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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International plc Third Quarter 2018 Earnings Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded.

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

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

Good morning, and thank you for joining us to discuss our third quarter 2018 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 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 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 measure is contained in our earnings press release issued prior to today's call, unless otherwise noted therein.

I'd now like to 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 the chance to review the company's earnings release issued earlier this morning.

Let's turn our attention to the third quarter 2018 earnings presentation. Beginning on Slide 2, here's a brief agenda for today's call.

Moving to Slide 3. Everything we do at Endo is grounded in the execution of our strategic priorities. I'm proud of the progress we've made over the past 2 years to reshape our organization and to help position us for future growth. I'm very pleased to report that our strong Q3 adjusted operating results reflect continued progress on that journey.

Moving to Slide 4. Revenues for XIAFLEX and our Sterile Injectables segment continue their double-digit growth momentum. Our third quarter performance also reflects solid adjusted EBITDA and an expansion of adjusted gross margin compared to the third quarter 2017. This adjusted gross margin expansion was driven by a combination of cost efficiencies and favorable year-over-year product mix, as we continue to focus our efforts on driving growth in higher-margin areas of our business.

Based on these results, we are happy to report that we are raising our full year revenue, adjusted EBITDA and adjusted diluted EPS financial guidance. Blaise will walk you through our updated financial guidance in greater detail later in our presentation.

Moving to Slide 5, you'll see a snapshot of our segment revenues for the third quarter. From a total enterprise perspective, the quarter's performance versus the same period last year was primarily attributable to competitive pressures and product discontinuations in the U.S. Generic Pharmaceuticals segment; the divestiture of Somar, our former Mexican business; and our voluntary market withdrawal of OPANA ER.

These factors were partly offset by the launch of ertapenem for injection, the authorized generic of INVANZ; and the colchicine tablets launch, the authorized generic of COLCRYS; continued strong growth in both our U.S. Branded Sterile Injectables segment and the Specialty products portfolio of our U.S. Branded Specialty & Established Pharmaceutical segment.

On a sequential basis, total enterprise revenues increased 4% from $750 million in the second quarter of this year to $745 million in the third quarter this year, which was our second quarter of sequential growth.

Now moving to Slide 6. Our Branded Specialty portfolio continued to advance in the third quarter, with growth of 13% year-over-year. This is largely driven by the significant growth of our XIAFLEX franchise, which grew 22% in the third quarter versus the third quarter of 2017. Branded Established Product performance reflects the voluntary market withdrawal of OPANA ER in generic competition.

That said, I'm extremely proud of what our Branded commercial team has been able to achieve. Our key product franchise, XIAFLEX, grew an outstanding 22% year-over-year, fueled mainly by strong demand growth, driven by our focused execution and continued investment in our integrated commercial strategy. This includes expanded consumer awareness and activation from both Peyronie's and Dupuytren's contracture indications.

Based on robust year-to-date XIAFLEX revenue growth, we now expect XIAFLEX full year revenue growth to be in the low 20s percentage range versus our previous guidance of high-teens percentage growth.

Moving on to CCH for cellulite treatment development program. We are extremely pleased with the positive results from the Phase III trials and look forward to taking the next step to bring this innovative injectable treatment to market for patients.

As you can see from Slide 7, subjects receiving CCH showed highly statistically significant levels of improvement in the appearance of cellulite with treatment, as measured by the trial's primary endpoint, which was a 2-level composite response improvement in the target buttock at day 71 compared to those subjects receiving placebo.

Additionally, the RELEASE-1 study passed 8 out of 8 key secondary endpoints and RELEASE-2 study passed 7 of 8 key secondary endpoints. Finally, CCH was well tolerated in the actively treated subjects, with most adverse events being mild to moderate in severity and primarily limited to the local injection area.

Let's highlight 2 of the secondary endpoints. First, 54.3% of subjects in the RELEASE-1 study and 57.9% of subjects in the RELEASE-2 study receiving CCH demonstrated a highly statistically significant one level improvement on the patient's assessment of the appearance of cellulite in the target buttock at day 71, as measured by the patient reported photonumeric cellulite severity scale scores compared to only 36.2% and 29.6% of placebo subjects, respectively.

Moving to the far right of each chart. 73.3% subjects in the RELEASE-1 study and 67.8% of subjects in the RELEASE-2 study receiving CCH were reported as improved or very improved or very much improved in the global appearance of their cellulite area as assessed by the subject global aesthetic improvement scale in the target buttock at day 71 compared to only 43.2% and 24.1% of placebo subjects, respectively.

And finally, one of the things that we've learned over the past year is the importance of before and after photos. On Slide 8, you will see a subject before and after photo illustrating the achievement of our primary endpoint. We believe we are well positioned to fulfill a high unmet patient need with new, innovative and clinically meaningful option to address cellulite if this product is approved. This is a great accomplishment by our clinical development team, and I couldn't be more proud.

