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ENDP - Q1 2019 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 1Q19 adjusted net income of $122m and GAAP diluted loss per share from continuing operations of $0.06.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the First Quarter 2019 Endo International plc Earnings Conference Call. (Operator Instructions)

I would you like to introduce your host for today's conference, Laure Park, Senior Vice President, Investor Relations and Corporate Affairs. Please begin.

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

Good morning, and thank you for joining us to discuss our first 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 Berry, 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 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 today's press release and in our U.S. and Canadian securities filing.

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 today for Endo's reasons for including those non-GAAP financial measures in today's earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in our earnings press release issued prior to today's call unless otherwise noted therein.

During the first quarter of 2019, Endo changed the name of its reportable segment. This change, which was intended to simplify the segment's name, had no impact on Endo's consolidated or segment results.

I'd like to now turn the call over to Paul.

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

Thank you, Laure. Good morning, and thank you for joining us for today's call. I hope you've had a chance to review the company's earning release issued earlier this morning. Let's turn our attention to the first quarter 2019 earnings presentation beginning on Slide 2. Here's a brief agenda for today's call.

Moving to Slide 3. I'm very proud of our strong operating performance in the quarter. We reported a second consecutive quarter of revenue growth. The 3% revenue growth versus the same period last year was primarily attributable to continued strong performance in both the Specialty Products portfolio of our Branded Pharmaceuticals segment and the Sterile Injectables segment. In March, we executed a debt refinancing, which increases our operational flexibility and significantly would reduce the amount outstanding on our most near-term debt maturity. And we are on target to meet our full year financial guidance. Blaise will walk you through our financial performance later in our presentation.

Moving to Slide 4. You'll see a snapshot of our segment revenues for the first quarter. We delivered continued strong growth in both the Specialty Products portfolio of our Branded Pharmaceuticals segment and the Sterile Injectables segment in the first quarter, which was partially offset by competitive pressures in the Generic Pharmaceuticals segment, the Established Products portfolio of the Branded Pharmaceuticals segment and the International segment.

In the first quarter of 2019, we reported adjusted EBITDA of $334 million, which was comparable to the first quarter of 2018.

Now moving to Slide 5. Our Branded Pharmaceuticals segment grew by 2% year-over-year. The Specialty Products portfolio of our Branded Pharmaceuticals segment continued to advance in the first quarter with year-over-year growth of 19%. This was largely driven by the significant growth of our XIAFLEX franchise, which grew 20% in the first quarter compared to the first quarter of 2018. This year-on-year growth reflects continued strong underlying demand due to expanded consumer awareness in activation for both our Peyronie's and Dupuytren's contracture indications. Additionally, NASCOBAL and the V grew by 24% and 38%, respectively, in the first quarter compared to the prior year, primarily driven by volume.

Based on the continued strong underlying growth in our Specialty Products portfolio, we are affirming 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.

As noted earlier, the first quarter performance of the Established Products portfolio of our Branded Pharmaceuticals segment reflected ongoing generic competition.

Moving to our CCH development program for assessing the treatment of cellulite, we continue to prepare on both the commercial and regulatory front and are on track for a second half 2019 BLA submission with a target market launch in the second half of 2020, subject to FDA approval. As part of our plan to introduce Endo aesthetics to the physician community, we expect to attend between 25 and 30 congresses and medical meetings in 2019.

Additionally, our Phase III data was recently presented at the American Academy of Dermatology Conference. This data will also be highlighted at Hot Topics at the upcoming American Society for Aesthetic Plastic Surgery Conference in New Orleans by Dr. Lawrence Bass. Additionally, we're pleased with the peer-reviewed publication of our Phase II data in dermatologic surgery in the first quarter of 2019.

Turning to Slide 6. Our Sterile Injectables segment continues to deliver with net sales growth of 25% in the first quarter of 2019 versus the first quarter of 2018. This performance was driven by growth of ertapenem for injection, the authorized generic of INVANZ, with net sales of $32 million.

Also contributing to the revenue growth were ADRENALIN with net sales of $47 million, a 59% increase versus the same period in 2018 and VASOSTRICT with net sales of $139 million in the quarter, up 22% compared to last year.

While we anticipated a drag on Sterile Injectables net sales in the quarter as a result of the unwinding of the fourth quarter 2018 stocking benefit, the Sterile Injectables first quarter net sales actually included a stocking benefit driven by the timing of VASOSTRICT shipments. We expect this benefit to reverse in the second quarter. Blaise will provide additional related commentary on this later in our presentation.

