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ENDP - Q4 2018 Endo International PLC Earnings Call

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OVERVIEW:

ENDP reported 4Q18 revenues of $786m and GAAP diluted loss per share from continuing operations of $1.18. Expects 2019 revenues to be $2.76-2.96b and adjusted EPS to be $2.00-2.25.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Fourth Quarter 2018 Endo International plc Earnings Conference Call. (Operator Instructions) As a reminder, this conference 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. Please begin.

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

Thank you, and good morning. Thank you for joining us today to discuss our fourth 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 the 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.

I would 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 a chance to review the company's earnings release issued earlier this morning.

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

Moving Slide 3. Approximately 2 years ago, we outlined a strategic vision for Endo and laid out our key strategic priorities. We articulated a clear vision in which we aspire to be a highly focused generics and specialty branded company, delivering quality medicines to patients in need through excellence and development, manufacturing and commercialization. We also told you that this represented a multiyear turnaround plan. I am proud of the significant progress that we've made towards our goal. To recap, we simplified our company through centralization and unification, and these actions have also served to drive productivity improvements. We've created a new Endo culture that is customer focused and performance driven, with a relentless commitment of flawless operational execution. We transformed our legacy U.S. Branded Pharmaceutical business focused on pain and to a highly focused U.S. Branded Specialty Pharmaceutical business with best-in-class commercial capabilities. We divested noncore assets and businesses, and we repositioned our U.S. generics business by executing a comprehensive product portfolio and manufacturing footprint rationalization initiative.

Through these actions, we've been able to drive margin improvement, make targeted investments to further enhance our capabilities in the development high barrier, technically challenging generic products and reallocate resources to our core growth areas, U.S. Sterile Injectables, our Specialty Products portfolio of our U.S. Branded Specialty & Established Pharmaceuticals segment and the development of CCH and cellulite, including the recent successful completion of our CCH cellulite Phase III trials.

Recognizing the progress that we've made today, we believe we have now established the right foundation to transition to the next phase of our plan. As we make this transition, our 3 core strategic priorities are unchanged as is our commitment to operational execution, expanding our portfolio and capabilities to drive growth and our goal of expanding adjusted EBITDA and delevering to the 3 to 4x over -- range over time. What has evolved are the next set of specific steps that will move us forward in our journey to becoming the company we aspire to be over the long term. In this context, we have taken and we'll continue to take a long-term approach in terms of how we manage the business with a laser focus on methodically executing against our strategic priorities.

I am pleased with what we've accomplished today, and I'm excited for 2019 as it represents a critical transition year into the next phase of our plan. I remain fully confident in our team and our strategic focus as we move forward together.

Now moving to Slide 4. From a total enterprise perspective, we are pleased to report year-over-year quarterly revenue and adjusted EBITDA growth. The 2% revenue growth versus the same period last year was primarily attributable to continued strong growth in both our U.S. Branded Sterile Injectables segment and in the Specialty Products portfolio of our U.S. Branded Specialty & Established Pharmaceuticals segment. Our fourth quarter performance also reflects a 5% growth in adjusted EBITDA when compared to the fourth quarter of 2017.

We saw continued progress in our pipeline and investments. This was highlighted by positive top line and secondary results from 2 Phase III CCH clinical trials for the treatment of cellulite. We are continuing with our regulatory and precommercialization activities, and we expect to submit a BLA in the second half of 2019 and if approved, launch commercially in the second half of 2020. Blaise will walk you through our full year 2019 financial guidance later in our presentation.

Moving to Slide 5, you will see a snapshot of our segment revenues for the fourth quarter. We experience continued strong growth in both our U.S. Branded Sterile Injectables segment and the Specialty Products portfolio of our U.S. Branded Specialty & Established Pharmaceuticals segment in the fourth quarter, which was partially offset by competitive pressures in the U.S. Generic Pharmaceuticals segment and the divestiture of Somar, our former Mexican business. In addition to the continued strong underlying performance of our core areas of growth, the fourth quarter increase in these areas reflect a benefit from timing of shipments compared to the prior year. On a sequential basis, total company revenues increased by 5% to $786 million from $745 million in the third quarter of 2018, which represents our third consecutive quarter of sequential revenue growth.

In the fourth quarter of 2018, we also reported adjusted EBITDA of $344 million compared to $327 million in the fourth quarter of 2017. The increase was due to lower adjusted operating expenses.