I'm also excited by our progress in preparing to enter the medical aesthetics market. In 2018, we attended and sponsored 9 key aesthetic congresses, presented Phase IIb data and hosted several advisory boards. This provided us with platforms and credentials at Endo in medical aesthetics and to showcase the encore Phase IIb data to key plastic surgeons and cosmetic dermatologists. Moving forward, we will continue with our regulatory and pre-commercialization activities and are targeting a market launch in the second half of 2020.

Turning to Slide 9. Our U.S. Branded Sterile Injectables segment continues to deliver with sales growth of 17% in the third quarter of 2018 versus the third quarter of 2017. This growth was driven by the July 26 launch of ertapenem for injection, the authorized generic of INVANZ, with sales of $26 million. Contributing to the revenue growth was ADRENALIN, with sales of $35 million in the quarter, a 40% increase versus the same period in 2017; and VASOSTRICT, with a 6% year-over-year quarterly sales increase to $112 million.

Based on our strong year-to-date results, we now project full year U.S. Branded Sterile Injectables revenue to grow in the low 20s percentage range. The continued strong performance of our Sterile Injectables business further validates our strategic decision to increase investment in this segment.

We are excited by our plan to further enhance our Sterile Injectables portfolio for today and the future, with additional products that will benefit patients by providing new treatments in the hospital and critical care environment through the previously announced Nevakar licensing deal and the Somerset Therapeutics acquisition.

Speaking of Somerset, the acquisition remains on track and we expect it to close in Q1 2019. We continue to be enthusiastic about the acquisition and we look forward to integrating Somerset and Wintac into our company.

Turning to our U.S. Generic Pharmaceuticals on Slide 10. The performance for this segment during the third quarter versus the same period in the prior year reflects competitive market pressures as well as previously announced product discontinuations. This performance was partially offset by the July 1 launch of colchicine tablets, the authorized generic of COLCRYS, which was the result of a first to file Paragraph IV settlement agreement. Performance has also benefited from delayed competition on certain products. We expect our full year 2018 U.S. Generics revenue to decline in the mid-30s percentage range.

Now with regard to overall generic retail market conditions, we continue to be encouraged that the downward pressures that we've experienced over the past few years appear to be stabilizing. We have seen promising early signals and remain cautiously optimistic. We are excited about our pipeline, our product selection process and the progress we've made to date to reshape our portfolio for the future.

Moving to Slide 11, let's briefly discuss International Pharmaceuticals. As expected, our International performance reflects the divestiture of Somar in the fourth quarter of 2017. Additionally, as we discussed in August, third quarter revenues were impacted by the cadence of ex U.S. XIAFLEX shipments in Q2 and Q3. For the full year 2018, we expect International Pharmaceuticals to decline approximately 40% compared to full year 2017.

Turning to Slide 12. The U.S. Branded Sterile Injectables and U.S. Generics Pharmaceuticals segments collectively launched 10 new products year-to-date, with approximately 15 new product launches expected for the full year. Once again, you'll see some of our key future first-to-file or first-to-market opportunities. We expect that the acquisition of Somerset will expand our near to medium-term pipeline.

We've been very pleased with our continued regulatory execution. Since we announced the acquisition in April, Somerset has obtained 7 additional FDA approvals, commercially launching 5 of the products. Additionally, our pipeline is further supplemented with strategic relationships with third parties, such as Nevakar, which will potentially provide 5 differentiated 505(b)(2) hospital and critical care based products.

We are proud of the many achievements to date and the steadfast focus of our employees to execute on all levels. Just as Endo looks different than it did 2 years ago, Endo will undoubtedly look very different several years from now as we continue to execute on our strategy. I'm grateful to all of Endo's employees for their commitment and hard work.

Now let me turn the call over to Blaise to further discuss the company's third quarter financial performance. Blaise?

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

Thank you, Paul, and good morning, everyone. First, on Slide 13, you'll see a snapshot of third quarter GAAP and non-GAAP results. Paul covered company segment revenues earlier, so I will not review that again.

On a GAAP basis, we had diluted loss per share of $0.65 from continuing operations in the quarter versus a loss of $0.45 per share in the third quarter of 2017. GAAP operating loss in the third quarter 2018 was $13 million compared to GAAP operating loss of $2 million during the same period in 2017. This was primarily driven by lower revenue and noncash asset impairment charges.

On an adjusted basis, third quarter results were stronger than expected. Third quarter adjusted operating income of $299 million and adjusted diluted earnings per share from continuing operations of $0.71 reflects an improved adjusted gross margin percentage compared to third quarter 2017. The improvement in the third quarter 2018 adjusted gross margin percentage versus the same period last year was primarily due to favorable business mix, driven by increased revenue in both our U.S. Branded Sterile Injectables and U.S. Branded Specialty Products, as well as benefits from our ongoing cost efficiency initiatives.

As anticipated, third quarter 2018 adjusted gross margin percentage was lower than second quarter 2018, primarily driven by the lower-margin authorized generics launched in the third quarter.

