when you hear normalization, it may really mean that we're able to navigate or understand how to react in today's environment and that's the way you need to be looking at it. But the companies that are going to navigate through this are the ones that are going to take a thoughtful, mindful process on their portfolios. In our particular case, our strategy is, we don't want to play in areas where we're going to have 5, 6, 7 players, right? So we're taking a very, very disciplined approach to products that we bring to market and products that we choose to develop. So that's the way I'm looking at the generic market thing.

Operator

Our next question comes from Ami Fadia from SVB Leerink.

Ami Fadia - *SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst*

Paul, I wanted to ask you about how you think about the trade-off between building out a commercial organization on the specialty side to support a CCH launch? Does that open doors for you to bring in additional assets on the specialty side or would you prioritize more towards using sort of your capital to focus on bringing in more injectables to market?

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

Yes. So right now -- thank you. We want to be -- we're going to be agnostic, right? I think that's the starting point. Now we're not trying to be all things to all people. Maybe I'll take one step further back, an area that I don't see us looking to expand is on the retail side, and I think I've made myself pretty clear in that regard. So I don't -- that's something that is very unlikely. However, I don't think we necessarily have to say there's a trade-off between building out injectables or should we want to go deeper into specialty. The starting point for us is we need to execute on our BLA plan, right? We've talked about filings in the back half of this year, we're preparing for success. I think over time as we advance through the regulatory process, that would allow our business development teams to go deeper into a filtering process of either company or product opportunities, that's clearly a priority for us. But we need to prove a little bit more success. That'll be on the come, but it's not too deep in time.

On the Sterile Injectable side, we have capabilities from a development standpoint. So I don't feel like we're giving up much. If there was a small company acquisition, would we consider? Absolutely. But where we don't go after an M&A opportunity, what we're excited about is internal development, which we're very aggressive on, and even partnership, product deals, where we may be developing collaborations, exploiting profits of some magnitude. So that's normal course, we're continuing to do that. And our business development teams are very active and focused on the sterile side and the Medical Aesthetic side. And lastly, we're not giving up either on the men's health side, right? So from that standpoint, it's the same team looking for in-licensing of products. These are not a -- this is not a real wide casting of a net. I think this is something that is manageable and exciting for us to execute on.

Operator

Our next question comes from David Amsellem from Piper Jaffray.

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

So on the retail market, Paul, just philosophically -- and I know your comments dovetail with your peers' about focusing on more complex products, but specifically on retail, where you think ultimately margins are going to settle? You've talked about commoditization. So do you think margins over the long term can be robust in the U.S. retail generics markets? So that's number one.

And then secondly on 505(b)(2)s, point well taken on your focus there. I just wanted to get your thoughts on potentially expanding your work with Nevakar since that company's focus is on 505(b)(2)s and potentially working with other companies or even internally with your -- working on your pipeline and cultivating more and more 505(b)(2)-based products, want to get a sense of how big of a priority that is within the context of the sterile business?

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

Sure, Dave. So I'll start with that. The 505(b)(2)s is a major priority for us. What we like about 505(b)(2)s is the potential to file intellectual property. If we have something novel and we can have a formulation, bring something to the market that, number one, obviously the patient needs,

differentiates yourself and add intellectual property, that is something that is very, very attractive for us. Specifically on the sterile side, we've got a sales force of about 20 reps. This bodes real well, it fits right into our strategy. On the specialty side, I mean, those 505(b)(2)s as well, right? Obviously we've got our sales force with respect to what we're doing here with Pat's team. So 505(b)(2)s are very exciting from a formulation standpoint and then intellectual property standpoint. So you should expect to see us aggressively move in that regard.

Regarding your question on retail margins, I mean that's a company-specific question and it's hard for me to put my hand on it. And it really kind of depends on a particular company's strategy. There are companies that still pursue volume and are looking to offset planned absorption issues and they'd be backward-integrated into APIs, these are typically offshore companies. They can operate on smaller margins and that's acceptable for their strategy. A company like Endo or our part-generic version -- part-generic subsidiary, we're focused -- our strategy is on first to file, first to market. Upon success, you're going to see -- hopefully you're going to see and realize higher margins, the sheer nature of what you're doing, what you're investing more dollars, and it's higher risk and higher reward. Ultimately, you're going to file a Paragraph IV that's going to cost you greater expenses to litigate but you can get the benefit of that and that something that's been our strategy, and we've been frankly quite successful over time. So it's a tough question. I would tell you that for Endo, I would anticipate margins being a little bit more robust because it's a different type of strategy.