Now moving to Slide 6. Our Specialty Products portfolio of our U.S. Branded Specialty & Established Pharmaceuticals segment continued to advance in the fourth quarter with year-over-year growth of 15%. This was largely driven by the significant growth of our XIAFLEX franchise, which grew 30% in the fourth quarter compared to the fourth quarter of 2017. This year-on-year growth reflects continued strong underlying demand and a benefit from timing of shipments compared to the prior year. Additionally, NASCOBAL grew 12% in the fourth quarter versus the fourth quarter of 2017 and AVEED grew 36% in the fourth quarter compared to the prior year. Needless to say, I'm extremely proud of our specialty branded commercial teams accomplishments.

In 2018, XIAFLEX full year revenue growth of 24% doubled the rate of XIAFLEX in 2017 revenue growth. This accelerated XIAFLEX growth rate has been driven by focused execution and continued investment in our integrated commercial strategy. This includes expanded consumer awareness and activation for both our Peyronie's and Dupuytren's contracture indications.

Based on the continued strong underlying fourth quarter XIAFLEX revenue growth, we expect full year 2019 XIAFLEX revenues to grow in the mid- to high teens percentage range and full year 2019 Specialty Products portfolio revenue growth in the low double-digit percentage range. The Established Products portfolio of our U.S. Branded Specialty & Established Pharmaceuticals segment performance reflects ongoing generic competition.

Moving to our CCH development program for assessing the treatment of cellulite, we are extremely pleased with the positive results from the Phase III trials. We are preparing for success on this front through the enhancement of our commercial capabilities, which leverage new talent with medical aesthetics experience and by building on our existing branded specialty capabilities. Looking forward, we will continue with our regulatory and precommercialization activities and are targeting a market launch in the second half of 2020.

Following our efforts in 2018, we plan to build upon our market presence, attending another 25 to 30 conferences and medical meetings in 2019. We expect data readout throughout the year, and in fact, we are excited that this Saturday, one of our study investigators, Dr. Joely Kaufman, will be presenting Phase III data at the American Academy of Dermatology conference in Washington, D.C.

Now turning to Slide 7. Our U.S. Branded Sterile Injectables segment continues to deliver with sales growth of 32% in the fourth quarter of 2018 versus the fourth quarter of 2017. This performance was driven by growth of ertapenem for injection, the Authorized Generic of INVANZ, with sales of $32 million. Also contributing to the revenue growth were ADRENALIN, with sales of $42 million in the quarter, a 60% increase versus the same period in 2017; and VASOSTRICT with year-over-year sales growth of 22% in the quarter.

Our Sterile Injectables fourth quarter growth also reflects a benefit from favorable year-on-year channel inventory changes, reflecting the significant level of channel inventory destocking experienced in the fourth quarter of 2017. Looking forward, we expect 2019 U.S. Branded Sterile Injectable revenues to grow 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 U.S. Generic Pharmaceuticals on Slide 8. The performance for this segment during the fourth quarter versus the same period in the prior year primarily reflects the impact of competitive market pressures. This performance was partially offset by strong performance of colchicine tablets, the Authorized Generic of COLCRYS, which was a result of a first-to-file Paragraph IV settlement agreement. As we noted at JPMorgan conference in January, we expect 2019 to be a transitional year for our U.S. generic portfolio. We started seeing competition materialized on a

number of our larger margin contributors, and we expect key Par generic launches to be in late 2019. In this context, we expect our full year 2019 U.S. generics revenue to decline in the mid- to high teens percentage range.

Moving to Slide 9. As expected, our international performance reflects the divestiture of Somar in the fourth quarter of 2017. For the full year 2019, we expect International Pharmaceuticals to decline approximately 20% compared to full year 2018, mainly due to the impact of generic competition on our business in Canada.

Now turning to Slide 10. We should focus to our diverse pipeline. The positive results from Phase III CCH for cellulite clinical trials positions us to pursue an exciting untapped market in injectable treatment for cellulite. We have additional real world CCH studies in development focused on dosing, injection technique and responses in target patient populations. Additionally, we continue to have optionality with CCH to develop new indications.