Turning to Slide 14. Based on our better-than-expected year-to-date 2018 performance, we are raising our full year financial guidance. We are raising our revenue expectation from our August guidance of $2.75 billion to $2.85 billion, and now expect 2018 revenues to be $2.87 billion to

$2.92 billion. We're also raising our adjusted EBITDA and our adjusted earnings per share from continuation operations guidance, and now expect them to be $1.32 billion to $1.34 billion and $2.65 to $2.75, respectively.

Please note that we are also updated our adjusted gross margin and adjusted operating expenses assumptions. The full year 2018 adjusted gross margin assumption of approximately 68.5% primarily reflects the impact of our increased revenue outlook, driven by the July authorized generic launches, which carries a seasonally lower adjusted gross margin than the rest of the portfolio. We now expect adjusted operating expenses to be 27% of revenues, at the high end of our previous assumption range.

This continues our previously stated priority to fully invest in our core areas of growth. In this context, consistent with what we shared in August, the majority of the higher spend is for selling and marketing and R&D initiatives, along with the increased litigation-related spend. The increase in selling and marketing reflects continued strong investments in XIAFLEX to further fuel our growth momentum. In terms of R&D investment, we are funding a number of additional promising development projects across our portfolio to further enhance our go-forward pipeline.

Slide 15 is a summary of the segment and product-specific guidance previously discussed.

Lastly, in terms of projected cash flow on Slide 16. For September year-to-date, we had $158 million in cash flow prior to debt payment and now expect cash flow prior to debt payment for full year 2018 to be in the range of approximately $35 million to $55 million. Our increase in full year projected cash flow primarily reflects higher adjusted EBITDA and a shift in the activated closing of the Somerset acquisition from Q4 2018 to Q1 2019. As of September 30, 2018, we have approximately $1.1 billion of unrestricted cash and a net debt to adjusted EBITDA leverage ratio of approximately 5.3x.

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

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

Thank you, Blaise. I continue to be extremely proud of our team in what we've achieved to date. The results of our actions over the last couple of years validate our belief that we have the right strategy and the right people in place to continue the successful execution of the next phase of the multi-year turnaround plan. We believe that our focus on enhancing our capabilities in Sterile Injectables and our Specialty Branded portfolio, including medical aesthetics, along with our emphasis on operational execution, positions us well for the future.

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, let's have the first question.

QUESTIONS AND ANSWERS

Operator

[Operator Instructions] And your first question comes from the line of Ami Fadia with Leerink Partners.

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

Congratulations on the good quarter and the CCH data. I've got 2 questions. Firstly, could you elaborate a little bit on your expectation for the regulatory pathway for CCH and your confidence level that you'll be able to file a separate BLA application for that, as well as sort of your initial

plan for commercializing the asset? And secondly, just on the opioid litigation. What are your latest thoughts around the potential for being able to reach a settlement prior to the trials beginning?

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

Sure. Thank you, Ami. I really appreciate the question. Thanks for the cellulite question to begin with. So maybe I'll start with that, and I'll pass it over to Pat. With respect to the regulatory pathway, we've had a lot of discussion around BLA versus sBLA. We'd like to remind everyone the starting point is we start with the difference of a formulation change. We've got a very different patient population on a go-forward basis. And again, we feel that we have a strong justification that we will be working with the FDA over the course of time. And I think that will play out. And I think maybe I'll pass that over to Pat for some additional color, and then I'll come back and maybe I'll touch on the opioids.

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

Sure. Sure. Thanks, Paul. I think your question is also related to the timing. So obviously, we're just looking at top line data. We're extremely excited by the fact that with such a stringent composite primary endpoint that we achieved that with a highly statistical significance, so that's a big win for the company, a big win for patients. 15 and 16 secondaries hitting the mark is really truly remarkable.

So we'll go forward with a great deal of confidence with our regulatory pathway because we've got very strong data. So we will be completing the -- we'll be looking at a complete data set obviously, and we're starting to do that right now. Ultimately, we will be engaging with the FDA early next year, with the submission in the second half of 2019. With the BLA submission, as Paul said, the timing on a commercial launch will be the second half of 2020.

In regards to our strategy on a BLA, we're very confident in that we feel like we have a very strong strategy that speaks to the inherent differences of the patient population, the inherent differences of the safety profile. And so for that reason and a number of reasons, we feel very confident with our regulatory submission. And again, it starts with confidence in our data.

In 2018, commercially, we've been very active. We've had a very successful introduction of Endo as a new disruptive innovator to the space. And so we've been in front of over 250 key opinion leaders in 2018. We'll broaden our reach in 2019. Some of the important work we will do, obviously, we will continue to size the market. We're currently doing the very important work in terms of segmenting both the HCP injector market, as well as the consumer market. We will be defining that [NorthStar] consumer patient.

And again, this market and the success from this market will begin and end with the strong consumer strategy. So we're working on developing the right tone in terms of how we want to engage with the consumer. We're beginning to staff up as well, which is really, really exciting. And so there's just a lot of work to do. 2019 will be very much a planning year and a market-conditioning year to ready ourselves for a successful commercial launch in the back half of 2020.