While we are pleased with the FDA's decision to remove vasopressin from the 503B bulks list, as a result, it is now unlawful for outsourcing facilities to sell compounded vasopressin products unless they compound those products using an FDA-approved vasopressin product.

Currently, VASOSTRICT is the only product to meet this requirement. Looking forward, we affirm 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 on Slide 6. The decrease in revenue for this segment during the first quarter versus the same period last year primarily reflects the impact of anticipated competitive pressures on certain generic products that had limited competition in the first quarter of 2018. This performance was partially offset by the benefit of product launches, including colchicine tablets, the authorized generic of COLCRYS.

As we noted on our fourth quarter earnings call, we expect 2019 to be a transitional year for our generics portfolio with competition materializing on a number of our larger-margin contributors and key product launches expected to be in late 2019. We affirm our guidance for full year 2019 Generic's revenue to decline in the mid to high-teens percentage range.

Moving to Slide 8. As expected, our International Pharmaceuticals segment performance reflects the impact of ongoing generic competition on our business in Canada and a shift in timing of our sales on certain products. For the full year 2019, we affirm our guidance of International Pharmaceuticals revenue declines of approximately 20% compared to full year 2018.

Turning to Slide 9. We shift focus to our diverse pipeline. We continue to progress through our regulatory and precommercialization activities for CCH for cellulite and remain on track for 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. We also continue to have optionality with CCH to develop new indications. We remain on track to launch approximately 15 new products in 2019 across our Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals segments and have launched 4 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-based products. We continue to expect the first launch on our Nevakar agreement in late 2020.

The table on the bottom of the Slide 9 shows some of our key disclosed future first-to-file or first-to-market opportunities.

Let me turn the call over to Blaise to further discuss the company's first quarter financial performance and 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 on 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 a diluted loss per share of $0.06 from continuing operations in the quarter versus a loss of $2.23 per share in the first quarter of 2018. GAAP operating income in the first quarter 2019 was $16 million compared to a GAAP operating loss of $361 million during the same period in 2018. The improvement was primarily driven by a gain related to the March 2019 debt refinancing transactions, a reduction in asset impairment charges and an overall reduction in operating expenses. On an adjusted basis, first quarter adjusted net income of $122 million and adjusted diluted earnings per share from continuing operations of $0.53 was lower than the previous year driven by higher interest expense and a higher adjusted effective tax rate as well as lower adjusted gross

margin due to sales mix reflective of the strong performance of our largest authorized generic products in the quarter, certainly offset by lower adjusted operating expenses.

As we noted on our year-end call, the first quarter 2019 adjusted effective tax rate is well above the full year estimated rate and is projected to be the highest quarterly rate of the year due to jurisdictional adjusted pretax income mix within the quarter.

Our better-than-expected net sales performance in the first quarter was primarily driven by our Sterile Injectables segment. Sterile Injectables net sales were higher than anticipated driven by our volumes as the destocking expected in the first quarter did not occur, and in fact, there was actually a stocking benefit for VASOSTRICT in the quarter. Also contributing to the performance was higher net price mainly due to favorable customer mix in the quarter.

We now anticipate our second quarter 2019 Sterile Injectables net sales to be lower than first quarter 2019 by an estimated $25 million to $30 million. This reflects the nonrecurrence of the first quarter stocking benefit and the estimated destocking in the second quarter with channel inventory levels, which we expect to revert towards historical average levels by the end of the second quarter as well as lower net price.

Additionally, while we expect the second quarter total adjusted operating expense to remain relatively flat with the first quarter 2019, a higher portion of adjusted operating expenses will be included in the second quarter adjusted EBITDA due to quarter-on-quarter increase in nonstock compensation-related expenses.

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

In terms of quarterly phasing, we expect the split of total enterprise revenue, adjusted EBITDA and adjusted earnings per share to be slightly more weighted to the second half of 2019 due to our expected revenue, adjusted operating expense and adjusted effective tax rate cadence. The higher anticipated second half 2019 revenue reflects the expected timing of 2019 new product launches.