Operator

Our next question comes from Annabel Samimy from Stifel.

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

So I know you're doing a number of additional studies for CCH in cellulite to just establish the experience in real-world of treatment. I was just wondering if you can give us a sense of some of the goals and endpoints of these trials. And whether we'd be seeing any data merge as well as the extent to which any of them are acquired for the BLA filing?

And then a follow-on in Medical Aesthetics. Clearly, you have to build a different presence here with some new infrastructure, I think in the past, you've mentioned that you have certain systems and procedures in place with your existing portfolio that you can leverage. Can you articulate exactly what you can leverage, what you still have to build? And any plans to add additional products to leverage the entire platform?

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

Sure. So Annabel, I'll start and then I'm going to hand it over to Pat. In terms of adding additional products, I think I've basically answered that question. And I think that's going to be over time, assuming success with our BLA and launching into CCH. Our business development team is already building a portfolio of either products or companies for consideration. But that's going to be a bit in the future. But clearly, it's an area that we're excited about, we plan on building out and we want to expand when appropriate. I'll pass the call over to Pat, he can talk a little bit more about the trials.

Patrick A. Barry - *Endo International plc - Executive VP & Chief Commercial Officer*

Yes. Sure. Thanks, Paul. In terms of the BLA submission, obviously with the Phase IIb trial and the Phase III trial being the largest cellulite trial ever conducted, both of which have rollover designs as well, we've got a robustness of data and a very, very strong submission. So as Paul said, we're excited to be in a position to submit that BLA and that would trigger the review clock for us. We've also been mindful of understanding what it will take to be successful in Medical Aesthetics with an ear towards what our KOLs are telling us in terms of data generation and having that available at launch. So the timing is really about having a successful submission, which we're on track. And also at commercial launch, having a robustness of data in the real-world setting. And so a couple of things I would say. As I mentioned, the Phase IIb and Phase III have rollover designs so that'll be important for us because that will provide durability data, which I think is an insight and an understanding that KOLs and injectors will want to know about the type of durability of the product. We also just completed a 209 study, which is an injection and dosing technique. We -- you can

anticipate most of these studies being up for publication and presentation as we get into next year and as we get right at the timing of the commercial launch. But what 209 did was validated our buttock technique and also unveiled some new insights for thigh. And again, we'll be publishing and presenting this data as we get closer to launch. The technique for thigh, good news for us is it's consistent with how thought leaders have used other injection modalities. So that -- those are meaningful insights to be able to drive strong patient outcomes and so we'll be publishing and presenting that.

We will also be embarking upon a 212 trial, which is an open-label trial evaluating CCH for cellulite in mild, moderate and severe patients in thighs. Also these patients are probably mirroring more closely what a physician would see in the clinic, not obese, active, younger patient, likely even potentially aesthetically experienced. So we're excited about what that data may show.

And then finally, the 305 real-world study is an open-label trial in buttocks and thigh and we'll be assessing efficacy as well as patient satisfaction using the -- an investigator Global Aesthetic Improvement score at day 90. And so -- and we'll continue to follow all these patients.

So the takeaway is that we've got really strong regulatory science and we're complimenting that with real -- very strong real-world science in the form of data generation plans. So we're going to have lots of great data focused on patient outcomes, when we get ready to launch.

And I think the other -- yes, on the capability question, it's a fair question. Again, we've built very strong sales and marketing and distribution capabilities on the Branded Specialty side. So what I would say is that our ability to be able to master distribution channel, again, a Medical Aesthetics injectable is a direct buy-and-bill model and so we have mastery of that. We've also built a very, very strong direct-to-consumer capability, which will absolutely have application. And so we also know how to support sales and marketing infrastructure. So we have strong sales operations, backroom support function in place. So what that will allow us to do is hire out of sales force, and we've already made the strategic hires on the marketing side and we'll continue to build out those teams as we prepare for the launch.