I'll turn it back over to Paul for the opioid question.

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

Yes. Thanks, Pat. And unfortunately, I really will not be able to place enormous amount of color with respect to timing on negotiations with plaintiffs and AGs prior to the bellwether trial. I think what we can say at this point in time is that we've had constructive dialogues. Obviously, we're very committed if there's a way to have that settlement, if it's possible and it made sense to the company, obviously we will -- we're entertaining it. Discussions have occurred, but there's no way to make a commitment that a settlement is possible prior to the September bellwether cases. So I think that's really where we are. Interactions are ongoing in constructive dialogue, and that probably is about as far as I'm able to take it at this point in time. Thank you for the questions.

Operator

And the next question comes from the line of Liav Abraham with Citi.

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

Another question on the cellulite data. Paul or Pat, I'd be interested in your thoughts on the magnitude or the exact size between the active and placebo on the trial on the primary endpoint, taking account the stringent endpoint, but also the fact that the [minorities] was a little bit below the Phase IIb. So your thoughts on that. And then, Paul, as we're sitting at the end of '18 looking into 2019, I'd be interested in your preliminary thoughts on your ability to grow EBITDA next year, especially given the anticipated contribution of Somerset?

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

Yes, sure. So thanks, Liav, I'll start out and may begin with some -- with the cellulite question, I'll pass it over to Pat again. I think what I wanted to just remind everybody, we -- the way we're looking at this is we're incredibly, incredibly excited about the statistically significant levels of the improvement. Like we are 3 for 3 when we look at the mandated endpoints from the FDA. So incredibly excited. And we like to kind of point everybody back to the secondary trials which we're really, really excited about. In terms of when we looked at the secondary endpoints, where -- or maybe perhaps it's even more commercially relevant, highlighting, as we did on the slides, where we had 54% of the patients in the RELEASE study 1 and 58% of the patients in RELEASE study 2 receiving CCH, having a statistically significant response. Something we are very, very excited about.

Additionally, we showed on the far right of the slide deck the second of our secondary and primary endpoints where we showed 68% and 73%, respectively, in the secondary endpoints tied back to the global aesthetics improvement scale. I think those are incredibly important because that's really more on a patient side where our results were very compelling. So from that standpoint, large trial, 3 for 3, statistically significant, things that we're incredibly excited about and preparing for success. I'll pass it over to Pat, and he can probably add a little more color on the placebo side.

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

Sure. Thanks, Paul. I think good comment on the results. I would add to the fact that we believe these are great results. To be able to achieve a primary composite endpoint that's such a stringent endpoint, that's a very important regulatory hurdle for us to be able to clear. Despite all-comers on BMI, age, cellulite severity, to be able to achieve that separation from placebo is remarkable. And I would characterize the Phase III consistent with the Phase IIb. And again, that's why you do Phase IIIs and you learn from the Phase IIbs.

So I think they're very compelling results, as Paul indicated, to be able to hit 15 or 16 secondary endpoints, 6 of those 8 secondary endpoints are really focused on the patient, which again acceptance from the patients is going to be the currency of the round. That's what really is going to be a motivating factor for our aesthetic physicians, giving them something and putting something in their hands that they can effectively address, an underlying condition that they are not able to today.

And so given that we see that consistency versus the Phase IIb results, what we can share with you is, obviously, we've had those results for a while. And as we've engaged with key opinion leaders and shared the Phase IIb results, what's been remarkable is the consistency of response from the key opinion leaders and really understanding the opportunities that they have. Currently today, there's not an injectable that's approved that allows them to be able to address this very large unmet need. So the fact that we further validated in Phase III consistent with what we showed in Phase III is remarkable, and that we are really on a strong path to be able to introduce a disruptive technology and to be able to have an injectable in the hands of physicians. I think they will find as they target the right patients, there's a bolus of patients. Right now, they're only treating about 1 out of every 10 cellulite patients that presents on their doors. So we've got a large market that's there for us, and we believe that there's a strong potential for a product like CCH in cellulites.

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

Thanks, Pat. Maybe just -- and we have -- as you would expect, I'm not going to be able to, at this point in time, provide a lot of color on growing EBITDA for 2019. I think what I can just focus on, we are incredibly excited about Somerset. As I mentioned in my opening remarks, we are working very, very hard to close this deal as close to Q1 as possible. We believe it's on time. They're working very, very hard to do the same. It's going to infuse us with over 40 products. There is about 19 to 20 products already at the FDA. I caution everyone, it's -- this is kind of a ramp-up. It's near the medium term in terms of the expectations, and we'll put more color on that at an appropriate time. But that being said, we're incredibly excited about the Somerset deal, and we'll certainly be providing more color as we enter into 2019 as we typically do our typical cadence. Thank you for the question.

Operator

Our next question comes from the line of Randall Stanicky with RBC Capital Markets.