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. For the first quarter 2019, we had a $142 million use of unrestricted cash prior to debt payment. We ended first quarter of 2019 with approximately $1 billion of unrestricted cash and a net debt-to-adjusted EBITDA leverage ratio of approximately 5.3x. We are updating our 2019 guidance for our expected use of cash -- of use of unrestricted cash prior to debt payment in the range of approximately $100 million to $200 million from $75 million to $175 million before. This change reflects the impact of the debt refinancing we executed in March 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 steadfast focus of our teams to execute on all levels. We have taken and we will continue to take the actions needed to become a company we aspire to be over the long term. We believe that our focus on enhancing our capabilities in Sterile Injectables and our Branded Specialty Products portfolio, including medical aesthetics positions us well for the future.

We will continue to invest in our key growth drivers and maintain optionality when it comes to how we maximize the value of our assets in our portfolio. We'll continue to take a prudent and highly focused approach to our capital allocation decisions. However, our ultimate path to success lies in our ability to grow adjusted EBITDA by building and investing in the portfolio we need for the future. The capital allocation priorities we have set for ourselves are aligned with this call. I'm grateful to all of our Endo colleagues for their commitment and 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. (Operator Instructions) Operator, may we have the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from Randall Stanicky with RBC Capital Markets.

Ashley Ryu - *RBC Capital Markets, LLC, Research Division - Senior Associate*

This is Ashley Ryu on for Randall. Can you talk a little bit more about your expectation of 2019 as the transitional year? Does that imply more kind of revenue stability overall in 2020 as your competitive pressures abate and the new launches ramp? And would you also talk a little bit about ADRENALIN? Obviously, it's a nice product for you and a grower and you have your trial in July, I believe, with the 30 months day expiring in December. Can you just talk a little bit about your expectations around that?

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

Yes. Sure. So we're probably not going to go too deep with respect to anything beyond 2019. What I can maybe shed a little light on, on ADRENALIN. We have a trial that we're embarking on with respect to a Paragraph IV filer on the one hand now. That filer has developed an ampule. Right now, I would tell you that we believe in our intellectual property. When I look at our market share with respect to that 1 milligram presentation, we actually have a vial, which is different than the other product that the Paragraph IV filer is pursuing. We control about 35% of that 1 mL market. There's another company already on the market that controls about 65% of that presentation, that company is called Belcher. So that's pretty much where we -- that we're focused. I believe that 1 mL presentation is somewhere around $33 million to $35 million in net sales. So that's really what we're dealing with regarding the Paragraph IV on ADRENALIN. And as I said, in terms of our -- our comments will -- at this point in time, I think we'll just stick to 2019 and we'll need more time later in 2020 to comment on how we're looking at new launches.

Ashley Ryu - *RBC Capital Markets, LLC, Research Division - Senior Associate*

Sure. And if I could sneak in one more. Just on the CCH BLA filing. You said before that you think that you can get kind of a separate BLA filing for this to get some pricing. At what point will it be kind of more clarity whether the agency will kind of accept that strategy? Will it be within the typical filing acceptance period? Or at what point will there be a little bit more visibility around that?

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

Yes, sure. So I'll take the first part of that question, and I'll pass it over to Pat Barry. As we indicated, we're very confident in our expectations that we will continue, and as I indicated in my prepared remarks, our expectation is that we will be filing a BLA in the latter half of 2019. And Pat, maybe you can add a little more color?

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

Sure, Paul. We believe the BLA to be an appropriate regulatory pathway and again, we've had very productive discussions with the agency, as Paul has said. Regarding the inherent differences of the 2 products, again there are 2 distinct products in terms of safety profile indications, patient populations in the treating -- and the treatment regimen as well. So for those reasons, we are very confident in our regulatory submission. We're

confident based on the interactions that we've had with the agency thus far. And we're right on track, as Paul said on the call, for that submission in the second half.

So in terms of how we'll communicate, obviously, we want to maintain the protocol with the agency and keep those discussions specifically between we and the agency. And then once we file the submission, then it will be incumbent upon the agency. Once we submit the file, it will be incumbent upon the agency to actually file. And then once we get that filing, obviously, we would be in a better position to communicate. But again, all systems go with our BLA submission at this point.

Operator

And our next question comes from Gregg Gilbert with SunTrust.

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

Paul, on the more important part of the ADRENALIN franchise, Amphastar filed and you did not sue them. Can you shed some more light on that as you see their product is fundamentally different and therefore, potentially not substitutable? Or is there something else going on there? And the second part of my question is about the opioid overhang. I know there have been no big external data points here in the recent months, but maybe if you could comment on any progress you see brewing behind the scenes as the 2 sides -- remaining sides discuss how to get this tied up in a responsible way?