Operator

Our next question comes from Liav Abraham from Citi.

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

Paul, I was hoping you could provide a little bit more color on your business development strategy. Do you need more clarity on the opioid situation and potential liability there to get more aggressive on the business development given your access to cash flows that will be relatively unencumbered in 2020? And then second question, given where we are in 2019, any preliminary comments on EBITDA this year and whether this year is -- could be the trough and what the pushes and pulls there are with that respect? That would be helpful.

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

So Liav, I apologize, we're probably not going to get too deep into the future on EBITDA. With respect to the BD strategy in the opioids, we're not looking at the opioid situation as impeding our ability to do business development deals. I mean, at the end of the day, yes, we've had some BD deals on the table here over the past year that we've announced before and they didn't go forward for appropriate reasons. I think right now where we are is the right deal at the right size comes through, of course, we would consider it. And I think the Nevakar deal, while a small deal, works well for us. Those are things that if we can bolt-on, we'll continue to do and excites us, and we are by nature, lower risk. But if the right opportunity came for an injectable company that's an appropriate size, sure we would consider that. And as I said, at an appropriate time, showing more success on the Medical Aesthetics side, we would consider that. And the BD team's out there right now looking for urology. So no, I don't believe that the opioid situation impedes our ability to execute on our BD strategy, no.

Operator

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

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

Paul, how would you characterize the timing of FDA approvals for your key pipeline products relative to expectations, especially Sterile Injectables? Have there been any meaningful delays and have you experienced additional challenges when launching new products? And secondly, is VASOSTRICT now at a normalized run rate after the stocking benefit in 1Q?

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

So I'm going to -- I'll pass the latter question on the VASOSTRICT run rate over to Blaise.

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes. So Gary, in terms of VASOSTRICT, as we had indicated, we would see destocking Q2, which we did see come through. And now we would expect VASOSTRICT in Q3 to be back to a normal run rate.

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

Regarding the FDA time lines, I mean, Gary, it's a tough question. I mean, it's -- every product has a story, right? And in a first one in terms of delays, much of our portfolio is in Paragraph IVs, right? So the inherent nature of a 30-months stay and then appeal are typically things that we're dealing with. So from that standpoint, when we're dealing with that type of cadence, I don't see delays coming out of the FDA with respect to our injectable portfolio or our salivoral dosage so you always have to take that into consideration from a Paragraph IV standpoint.

Things that are on our mind, I mean, right now I would tell you that you need to be closely watching your API sources from an inspection and a quality standpoint. Those are things that can create delays but I think you're only as good as your quality systems and the people that you appoint, I would tell you here at Endo, this is the strength of our company. So from a delay standpoint, it's something that we manage through but I wouldn't say that it's a problematic issue for us at this point in time. So I think we're executing on our plan as we've indicated, when we say we're going to launch about 15 products and we're around 6 or 7 year-to-date. I mean we're kind of hitting exactly where we thought we would be. So we're focused on operational execution, and I think that's proving a success here at Endo.

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

Okay. And just when you launch a product, are you seeing any additional challenges just given the competitive dynamics that you talked about earlier?

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

So in terms of heavy competition, is that what you're referring to?

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

Yes. Exactly.

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

Again, it's -- every product is different. So if we're launching a high-barrier product -- as an example, we launched ertapenem with little to no competition over time. So we got a little more of a runway, it's a difficult product to make here with Authorized Generic. That would be an example where we didn't realize multiple competition. If we're going to look at a product that doesn't have a patent barrier, it's not difficult to manufacture and you elect to launch that product, yes, we're going to have heavy competition, you're going to have 4, 6 players coming to the market, that's not changing. But that's no longer our model. As we move forward, you're going to see us, we are moving away from that. So that's exactly what we want to avoid.

Operator

Our next question comes from Irina Koffler from Mizuho.

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

As you build out your cosmetics segment and -- through business development or internal development, are you thinking about this as a pure cash pay segment of products and that's how you're going to build out this segment? Or could there be medical dermatology or other medically reimbursed products within this segment? And is there any plan to disclose the financials and performance of that business separately?