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

Paul, just 2 questions. First, keeping on trend with CCH. Can you just talk about your thinking between commercializing versus partnering, where you'd still take on a royalty going forward. And then when we think about the costs to commercialize or the infrastructure that you'll need, how do we think about those needs for the launch of CCH?

And then secondly, Paul, you -- again, you called out generic stabilization and stuck with the cautiously optimistic messaging. But as you look at the cyclical turn in genetics, what's the biggest risk from here? I mean, is it as you look at some of the India-based competitors, are you seeing any irrational behavior around price as some of the U.S. players continue to prune? Is it FDA from an approvals perspective? What concerns you the most that may prolong this generic downturn?

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

Yes, sure. So let me see if I can take this one at a time. Starting with the commercialization portion of it. I think we've been pretty clear in terms of our strategy and planning for success. What I'm most excited about -- obviously, have gotten past the Phase III study is remarkable. But having said that, knowing where we were headed in the Phase IIb, we started to attract talent. And I think that says a lot about the people that we have here and the product that we're mostly excited about here today.

So we are planning for success. We think that, frankly, I don't believe anybody knows this category or space with respect to medical aesthetics for cellulite more than we do. I mean, we live this every day. Pat certainly has experience. We've brought and been able to attract quality talent from companies that have aesthetics capability. So right now, our plan is to prepare for success. That being said, as you would expect, if there was an option that was compelling, I would have to always listen to it, as you would expect us to do. That's normal course. Absent of that, we are geared up, and we are planning to launch this thing the second half of 2020.

From the costs of the infrastructure, again, it's -- the cost of the entry into the market, we're not going to, at this point in time, commit to what we think the value of the product is, but it's something that does excite us and something that we believe warrants the ability to build out the infrastructure from a sales and marketing standpoint. I don't think it's in an enormous sales force, but more color will come on that as we get further in the regulatory process. And a lot will also have to do with the path in which we submit our application, whether it's an sBLA versus an sBLA -- BLA versus sBLA. So more to come out in the future. But that way we're looking at it is we're planning for success.

The question regarding the generics environment. And we say that we're cautiously optimistic, and your question is a little bit around what keeps me up at night. Things are stabilizing, and we are not seeing the mass full line portfolio bids that were out in the past. And I think perhaps that day is behind us, because pricing parity in the environment is very close. When you have these 3 large consortiums, the reality is that your pricing flexibility within these categories are remarkably close.

That said, and I've said this consistently, whenever there could be a disruption within a consortium, the sheer nature that a company jumps in and out is something that I always will focus on, right? I'm going to be very curious to see what happens with Rite Aid as their -- as I understand it, their contract with ClarusONE expires I believe March 31. That is where I will be focusing. But again, pricing parity is within these 3 large consortiums. I think there's been, from the ex U.S. side, from the offshore players, I think they're starting to adjust their models very similar to what you're seeing here in the U.S., where a lot of companies are focusing on gross margin more so than top line revenue. I think that's also helpful for stability standpoint.

But to answer your question, FDA, I think the approval is coming out of the FDA is also now tied back to the quality of your application, right? If you are submitting a high-quality ANDA, you have a higher probability of getting out quicker. But it really gets down to what's your strategy, are you filing an application where you're not tied behind a Paragraph IV or are you just looking to be a first to market player. These are all the things that are really kind of wrapping around to the stability in the market. But I think right now, things are feeling good. I want to be cautious because you still have 3 large consortium players that control a lot of the buying and the selling. So I hope I answered your question, Randall.

Operator

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

Jennifer M. Kim - *Cantor Fitzgerald & Co., Research Division - Analyst*

This is Jennifer Kim on for Louise. I had 2 questions. First, could you probably break down what the puts and takes are for 2019? And then second, just going back to CCH, how commercial do you think the product is given what some people view as a lower-than-expected responder rate? And I know you talked about before how the primary endpoint is pretty stringent. But if you could compare the available data that we have for CCH with other currently available cellulite treatments, that would be great.

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

All right. So I'll try to tackle some of those questions. So the first thing, Jennifer, we're pretty clear, we don't provide any guidance, insight on 2019. So we're asking people to be patient. As I said earlier, our normal cadence we -- that we will provide guidance, that you'll see in 2019. In terms of the commercial viability, I'm going to pass it back over to Pat in a second. But I can't tell you how excited we are about the company. We are statistically significant results. We passed. We're 3 for 3. 843 patient study. No one's ever run a study this large. This is a very, very complicated study, and I love the secondary endpoints in terms of what that could mean for us commercially. And this market is desperately in need of innovation, right? There is no innovation in this particular area for cellulite. So I think from that standpoint, we are remarkably excited. I'm going to pass it to Pat to maybe add a little color.

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

Yes. Sure, Paul. I mean, I think the commercial viability is obvious and large, and that's why we're excited to have statistically significant, highly statistically significant results to be able to pursue an indication. When you think about the viability of the market, we know that 85% to 98% of women have the condition of cellulite, the vast majority are bothered and the vast majority would seek treatment. We know that despite great options, for example, in the OTC market, there's over $3 billion of spend with not a very good promise on the other side of that spend.