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

Sure. Thanks, Gregg. So I mean I will just stick with the opioid question first. And I think as you're aware, there is no new update with respect to opioids since the last earnings call that we had our prepared remarks. So again, what's in the public domain with the press reports on is, as we know, the first trial is scheduled for Oklahoma in May, I believe it's May 28, we are not part of that trial again. I think that's well understood. Track 1 is scheduled for October 21, and I would tell you the same response as we said back in Q4. We don't know if we're part of that Track 1 at this point in time. We have and continue to have dialogue with plaintiffs and if there is a way to settle out Track 1, we continue to do that. Absent other settlement that we are prepared for trial. Should we enter into Track 1 for October, we're prepared. I think that's probably as accurate as we can get with today's set of facts.

Regarding ADRENALIN, so your question really goes to why we did not sue Amphastar. And I think you folks know us fairly well. If we had a very bullish opinion on our intellectual property with respect to this filing, we would have asserted our intellectual property rights a little bit different than the previous question with the Paragraph IV first-to-file on the 1 mL, a different situation.

Regarding the reason we didn't sue, we also have a regulatory strategy, which should allow us to stay on the market a little bit longer. Again, this is a complicated ANDA submission. I should say a 505(b)(2) submission rather. So there's a lot of moving parts to it. We spent an enormous amount of resources with respect to the 505(b)(2) and there are regulatory challenges that will -- that we will work with the FDA regarding ANDA applicants. That's probably as far as I can go on that.

Operator

And our next question comes from Dewey Steadman with Canaccord.

Dewey Steadman - *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

I guess, a couple on sterile and VASOSTRICT. Is there any update on litigation there in terms of VASOSTRICT? And is there an ability for the compounders to appeal this March FDA bulks decision? And then going -- looking at the stocking component of Vaso for the quarter, is the $240

million run rate that we could see in second quarter appropriate to use going forward? Or is there some adjustments we need to make to get between $240 million and $270 million?

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

Yes, sure. So Dewey, I'll take the first questions here with respect to compounding in Athenex. Your question in terms of is it appealed? I would tell you that it's already being litigated, right? So it's already in progress. So we're waiting for a decision. And I think that decision will be about 4 to 6 weeks or so. So that's where we stand on the Athenex situation on compounding.

On the Paragraph IV situation, there really is no -- there is no update with respect to status. It's a timing issue right now. We are scheduled to go to trial just over a year from now, right? So I think we're scheduled for May of 2020. That is -- that trial will last a series of weeks and there'll be obviously a decision that will come off of that and we will be prepared for an appeal one way or another. And I think that's probably the way we're looking at it. So there is no new materialization regarding the status of the Paragraph IV. There has been a couple of other filers that have submitted ANDAs and certified against our intellectual property. Absent of that, there is no material update regarding the Paragraph IV in VASOSTRICT.

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

And then just in terms of your cadence question and run rate question, I think as we talked about on the call, we did see a benefit in Q1, specifically on VASOSTRICT from a stocking perspective. We also saw some favorable price mix as well. So we should think about the Q2 number, that would be below a normal run rate and then we would expect to see Q3 and Q4 revert back to a more normalized run rate from there.

Operator

And our next question comes from Gary Nachman with BMO Capital Markets.

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

First, curious how much of the 4 new product launches contribute in the first quarter? How is the environment executing on new generic launches? And maybe you could speak at a high level for expectations on the new launches later this year. And then, just on XIAFLEX. Just talk about the promotional efforts behind Peyronie's and Dupuytren's. It seems like you're still getting traction there and if those will be stepping up over the course of this year?

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

Yes, so Gary, what I'm going to do is I'm going to pass the XIAFLEX question over to Pat. We'll start with the branded side.