In the fourth quarter, we launched 3 new products, bringing the total number of Generics and Sterile Injectable new product launches to 10 for 2018. We plan to launch approximately 15 new products in 2019 across our U.S. Branded Sterile Injectables and U.S. Generic Pharmaceuticals segment. Our Branded Sterile Injectable 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.

Now yesterday, we announced that we made the decision to terminate our agreements to acquire Somerset and Wintac. While we work diligently to complete the transaction, certain regulatory approvals in India have taken longer than anticipated, and we do not have clarity on when those approvals could be received. There are no penalties or other payments associated with terminating the agreements. Notwithstanding the termination of Somerset Wintac acquisition, we will continue to be opportunistic in pursuing promising external opportunities that are aligned with our stated corporate goals.

The table on the bottom of Slide 10 shows some of our key disclosed future first-to-file or first-to-market opportunities.

Now let me turn the call over to Blaise to further discuss the company's fourth 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 11, you will see a snapshot of the fourth quarter GAAP and non-GAAP financial results.

Paul covered company and segment revenues earlier, so I will not review that again. On a GAAP basis, we had diluted loss per share of $1.18 from continuing operations in the quarter versus a loss of $1.22 per share in the fourth quarter of 2017. GAAP operating loss in fourth quarter 2018 was $150 million compared to GAAP operating loss of $304 million during the same period in 2017. The reduction in loss was driven by an overall reduction in operating expenses, including the impact of lower litigation-related charges and R&D expenses, partially offset by higher asset impairment charges.

On an adjusted basis, the fourth quarter adjusted net income of $175 million and the adjusted diluted earnings per share from continuing operations of $0.75 exceeds the upper end of our implied fourth quarter financial guidance range provided in November. The better-than-expected fourth quarter performance was driven by higher net sales across each of our segments, lower adjusted operating expenses reflective of lower G&A spend and a faster ramp-down in R&D spend post the completion of the CCH for cellulite Phase III clinical trials in early November. In addition, our fourth quarter adjusted effective tax rate was lower than expected primarily due to favorable adjusted pretax jurisdictional earnings mix. Partially offsetting the better-than-expected fourth quarter performance was a lower-than-expected adjusted gross margin due to unfavorable sales mix, reflective of the strong top line performance of our largest Authorized Generic products in the quarter.

Slide 12 provides a summary of Endo's 2019 full year financial guidance. We expect 2019 total revenues in the range of $2.76 billion to $2.96 billion. The midpoint of our revenue guidance range implies a low single-digit decline versus 2018 revenue. This implied decline primarily reflects the expected decline in our U.S. generics segment, driven by the annualization of 2018 competitive events, anticipated 2019 competitive events for several of our key U.S. generic products and the expected timing of our new product launches that are skewed towards the latter part of 2019. This

expected decline on U.S. generics segment is significantly offset by the expected continued strong growth in our U.S. Branded Sterile Injectables segment and U.S. Branded Specialty Products portfolio.

We expect adjusted EBITDA to be between $1.24 billion and $1.34 billion and adjusted earnings per share to be between $2 and $2.25. Please note that the company's guidance is based on the following assumptions: full year 2019 adjusted gross margin of 65% to 66%. Our adjusted gross margin assumption midpoint versus 2018 adjusted gross margin primarily reflects the shift in sales mix driven by the full year impact of the Authorized Generics relaunch in the third quarter of 2018 and the impact of competitive events to a number of our higher U.S. generic segment margin contributors.

We expect adjusted operating expenses to be between 24.5% and 25% of revenues. This assumption reflects continued investments in our core growth drivers, including an expected increase in our selling and marketing investments versus prior year in support of our successful XIAFLEX integrated commercial strategy and execution of our CCH for cellulite premarketing activities. These anticipated increases in investment are expected to be more than offset by reductions in G&A expense versus prior year driven by the benefits of ongoing cost-reduction initiatives and lower expected spend for certain corporate matters.

In addition, we expect R&D cost to be lower versus prior year, primarily as a result of the 2018 completion of our CCH for cellulite Phase III trials. We expect adjusted interest expense of approximately $550 million to $560 million.