So it's a remarkable market. It's an unmet need. We're going into the marketplace amongst the core physicians that we would be working with that are very comfortable with an injectable. We also have an experienced consumer to draw upon that's also very accepting of an injectable. We also see some really interesting trends, which are exciting for us. We see a market trending younger with millennials. We also see expansive growth with body contouring. I think in the last 5 years, if you look at some of the societal data, 300% of growth in body contouring. And those are -- all those markets converge for an opportunity for an injectable to address the underlying cause of cellulite, that's the fibrous septae.

So in reference to your question of comparative data, that's really not appropriate to be able to compare one data set versus another because it's really apples to oranges. I think our composite data really speaks for itself. I think what's important to know and I think what our key opinion leaders recognize, and I think -- look, you're going to be speaking with lots of industry experts and lots of key opinion leaders over the time between now and launch, and I think what you'll find is what we found, it is that the Phase III results are consistent with the Phase IIb results. So we believe that, based on what our key opinion leaders have told us, that it's clinically meaningful.

When you look at the before and afters and the beautiful results that physicians are able to achieve, they immediately go to an understanding of -- understanding whether they would operationalize it and place it into practice. Because they have the aesthetic eye and they have aesthetic technique and the hands, with an injectable in their hands, it's a beautiful opportunity for them to be able to address patients that they're not addressing right now. So I think the market size is a great opportunity for us. And the fact that there's not an injectable approved, and this will be the first, I think creates an interesting opportunity for us as an organization.

Operator

And our next question comes from the line of David Risinger with JPMorgan.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

It's Dave Risinger from Morgan Stanley. So I just wanted to better understand the trends in generics. I think you've spoken about and your competitors have spoken about improving trends and improving prospects. Yet, for example, on the guidance today, I believe that you guided to the fourth quarter generics being down 17% to 18% year-over-year, which is worse than the quarter that you just reported. The upside in the quarter resulted in U.S. Generics being down 13% year-over-year. So can you just help reconcile the guidance versus your commentary?

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

David, I'll take the first part of that, and maybe Blaise can put some specifics in. When we talk about the trends, I think we've been pretty clear of what we're saying here. We're -- and I don't want to have any mistake here because people ask me about pricing in the generic industry, is pricing getting a little better. We're not saying pricing is getting better. What we're saying is that we're seeing stability, and stability meaning that we're getting back to what I call pre-2015 types of pricing pressures. We all know that we're in a commodities market. We all know that there's going to be erosion. So when you see the erosion within the portfolio, to me, what I'm trying to -- I hope I'm clear, is that we're returning to a normal rate of erosion within a generic portfolio. It's not disappearing, it's just going back to where it once was and it's not getting worse. So specifically, maybe Blaise can add some color.

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

Yes, sure. So David, just to reconcile that. When we look at Q3, we actually overperformed on Q3 in Generics than we anticipated. Paul explained that in the commentary that part of that was due to the colchicine performance. But we also saw delayed competition on a number of our key products in that portfolio. And our guidance, at least in this point of our guidance, implies that we'll see some of that competition materialize in Q4. So these are very specific product competitive events that we're expecting and they're -- just we're moving out from Q3 into Q4.

Operator

And our next question comes from the line of David Amsellem with Piper Jaffray.

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

Just a couple of quick ones. So first, on the injectables business.

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

David, David, we're having trouble hearing you.

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

Can you hear me now?

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

Yes, thank you.

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

Yes, thank you.

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

Okay. Sorry. Just a quick question on the injectables business. And specifically, looking at the drug shortage list, I mean there's still quite a number of injectables that are on that list. So can you talk about the extent to which you are looking at being opportunistic regarding taking advantage of shortages and how that could affect the business? And then secondly, and this is a broader question about your investment in brand assets. So obviously, you're making an investment in medical aesthetics and cellulite. But can you talk more broadly about your willingness to expand upon the overall brand business? Some of your competitors in the generic space have talked about diversifying more into higher-margin brand. How much of that is part of your strategy, whether it's medical aesthetics or other therapeutic verticals? And can you talk to how that may play out over the next couple of years?

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

Yes, sure. Thank you. So Dave, the way -- I'll take the second question first. So obviously, we're heavily invested in our Branded division. And the way we'd like to start out is we've reshaped this company. We've changed the portfolio. We are opportunistic and we are agnostic, right? And I think we've proven that out here on how we're going about, whether it's an injectable program, a generic side, or whether we're investing heavily into cellulite. Specifically, on the branded side, we get the question quite a bit is, is there going to be more to come on the medical aesthetics side? And the answer to that is we need to prove success.