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

Thanks, Paul. Thank you for the question regarding XIAFLEX. You pointed it out, we continue to see excellent execution in the marketplace from our sales force. That's a focus on quality interactions with our physician customers. It's also a focus on continuing to expand our injector base. So we've had the success there as well. And a big part of what we do is mastery of the distributor network, making sure that when the physician makes that treatment choice, that is an easy experience for them to acquire so that they can then treat. So we're seeing just quality execution across the board. And then, one of the decisions that we've made this year was to continue not only with consumer activation on the branded side digitally but also to increase and enhance our investments around direct-to-consumer broadcast television through unbranded media. So that's been highly successful. And as a result, in Q1, as Paul talked about on the earnings call, we saw a 20% net sales growth and -- largely driven by volume, which is exactly what we want to see. So the majority of that was volume driven. And then when we inspect what's happening underneath, in terms of

underlying demand, we continue to see both indications grow. Peyronie's grew at 17% from an underlying demand perspective and Dupuytren's contracture grew at 9%. So when we begin to evaluate what we're placing out in the market, those are good signs for us. And of course, there's just good qualitative metrics that we look at in terms of consumer activity, consumer sitting on our website, the number of click-through rates and the impressions that we are having in the marketplace. So we're seeing really good signs. And so as Paul said, we continue to hold firm on the guidance that we put out there for XIAFLEX, and we feel like the potential for sustainable growth is there.

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

Yes, thanks -- thank you, Pat. And I think the question regarding generic new product launches, what I would share at this point in time, it's very early in the process. We're not going to go too deep in terms of the contribution. We're really at market formation. So from that standpoint, we're really not going to opine too deeply. Now what we've said is, we need people to be patient as the lion's share of our contribution for new product launches will be late in 2019. Maybe the one sound-bite that I would put out there in terms of the new product launches, one of them is an AG. It's albuterol. It's an authorized generic product for Proventil with relationship with Merck. We're excited about this product as it is an albuterol product, which could potentially be substituted for a series of products. But again, we're very early in the process. We're at market formation and we need a little more time to pass.

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

And just a quick clarification of the product launches, one happened late in the first quarter and the others mentioned are actually in the second quarter, but they're early second quarter, so just want to get that timing right for you.

Operator

And our next question comes from Irina Koffler with Mizuho.

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

So we see physicians very interested in the CCH cosmetic part. They definitely want to understand more about injection technique and appropriate patients, so can you comment on the studies that you're working on and timing of the data? And also whether or not those data will be used to supplement the BLA or you're going to submit them after you get approval?

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

Okay. Thank you, Irina. Pat, I'm going to let you respond.

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

Thanks for the question. We're very excited. Of course, we're excited by the Phase III results, I mean, given the stringent endpoints and to be able to meet those stringent endpoints with the best 2-point composite is impressive. And of course, before and afters that have been talked about from the podium already have been well received. But we're also very excited about an aggressive data generation program that we have. And our aim would be, of course, to have this data available for manuscript publications and podium presentations. But we are putting ourselves in a position to make sure that, that data generation plan would be a part of the submission. So we've got multiple programs going on.

Of course, our Phase II and Phase III are rollover design, so that will give us important data regarding durability, which I think will make an impact in the marketplace with positive durability data. We also have some work -- some pharmacokinetic work, which will be important safety work. Physicians are going to want to know the safety aspect of treating multiple treatment areas. So we'll have that data as well.

I'm very excited about our 209 trial, which is a safety dosing and injection technique trial, which we just completed, which essentially validates our buttock technique, also has optimized our Fly technique. And interesting enough the approaches that were outlined in this trial was based on key opinion leader feedback and they validated that and it's consistent with injection techniques on another injectable modality. So that's really exciting for us.

We'll be embarking upon a 212 trial. And again, all this is really focused on generating real-world data. That's what our KOLs are telling us. So the 212 will be a open-label design, non-obese patients, younger patients in both buttocks and thighs, more like that real-world aesthetically experienced woman that's walking into the office today.

And then, we will be relaunching a 305 real-world trial, which will be a focus on efficacy and patient satisfaction in real-world patients. So when you begin to think about the profile that we have, the Phase III, the pivotal Phase IIIs, let me remind you that's the largest cellulite trial ever, and we believe that we've got a great profile for regulatory approval. And we've had great dialogue with our KOLs and our investigators in terms of the type of real-world data that they would want. And we're putting ourselves in a position to be able to disseminate that and publish that, but also submit with our regulatory filings. So we've got a great program. My hats off to the R&D team here at Endo who has really worked really hard in this program, and we're very excited about it.

Operator

(Operator Instructions) And our next question comes from David Amsellem with Piper Jaffray.