In terms of our adjusted effective tax rate, we've previously communicated in early 2018 that we expected to maintain a low teens adjusted effective tax rate in the midterm based on the newly passed U.S. tax reform and assuming a static jurisdictional mix of adjusted pretax earnings. We also communicated at that time our expectations in maintaining modest level of cash tax over the midterm based on the expected utilization of certain tax attributes. During the latter part of 2018, we took additional actions to further reduce our expected cash tax over the midterm. As a result of these actions, our jurisdictional mix of adjusted pretax earnings changed from what we've previously projected, and we expect our 2019 adjusted effective tax rate to be in the 17.5 to 18.5 percentage range. However, based on our cash tax-focused strategy, we expect a low level of cash taxes in 2019 and over the midterm period.

In terms of our 2019 share count, we assume full year adjusted diluted shares outstanding to be approximately 230 million (sic) [234 million]. Although we do not provide specific quarterly guidance, we expect the split of total enterprise revenue, adjusted EBITDA and adjusted earnings per share to be more heavily weighted through 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 as well as the expected drag on our first quarter 2019 revenue as the fourth quarter 2018 stocking benefit noted earlier unwinds. We expect the drag on first quarter 2019 total revenue to be approximately $15 million to $20 million.

In terms of our operating expenses, we anticipate the first quarter to be our highest quarter of spend in 2019 mainly due to the timing of certain corporate-related expenses. We expect the first quarter 2019 adjusted effective tax rate to be the highest quarterly rate, well above our fully estimated adjusted effective tax rate range, due to jurisdictional mix within the quarter.

Moving to Slide 13. This is a summary of the segment and product specific guidance previously discussed.

Advancing to Slide 14 and wrapping up the financial discussion. For full year 2018, we had $197 million in cash flow prior to debt payment, which is higher than we guided to in November. This favorability resulted primarily from higher cash provided from changes in working capital, higher adjusted EBITDA, significantly lower mesh settlement payments into the qualified settlement fund due to timing and the unplanned proceeds from the sale of our Huntsville facility received late in the fourth quarter. We ended 2018 with approximately $1.1 billion of unrestricted cash and a net debt to adjusted EBITDA leverage ratio of approximately 5.2x.

As we look forward to 2019, we expect the use of cash prior to debt payment in the range of approximately $75 million to $175 million. This assumes approximately $460 million in payments into the mesh Qualified Settlement Funds and from mesh legal expenses; $120 million in nonmesh settlement payments, primarily related to our previously announced LIDODERM manage trust and TRT product liability settlements; and $545 million in interest payments.

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

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

Thank you, Blaise. We are proud of the many achievements to date and the steadfast focus of our teams to execute on all levels. We've taken and we'll continue to take the actions needed to become the company we aspire to be. We believe that our focus on enhancing our capabilities in the Sterile Injectables and our U.S. Branded Specialty Products portfolio, including medical aesthetics, positions us well for the future. 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 the strategic priorities. I am 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) Our first question comes from Chris Schott of JPMorgan.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

The first one I had was talking about biz dev priorities beyond the Somerset announcement from last night, should we think of more assets of that scale that could make sense for the company? Or is that more of a one-off opportunity? And just a quick second one. We're just wanting a little bit more color on OpEx as a percent of sales. Obviously, you're stepping down in 2019. If I think up to 2020 and beyond, should we think about that trend starting to move back up as we think about the infrastructure for the cellulite indication, et cetera, starting to come onboard? Just trying to get a better sense of where that ultimately is going to shake out longer term for the company.

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

Sure, Chris. Thanks. I'll take maybe the business development, and I'll hand it over to Blaise. I think in terms of the business development opportunity, when I look at the Somerset deal that we were in, it was probably at the upper end of where we're probably focused in terms of acquisition price. I would tell you, though, when we go out from a business development standpoint, we are very agnostic in terms of where we can generate potential value. So if we were to find something, whether it was on the specialty side or the sterile side, that really wouldn't make too much of a difference to me. If they're small bolt-on deals, which would fit well with our core strategy, we continue in that regard. The generics side, I would tell you, we have a lot of resources from a development standpoint. So that would probably be less of a likelihood. But at this point in time, I would keep it open to both the specialty side and the injectables side. And I'll pass it over to Blaise.