And I think passing the Phase III trial obviously is a big part of our ability to expand into that indication. I don't think it's needed. But if we find the right opportunity, we'll put another product in Pat's team's bag, right? That certainly is something that our business development team is going to continue to look for opportunities. I'm not going to limit ourselves to medical aesthetics. We've got a great urology sales force. We've got a great orthopedic group. So if we can find products that we can put into programs that will fit into NASCOBAL and SUPPRELIN or Dupuytren's or Peyronie's, we're always going to be opportunistic.

That said, if you move back to the injectables question -- actually before I go to the injectables question, we -- I also want to make sure that we always remind people that we are focused. We're highly focused on debt pay-down, right? So it's going to have to be something compelling to go

forward. We're taking $190 million, and we're acquiring Somerset and we're heavily invested in the branded side. If we find something, so be it. It's got to be compelling. But we're focused on debt pay-down.

On the drug shortage side, your question is, would we be opportunistic? When I see drug shortages on the injectable side, I don't see that as an opportunity necessarily for a company like Endo or (inaudible) generic. Typically, when I see drug shortages, a lot of times because products are at a low cost or they're not profitable. I don't see going back in redeveloping a product that's in a drug shortage is something that's opportunistic. The way we're looking at it is on a go-forward basis. That's the way we're looking at Somerset. That's the way we're looking at our internal R&D right now. We're highly focused on technically challenging products in Paragraph IVs. And it really doesn't matter whether it's injectable product or a dosage. But I don't see our company going back in time on a drug shortage list to try to redevelop a product. I hope I answered your question.

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

(Operator Instructions)

Operator

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

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

My question, another one for me on CCH. I know it's early, but any high-level thoughts you had on pricing to ensure a good value proposition for patients relative to the results that you saw that's obviously is going to be crucial for uptake? And we've seen other injectables that maybe didn't price appropriately that had more disappointing uptake. So how are you thinking about that at this point?

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

Yes, so Gary, I'm sorry. I think we've answered this a little bit. I'll add a little more color. We'll hand it back to Pat. But at this point in time, we're not going to -- we're not adding color on pricing. I think that's going to come over time. We're focused now on the regulatory process. We want to get the application filed. We'll build out -- we'll communicate our commercial strategy in detail as we get closer to launch, so people are going to have to be patient. I think Pat has done a pretty good job of maybe showing some color on what the aesthetics market is. And maybe, Pat, you can add just a couple of highlights back for Gary.

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

Sure. Thanks, Paul. I mean, we obviously have some time to be able to set the price, and we've been giving it obviously a lot of thought up to this point. While we haven't determined price, we do understand that we want to be able to price appropriately to be successful in the aesthetic market. So we understand the space that we would play in, in that injectable piece. But we also understand that we want to make sure that we're not undermining the value proposition of the disruptive innovation. So more to come on that. Again, we would try to price for wide scale as option both from a physician injector perspective, but also from a consumer adoption perspective.

Operator

And the next question comes from the line of Dana Flanders with Goldman Sachs.

Dana Carver Flanders - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Mine is just on the generic gross margin profile for your business. I saw you raised it to the mid-40s for the year. How should we just think about that trending longer term? I know there is some competitive events across some of your bigger products, but you're also going to be launching some more complex ones getting into 2019 and 2020. So should we think about this as just trending upwards closer to 50% plus over time? Or what's the right way to just think about the margin profile you can achieve?

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

So Dana, this is Paul. I'll start off and then I'm going to pass it back to Blaise. We're not going to get too deep into the future of the gross margin. Again, we'll provide guidance moving out in time in our normal cadence. That said, I'd just remind everybody, we covered in our prepared remarks, we have 2 exciting authorized generics in colchicine and ertapenem. And as most people understand, those are typically revenue-driven products with lower gross margin. That being said, it's always exciting to be a marketing distribution partner for a brand company when they need a generic distributor. So I'd just caution you as we look out with these 2 exciting products. With that, maybe I'll pass it over to Blaise.

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

Yes, I think Paul you covered it well. I'll just say at the end of that, as we move forward, obviously, product mix as you indicated will be a key variable in terms of what that margin looks like. And as Paul said, we'll provide more guidance on that as we move into early '19.

Operator

And the next question comes from Annabel Samimy with Stifel.

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

So I'm just looking at some of the cash flows that you have. You have the Somerset acquisition, you still prioritize debt pay-down. You have $1 billion in cash, but you still have a lot of commitments and maybe some possible litigation overhang. So I guess now you're entering a consumer market with cellulite that's going to require heavy promotional activity to reach that customer. Can you talk about I guess your needs going forward, and if you have a capital flexibility to launch this appropriately the way a consumer product needs to be launched?

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

So I'm going to pass that over to Blaise with respect to focusing on our cash needs.

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

Yes. I mean, listen, we -- as you can imagine, as Paul said, we're planning for success in aesthetics. We have full confidence in our ability to be able to invest in this the way we needed to be successful. We feel comfortable with our cap structure, I think we've been very clear in terms of taking actions when necessary to create that operational flexibility. We have optionality in front of us. We have a fair amount of secured capacity. We do have cash on the balance sheet. Obviously, some of that cash is going to go towards finalizing the payments on our outstanding mesh liability and on completing with Somerset acquisition. But we believe we have the right operational flexibility to be able to do the things we need to do to grow the business going forward, including fully investing in the CCH opportunity.