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

So on the injectable businesses on VASOSTRICT, and I apologize if I missed this. Just putting the files -- other genetic filings aside, can you talk about the extent to which you can get more volume capture in terms of the injectable vasopressin market over the long term? I mean, I'm just trying to get a better sense of the runway for organic growth of that product. And then, secondly, regarding the injectables pipeline and more of a focus on the 505(b)(2), can you give us some color on the pace of filings and potentially pace of approvals over the next couple of years? And I guess, part of that question is also how aggressive do you think you can be in terms of adding injectable products via acquisition as you look to diversify that business.

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

Sure. Yes, thank you, David. So I would start with in terms of being able to grow on VASOSTRICT. I would tell you that my understanding of the market is about 3.5 million to 3.6 million vials. That's pretty much within a historical trend. Now what we're finding is that the volume growth in this particular product is going to only be in the low single digits. So from that standpoint, it's -- I think we've maximized the volume situation here. And again, this product has long been converted from unapproved sources, back probably 18 months ago. So I think we pretty much maximized the volume situation, again just seeing small single-digit growth.

Regarding pipeline color in terms of pace, what we have is we are -- we've taken a new approach about how we're looking at products. And if you went back several years ago, we, along with many other companies were focused on a volume game, right? Our goal was to file 25, 30 applications. And what we've seen is that the environment has changed. Now your question is specifically to injectables, but our R&D program is really overlapping frankly 3 segments.

Our current strategy, and I say current, it's really not anything new we've communicated this over the last 12 months or so. We're looking at the ratio of our R&D dollars from the generic retail side to the injectable side, we are on target to file about 15 applications per year. Now we haven't quantified how many are going to be generic retail versus sterile injectables. But I would tell you the majority is going to lean towards sterile injectables. And that's just because of where we see how we can create value and our communications on where we see core growth for Endo. So lion's share is going to be moving towards the sterile injectable side.

And then, maybe your last question in terms of how we look at adding on products through acquisition. So again, we're incredibly proud of our Nevakar deal. The Nevakar deal provides an extended reach to products in which we do not have the capabilities today. So this is taking standard injectable products, putting them into different presentations, whereby we're really trying to get to the patient and to the caregiver, so these are emergency room-type products. They are critical care targets. This is an area that we want to continue to work with Nevakar and look to add products into that particular category.

At the same time, we are in the process, and we've previously communicated this as well, we are increasing our injectable capabilities ourselves here at Endo through our research and development program focused in Mumbai, India. So many people are aware that we have our R&D up and running in India -- our R&D is up and running in India. You'll start to see applications coming in the 2020 or the 2021 time frame with respect to our own internal development coming out of India, which will be supplementing our current R&D program at our Rochester facility. So M&A, I should just, say product acquisition is clearly going to help us with new product presentations and then products that are prefilled syringes and vials, we have the internal capabilities and you're going to see a heightened development program coming out of Endo.

Operator

And our next question comes from Ami Fadia with SVB Leerink.

Eason Lee - *SVB Leerink LLC, Research Division - Associate*

This is Eason Lee on for Ami. Just on U.S. generics. For the quarter, the year-over-year decline was about 12%, which is sort of above the guidance range. Does that sort of mean that sort of loss of exclusivity that maybe you're on certain key products haven't yet come and we should sort of expect this to take forth later this year? And then maybe bigger picture, just within U.S. generics, are you sort of continuing to see stabilization in the marketplace and sort of how do you sort of see this going forward?

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

Sure. So I'll take the stabilization question and I'll pass it over to Blaise regarding how we're looking at the financial portion of it. So I want to be really careful on how we choose our words here with respect to stabilization maybe versus we're calling it more of a normalization, right? And we've used words in explanations that we kind of go to pre-2015 time frame. That's what I'm seeing in the generic retail section right now. It's a normalization in terms of how things were pre-2015 and what I'm saying here is when you go back to that period of time, we would have a cadence and a frequency of right of first offers, mini-bids, things of that nature. So we're not seeing these large, large portfolio shifts and swings that we're -- that we had seen in may be late 2015 and 2016 due to changes in consortiums. So from my standpoint, that's the normalization portion of how we communicate it.

That said, the challenge as we see the right of first refusals and the mini-bids, keeping in mind that today, the consortiums are much bigger, so the impact to changes in product swings, whether you win bids, whether you lose bids, how you launch a product, generally speaking, 3 consortiums holding about 30-plus percent, you're going to have material swings. That's what we need to be cautious about, right? So the normalization or the stability aspect is that we're starting to see things that were maybe a normal course of frequency and cadence, but the results of what happened are much more material. And I think that's what we need to be careful about in the generic segment. And I'll pass the second question over to Blaise.