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

Sure. So Chris, just in terms of the OpEx profile, in our guidance for 2019 as a percent of sales, you do see the midpoint of our assumption range to be lower than what we saw for full year '18. And when we spoke a minute ago about what the drivers of those are is we continue to fully invest on the selling and marketing side that we are seeing [fewer] efficiencies on the G&A side, and we're seeing the step-down in R&D spend primarily related to the wrap-up of the Phase III trial for cellulite. We're not -- Chris, we're not going to guide in terms of what we think the profile is going

to be going forward. Clearly, as we've talked about, we are going to continue to fully invest in what we need to, to be successful with the launch of the cellulite indication, and we'll continue to invest against our priorities from an R&D perspective. We obviously also will continue to drive continuous improvements and look for cost efficiencies. So more to come on that, but those will be our priorities moving forward as to how we invest.

Operator

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

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

Paul, can you maybe comment on the generic environment? Is it getting better, staying the same? And specifically, when you look at your generic gross margin guidance, last year, you're looking at mid-40%; this year, low to mid-30%. Can you talk about the pushes and pulls in there? Is there Authorized Generic impact? Ultimately, I'm trying to get a sense of where do those gross margins on the generics side normalize that going forward?

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

Yes. Thanks, Randall. I mean, I think you hit the nail right on the head. At the starting point, we have the colchicine Authorized Generic. That was part of a Paragraph IV. So -- I mean, at the end of the day, that was a product that was developed by Par. So I put that a little bit into the side, but needless to say, it does pull down our gross margin percentages. On the ertapenem side, that will be a traditional marketing agreement with Merck where they -- where we're looking for a distribution partner. So clearly, that really has to drag on the GM percentage. But we will continue to take those deals and pursue them as we have historically. So that's going to ebb and flow. That's the bottom line. In terms of the pricing environment, well, we get that question quite a bit. Was pricing getting better on the generic industry? Pricing is not getting better. But what's happening is that clearly, we are stable, right, from what I like to refer to the pre-2015 time frame where while you're getting the rolfers and you're getting request for price reductions, it's more a stabilized environment. So from that standpoint, we're able to manage. We're able to be able to predict those types of -- those type of requests. And we're better positioned, actually, to defend against the rolfers. So from a normalization standpoint, it's a harder question to answer because it also deals with we're successful with future Paragraph IVs. So again, we're probably at this point at the right percentage given that our generic launches are towards the latter half or late into 2014. But as we -- sorry, late fourth quarter 2018 -- '19, rather, late fourth quarter 2019. But as we have more successes in Paragraph IVs, then I would anticipate gross margins in the generics to increase once again.

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

Should we think about that mid-30% level being roughly -- on the generics side, being roughly stable or consistent throughout the year? Or is there a back end versus front end weighting?

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

Yes. As we launch those new products, Randall, we would expect to see that weighting increase in the second half of the year.

Operator

Our next question comes from Liav Abraham of Citi.

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

Paul, I understand you're not providing guidance beyond 2019. However, based on the pushes and pulls that you're seeing over the longer term, can you kind of contextualize the 2019 EBITDA? Is this, in your view, a trough year from what we can potentially see growth going forward? And then on the tax rate, is the -- on the reported tax rate, is this 17.5% to 18.5% range, is this the new run rate going forward?

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

Yes, Liav. In terms of being it a trough year, it's really difficult to predict right now. I think for today, we're going to have to just stick to our position for 2019. There's so many uncertainties that we are dealing with on a daily basis, on a go-forward basis. We are preparing for success with cellulite, which we're hoping that we will be expecting to launch in the back half of 2020. So that's certainly going to help us as we look out into the future. We have our fair share of generic launches that we placed on the slides that we're incredibly excited about. But it's just hard to predict when our competitors come to the market. It's hard to predict FDA timing, specifically with the shutdown that we're dealing with. So I think for today, we're going to just have to comment on 2020. I'll pass it over to Blaise on the second question.

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

Sure. So on the effective tax rate, we do expect, over the midterm, our adjusted effective tax rate to be in the mid- to high teens. But what's very important is that from a cash tax perspective, and our focus here is on driving cash generation, we expect that to be lower than what we previously projected to be going forward. So very important that we understand we're focused on cash taxes. We believe that'll be lower than we anticipated going forward. However, there was a trade-off on the adjusted effective tax rate. We're going to see that in sort of the mid- to high teens.

Operator

Our next question comes from Dana Flanders of Goldman Sachs.