Operator

And our next question comes from the line of Dewey Steadman with Canaccord.

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

I've got one on Somerset. Does that modest delay in shipment to 2019 impact EPS guidance either positively or negatively for 2018? And how should we look at the full year impact for that Somerset business from a revenue and EPS perspective?

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

Yes, Dewey, this is Paul. Again, we haven't -- we really haven't dimensionalized Somerset at this point in time. This is a very minor delay. I think you've got to look at it from that standpoint. I don't think we were -- number one, we're -- it's not a huge driver. Initially, as I said, it's more near term to medium term, so it's something that excites us. It is an R&D play, but it's not a -- we're not looking way out in the future. So I don't -- I wouldn't view this as a material delay that would really impact us from an EPS or in EBITDA standpoint. More to follow when we provide color in 2019. Thanks, Dewey.

Operator

And our next question comes from the line of Chris Schott with JPMorgan.

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

This is Ekaterina in for Chris. And just one more question on the CCH opportunity with cellulite. So in a real world setting come how durable would this therapy be for women? How frequently would patients need to get this treatment?

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

Sure. So Ekaterina, I'm going to pass it over to Pat and he can talk a little bit about our Phase IIa and some of the things that we're doing.

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

Yes, sure. In regards to durability, I think durability is an important attribute for injectables, and so obviously that's something that we are considering as we do our clinical development program and how we capture the data over time. As we get ready to launch, we will have data out to 12 to 18 months. Our Phase IIb and our Phase III have a rollover design, and so we'll be able to add over time to the durability story as well. So we feel very confident in terms of the fact that when the fibrous septae is addressed and dramatically disrupted, that whether it grows back or not, I think is I think a hypothesis statement, but we do think it will have a durable effect. We also believe that based on the patient satisfaction, we hope that patients would come in to get other treatment areas addressed as well. So again, I think the durability question will be determined over time, and it will be a story that we are able to add to over time based on our clinical development program.

Operator

Our next question comes from the line of Elliot Wilbur with Raymond James.

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

Paul, I'm not sure I've ever heard a guy more excited about cellulite than yourself.

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

I know it. You can just hear the excitement coming out of my voice, Elliot, right?

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

Yes. Yes, exactly. Brimming with enthusiasm. My question and I apologize if I missed this in your prepared comments. But just any updates with regards to the compounding situation in formulations of VASOSTRICT that may have entered the market. Obviously, there doesn't seem to be any impact based on your performance, but sort of hard to track what's going on there. Just any commentary you could share there will helpful.

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

So that's great, Elliot. I just can't wait to express my excitement. So I think the update, it's been pretty much established, right? So I think in August, we actually lifted the stay with respect to compounding with the FDA due to a communication we have heard in the market of a potential compound coming to market. We started to reengage the FDA. And then back in September, we agreed to stay the case once more until December 31 of this year.

And I think at this point in time, the prevailing wind is at our back. The FDA has recommended that VASOSTRICT is off of the 503B category, and there was, at this point in time, no justification of a clinical need and there is no drug shortage. As you know, comments were heard. And I think up until in October 29, comments were submitted to the code of Federal Register, they'll be evaluated by the FDA. And at this point in time, we feel bullish that the FDA will stay to their current position that VASOSTRICT should remain off of the 503 category B list.

Operator

And our last question comes from the line of Irina Koffler with Mizuho.

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

I was just wondering if you'd had a chance to look at the cellulite data in more detail, as in subgroup analysis and to determine if there's even better results possible for perhaps younger patients or [leaner] patients, and if we could be seeing that data later at medical meetings.

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

Yes. So Irina, I'm going to -- I mean, right at this point in time, we only have top line data, more data is forthcoming. Pat, can you add color on that?

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

Yes. Well, actually, you hit on 2 important things. Number one, as Paul said, we just received the top line data. We haven't received the complete data set. What I would also remind you of what is particularly exciting is the breadth and depth of data that we're going to have. So as we go through the data analysis and we get into next year and leading up to launch, we'll have an aggressive publication strategy. And we will be looking for opportunities as early as next year to have major presence at the right aesthetic congresses to be able to release that data.

So we have the plethora of data that we think we're going to have at our fingertips is going to be really exciting. And that's one of the things that the key opinion leaders have expressed to us is an appreciation for the depth and richness of the science that we're putting behind this program. So we're really excited to be able to have some podium time at upcoming congresses at the right meetings next year and into '20.

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

I think that wraps the Q&A. Paul?

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

Yes. Thanks, Laure. Folks, we appreciate your continued interest and support of the company. We look forward to providing you all with updates as we move forward. I want to thank you all for joining us here this morning. I look forward to our next conference call. Thank you, all, and goodbye.

Operator

Thank you. Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program, and you may all disconnect. Everyone, have a wonderful day.