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

Sure. Yes, thanks for the question on generics for Q1 performance. So the Q1 performance you saw in our generics revenue was consistent with our internal expectations. And then in terms of relationship between Q1 sort of annualized run rate opposite to midpoint of our generics full year guidance, the guidance does imply that we will continue to see some pretty significant competitive pressures throughout the year. That will be

partially offset by the new product launches that Paul spoke about earlier in the call. But as we've noted, those are going to be very late in 2019. So that's really the dynamic you see playing out there.

Operator

And our next question comes from Louise Chen with Cantor Fitzgerald.

Sudan Loganathan

This is Sudan Loganathan in for Louise. So first question is how are the formulation of XIAFLEX for Peyronie's and Dupuytren's different than from the -- for the cellulite treatment? And how will the pricing be changed or be similar to the Peyronie's and Dupuytren indications? And then secondly, how is the termination of the Somerset Therapeutics acquisition effect, future plans for business development, if any or any other pipeline advancements? And kind of if you can elaborate on any other business development in 2019 as well and timing on that would be great.

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

Sure, so Sudan, I will take the Somerset question and I'll pass the formulation and presentation on XIAFLEX and CCH over to Pat. I would say, while we were disappointed in the Somerset transaction terminating, we always have multiple shots on goal. And I think, as I previously just mentioned here, the Nevakar deal provides us with a portfolio of ready-to-use products. So again very important to us, an area that's untapped and an area that we want to grow in. Our business development team is out all the time looking for products and/or small potential acquisitions that are going to fit with our corporate strategy. We are agnostic when we look across our segments where we can build value and create value, that's going to be the focus area. The normal view towards that, it's always going to lead towards our specialty business and our sterile business. So where we have opportunities, BD has always got a portfolio that we're evaluating. And some we may execute on and some we will just be mindful of how we look at our capital allocation. And as I said maybe earlier today, what I'm very proud of is our aggressive R&D program that is back up and running at full strength here in both India, in Mumbai and also in Rochester. So 2 shots on goal from an R&D standpoint. And I think we'll start to see the fruition of applications being filed starting in the middle of 2019.

With that, I'll pass the formulation question over to Pat for CCH and XIAFLEX.

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

Yes, sure. Thanks for the question, Paul. Yes, as you cited, the formulations are different. Essentially, you're talking about 2 different products. So I want to keep it somewhat at a high level because some of this is obviously proprietary. But the formulations contain -- they're different presentations, they contain different excipients. The volume for treatment is much different. And so as a result with different formulations, there's clinical implications, right? So that's why it's important to understand that it's appropriate to separate out these 2 submissions for those inherent differences. Again, the patient populations are much different, presentation is different. So there is a safety play important to dose correctly, not underdose or overdose, that 2 presentations wouldn't be transferable within the indications. And obviously based on this, the different presentation products, not only is it appropriate but allowable to have a separate BLA submission. So that's what our regulatory strategy is based on. And so we understand that the price points are going to be different. We understand that the markets are completely different. And we feel like we have the freedom to operate to be able to price appropriately in the medical aesthetic market. I think you're really honing in on what's the price point of the CCH in cellulite. Obviously, we've got some time between now and launch. And as we -- upon launch, we would reveal our price point. In the meantime, we're doing an abundance of both qualitative and quantitative market research with plastic surgeons and dermatologists and other medical aesthetic physicians to reveal the right price point for us.

Our aim, as we communicated consistently, and will continue to be, is that we understand there is a sweet spot in the marketplace for an injectable product for the treatment of cellulite. Again, a reminder that there's not an injectable approved by the FDA today. And so should the CCH be approved, it would be a remarkable breakthrough. And so with that, we understand that we would want to price appropriately for wide-scale

adoption from both consumers and medical aesthetic physicians. And so we're going to do that work to determine what that price point is, to find that sweet spot for a wide-scale adoption. And so as we get closer to launch, we would reveal that price point, but it's really too soon to talk about specifically what that price point will be today.

Operator

And our next question comes from (inaudible) with Barclays.

Unidentified Analyst

Just a couple of quick questions as most of my business questions have been asked. Can you just give us an update on what your secured capacity is as of today? And does that include what you have available under your revolver?

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

Yes. Sure, so our secured capacity today, looking at our most restrictive covenant, is around $300 million, and so that would -- we could access the revolver today for that amount.