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

So I'll take the first part of it and I'll pass it over to Pat. So I got a preface by saying this is very, very early, we're focusing on CCH. In terms of building out in the future, assuming success with CCH, assuming the BLA success, clearly, the area that we like is going to be in a cash play area. Now I'm never going to limit myself and say no, but we can only do so much cash pay Medical Aesthetics clearly in areas that we want to be highly focused in on. And Pat, I'll pass it over to you in terms of -- if you have any...

Patrick A. Barry - *Endo International plc - Executive VP & Chief Commercial Officer*

Yes. No, thanks Paul. In terms of the type of sales force that we would be onboarding, this would be a Medical Aesthetic injectable sales force. So that is -- for those who know that space, that is a remarkably different type of sales model and sales rep capability than a reimbursed medical derm. So we would build out, obviously that team that would be successful with CCH for cellulite, and we would look to complement that portfolio with cash businesses, other cash businesses, injectables or injectable-like products that would be synergistic and complementary from an innovation perspective to CCH for cellulite. So we wouldn't be pursuing BD strategy where we would have medical derm products that would co-travel. If that were an opportunity down the line as an extension to our specialty strategy, that would likely be a totally different field force, but that's not part of our thinking right now.

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

Okay. And if I could just sneak in one more, on XIAFLEX pipeline, is -- are you moving forward any other indications? I know there used to be frozen shoulder but we haven't talked about it in some time?

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

Yes. So Irina, I think -- certainly we have access to other indications, we talked about the use capsulites, we talked about plantar fibromatosis, laxity is also a possibility. I think right now we're focused on execution for CCH, that's the #1 priority. As we roll up our budgets for next year, we'll start

considering other indications. I think that's where we are. But we -- but most importantly, we have the rights to follow on indications when appropriate. This is the area that we want to be in.

Operator

Our next question comes from Elliot Wilbur from Raymond James.

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

Paul, you mentioned that the impact of new competition on established generics has sort of been the key variable in terms of leading toward driving volatility in the generic space. And I guess a couple of your peers have been burned by, sort of, materially miscalculating the impact of incremental competition. Just wondering from your perspective, as you think about new interest coming into products like colchicine, if in fact you're seeing changes in behavior with respect to trying to take market share or whether just the current structure of the market is forcing companies to be much more aggressive in terms of wrestling share from the established consortium networks so that you're seeing a much more negative impact that you might have seen a couple of years ago?

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

Yes, Elliot, I think it's both, right? I mean, again -- so at the end of the day -- so clearly, there is aggressive behavior in the market, right? And the aggressive behavior you're going to see on both products that you have exclusivities and even where you have a saturation of mature generic price. So there is still that degree that you're seeing. The big change, when -- I keep on going back, when we used these words of normalization and stability, the change here between today and a couple of years ago is the obvious, right? A couple of years ago, we had 20 customers and we could cobble together the market share. That doesn't exist as well anymore, right? So we all know that when you have a change in the market at a consortium level, that you're talking about swings of 30%, right? This creates massive, massive supply chain challenges. That's what you're seeing in the environment. And clearly, we all know that if a company lands one of the consortiums, that doesn't necessarily mean that you get 30% of the market because they're going to split the formularies, but there's a lot of change within the environment and a -- with a products within a consortium which creates pressure on your supply chain. That's what I think is happening, right? And everything kind of also falls backwards a bit, right? So the consortiums came into existence, putting pressure on manufacturers. Today, there's pressure on API sources, right? So I think it's all intertwined. That's what I believe you're starting to see here in 2019. Those are the pressures that we said -- we've dealt with. I believe we were kind of first movers, obviously, a couple of years ago. We talked a little bit today about culling our portfolio. I think we're first movers again. We just want to be really smart about products that we bring to market, so we can have a durable segment with the generics division. So that's what you're seeing. I think that's some of the challenges that we have in the generic environment today.

Laure E. Park - *Endo International plc - SVP of IR & Corporate Affairs*

I think if there's no more -- are there any more questions in the queue?

Operator

No, ma'am. I'm showing no further questions at this time. I want to turn the call over to Paul Campanelli, President and CEO, for closing remarks.

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

Okay. Well, thank you, everybody. I just want to say we appreciate your continued interest and support of our company. We look forward to providing you with updates as we move forward. And again, thank you and have a great morning.