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

My first one is just on core XIAFLEX growth. We've obviously seen that really accelerate this year. Can you just remind us where we are on penetration in D.C. and Peyronie's? And just how you think about the levers you still have to continue to drive that level of growth going forward? And then just my quick follow-up, just appreciate the detail of the presentation on cash flows. Can you remind us when you expect the mesh and just the nonmesh legal settlement payments to end? Is 2020 a normalized cash flow year? Or will some of that still trickle over to 2020?

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

Sure, Dana. Thank you. So I'm -- we're going to pass the XIAFLEX question over to Pat, and then Blaise can certainly talk about the financial question regarding mesh. But I'll just start by saying, on XIAFLEX, we are incredibly proud of what Pat's team has done with respect to both of Peyronie's and the Dupuytren's indications, keeping in mind that Dupuytren's really launched in 2019 and Peyronie's indication launched in 3 years later. So I'm going to pass it over to Pat to give a little bit more color on how we think we can growth this.

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

Yes. Definitely. Thanks, Paul. Let me address your question on market penetration, starting with Peyronie's. When that decision to treat is made, the XIAFLEX is garnering almost 60% market penetration at this point. So we're doing very well from a market penetration perspective. But what we're excited about on the com is the fact that the diagnosis rate is still sitting around 2% or 3%, and the overall treatment rate is only 14%. So that's why we've been focusing on consumer activation and disease state awareness because we feel like there is plenty of opportunity for a sustainable growth. And based on similar pattern on Dupuytren's contracture, when that treatment decision is made, we're getting about 1 out

of every 4 patients. So there's room to grow there, which we're optimistic about. But again, we've got treatment rate -- diagnosis rate of about 3% and treatment rate of about 30%. So at the top of the funnel, we've got opportunities to generate potential growth, and that's why we've been focused on a branded consumer activation and also unbranded disease state awareness.

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

Dana, on your question regarding mesh and nonmesh settlements and the cash fall, we -- in our guidance, the mesh cash call assumes the full payout of the remaining liability in 2019. So at this point, we would not expect any additional payments beyond that for mesh. On the nonmesh settlements, the vast majority of the cash call on those settlements are also assumed in our 2019 guidance. It will be a small carryover related to those into 2020.

Operator

Our next question comes from David Risinger of Morgan Stanley.

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

So I have a couple of questions. First, with respect to VASOSTRICT, could you talk about the product's revenue prospects? And then just update us on the news flow to watch with respect to the FDA and potential competitive developments. And second, I think, Paul, you had mentioned a while back that the company is planning to enter the topical generic market and is currently building a facility. Could you just update us on that, including the timing of the facility will be able to shift products and when we will be able to see a meaningful revenue contribution from topicals? The final question, and I'm sorry for one more, but you had mentioned a stabilized environment. Could you just put some sort of framework around what that means? A lot of generalists think that means flat sales or prices year-over-year, and I constantly have to answer questions about what companies mean by stable and stabilized. But I'm pretty sure that you mean that those are -- that, that represents single digit declines in pricing year-over-year. But I'm not sure. I don't know if it means low single-digit year-over-year price declines or high single-digit year-over-year price declines. So if you could just put some parameters around stabilized, I would appreciate it.

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

Sure. David, there -- so let me see if I can tackle a few of these for you, and Blaise can certainly jump in. I think starting with the VASOSTRICT question, with respect to revenue prospect, I think what we're simply seeing, and we've put in our prepared remarks, at this point in time, we are seeing very small single-digit growth with respect to utilization, and that we take an appropriate annual price increase. And I think that's the way you really should be looking at VASOSTRICT on an ongoing basis. But I think it's also important just to remind everybody that the demand is actually going up in low single digits. The question on the topical facility, there must be a disconnect there. That's not something that's tied back to Endo or Par. We don't have any construction on topicals. We do have some small topical capabilities already in our Chestnut Ridge facility, but not -- we're not focused on building out. What we do have is an expansion in India in solid oral dosage, and we are also considering injectable expansion in India that would help us in the future with respect to our sterile and generic capabilities, but nothing on the topical front. With respect to generic stabilization, and I want to be careful. I'll start, and then maybe I'll just pass it over to Blaise. We want to be careful because if -- we're not going to go down the road of looking at our case business erosion, I don't think that's exactly your question, but we're not going to go down that path in terms of how we look at it because we do put ourselves at a competitive disadvantage when we start communicating these types of things. But maybe I'll just pass it over to Blaise to add a little color.