Unidentified Analyst

Okay. And then, you had some favorable rulings out of Pennsylvania on the mesh case. Is it safe to assume at this point that the mesh lawsuits are behind you? Or are there still open trials that you're going through?

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

So I think what we said probably on several earnings calls, though, that we resolved virtually all known mesh cases. So I would say that's probably where we left it. We're not seeing a lot of activity on our side. So we'll stand behind on our previous comments that it's -- that mesh is virtually -- all known mesh cases are virtually behind us.

Unidentified Analyst

Great. And then, just the last question going on VASOSTRICT. I know you have a bench trial starting in May of next year, but with regards to the other 2 ANDA filers, is there any update on their trials?

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

Again, I think they'll probably be enjoined in that particular case, right? So my understanding is that the follow-on on the 10 mL will be Sandoz and enjoined with -- in the main time frame.

Operator

And our next question comes from Liav Abraham with Citi.

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

Pat, perhaps you can talk a little bit more about the investments you're currently making behind the launch of CCH as you prepare for approval and launch? And then, secondly, can you just remind us how you're thinking about a potential ex U.S. opportunity for CCH in cellulite?

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

So Pat, maybe I'll take the ex U.S. first and then I'll pass it back over to Pat regarding the commercial question. So what we're simply doing ex U.S., we're evaluating our options. Our business development team and our commercial teams are looking at ways in which certain markets that we would partner if appropriate. So we've done, as you would expect, market research. We have a series of territories that could be appropriate and exciting to us, but I'd just need to let -- I've got to communicate and be very clear for that, all focus is on the U.S. We've got work to do. We're excited about the BLA target submission expected for the second half of this year. That's where the focus is. We'll get ourselves situated and then we'll look at how we can really go after the international market. Obviously, we don't want to do anything on the international front that could create any bumps in the road, so the heightened focus is on the U.S. and then we'll move forward into more material discussions on the international side.

With that, I'll pass it over to Pat.

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

Thanks, Paul. We've had a lot of activity. Actually, the activity started last year, where we introduced Endo to the medical aesthetic community, introduced Endo aesthetics. We've hired a lot of talent. We've got our head of sales and marketing Rob Catlin on board and he has been building out his team with a plethora of medical aesthetic experience and really credentialing Endo. So as we get into this year, as Paul mentioned on the call, we'll be at approximately 25 to 30 significant meetings. We're excited about rolling out some branding around Endo aesthetics and official

Endo aesthetic campaign and materials to support that at ASDS, which, as you know, is one of the premier meetings. We'll be doing several advisory boards, engaging with thought leaders and meeting medical aesthetic physicians as we build out the commercial plan.

I mentioned already that we've got our qual and quant pricing research in the market. In late 2019, we'll begin hiring our sales leaders and finalizing our territory footprint. Of course, the full-on recruiting in the sales force will come in 2020. And as we're getting closer to the launches, we get into the early 2020, the Endo aesthetic commercial team will begin communicating with physicians regarding unbranded communications around prevalence, the size and structural properties of cellulite, again some great market preparation. We will begin an unbranded consumer campaign and education likely to begin late spring or early summer of 2020. And then, we will also be reaching out in an unbranded fashion to provide education to media and influencers, likely to begin in Q1 of 2020. And we understand the importance of injection training.

And so we've got a very aggressive injection training program that at launch, we would be prepared to create a critical mass of medical aesthetic injectors that can focus then on targeting the appropriate patients and driving towards great patient outcome. So we've got a terrific plan in place. And you'll look -- you can look for us to continue to be more prominent at the medical congresses and the medical meetings this year, and we will build -- we'll continue to build that momentum and that presence in 2020. I mean it's important to understand that there's investment associated with that, but we obviously also can continue to lean on our internal sales and marketing infrastructure to support that launch as we complement that with the medical aesthetic experience necessary to have a successful commercial launch with CCH as an injectable product for cellulite.

Operator

(Operator Instructions) This now concludes our Q&A portion of today's conference. I would now like to turn the call back over to Mr. Paul Campanelli for any closing remarks. Sir, you may proceed.

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

Yes, thank you. I just want to close by saying how excited we are to report out on a very solid Q1. A great start to the new year here for us. I want to say that we appreciate everyone's continued interest and support of the company. We look forward to providing you with updates as we move forward, and thank you for joining us this morning all.

Operator

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