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

Yes. So David, when we're asked general generic environment questions, we give general generic environment answers. And when we're asked specific company questions, we give company-specific answers. So in this context, our commentary is that we've seen the underlying trends in U.S. generic stabilizing is simply us saying that the consortium-driven pricing pressures we faced in the last 12 to 18 months have moderated to a

certain degree. Now that -- what has not moderated but has actually intensified for us specifically is the product-specific competition for certain of our key product that we've talked about. And these competitive pressures are less driven by the consortiums and more driven by normal generic market dynamics. We just happen to have a number of products with limited competition that are now in markets that are becoming more competitive. So as we look at our U.S. generic portfolio, has also seen a significant number product discontinuations and is also seeing a temporary low point in terms of new product revenue due to the timing of our pipeline opportunities. So in summary, we can see stabilizing overall pricing in U.S. generic environment, but we do have some idiosyncratic factors specific to our portfolio at this certain point in time. So again, we have a very healthy generics portfolio and pipeline going forward. As Paul mentioned earlier, it's a transition year for us, and we see more significant opportunities for us late in 2019 and beyond that will help us move that business forward.

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

And David, I want to make sure I understood one of your questions, were you specifically asking about the Paragraph IV update with VASOSTRICT? Was that your question?

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

If you can update us on that as well, that would be helpful.

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

Yes. Sure. So I guess, at this stage of the game, I think everybody is aware that the first-to-file notification was received back almost a year ago, in April of 2018. That was on the 1 ml presentation. I think pretty much everybody was aware that we also received a notice on the 10 ml, which was back in June of 2018. And I think -- well, maybe the last component that's probably most important is that there is a scheduling order for both the [A&D] applicants, and that bench trial is scheduled now for May of 2020. So that's the time line associated with the VASOSTRICT.

Operator

And our next question comes from Irina Koffler of Mizuho.

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

So just going back to the generic pricing, one of your competitors mentioned that in the U.S., the stable headwind is about mid-single-digit pricing headwind. So outside of the idiosyncratic factors from this year, should we expect this to be the more normal range for your just regular oral generic business? And then a follow-up question is on the international. I didn't catch why we're looking at a 20% decline in 2019, and maybe you can comment on that going forward as well.

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

So I'll take the international question. I think it's just very simple. We're -- our Paladin business in Canada is predominantly a Branded business. And there was a couple of key products that received generic competition. So I think that's the reason of the decline in Canada. And then Blaise?

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

Yes. Again, we're not commenting on any expectations around what pricing erosion looks like for us in the industry, and Paul has commented on why we don't want to make comments around that. So we're just going to have to let it flip, let that topic stand there.

Operator

Our next question comes from Ami Fadia of SVB Leerink.

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

Paul, as you think about the generics and the Sterile Injectables pipeline that you've got and some of your commentary around a stabilization in the pricing environment, how do you see the lineup of your pipeline impacting the growth trajectory of the business in the next couple of years? Do you think that you have visibility into the business, especially the generics pharmacy business being flat to growing in either 2020, 2021? And then with regards to your 2019 guidance, can you elaborate on the percent of the portfolio in the generics side, or give it more color on a product basis as to where you see competition coming in, in the back half of the year?

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

So I'll take the first question. When you look at the generic business, there's no surprises here, right? Generic retail business remains a choppy business, and it always has, and it always will continue to be. And that's -- I mean, that's -- there's an exciting component to that, and there's a challenging component to that as well, right? So as you pick your products and you select your products, there's always going to be challenges of being able to pinpoint entry dates. We are a Paragraph IV company. There's always going to be a component of we're going to win cases, we're going to lose cases, we're going to settle cases, so that it's always going to be difficult to pinpoint with accuracy beyond where we are right today. So what we get excited about is when we placed products up on the slide here like lubiprostone, dexlansoprazole, the everolimus, these are products that we can talk about, that we're excited about, that are -- that have dates certain. And that's always going to be a major component to our business. However, the growth driver moving forward where we can really look and point to is going to be on Pat's specialty portion of Endo as well as Pat's counterpart, Tony Pera is running our injectable business. That's an area that we're going to continue to invest in. That's an area that we've been able to truly expand and have many successes beyond just VASOSTRICT and ADRENALIN. And we're excited about Paragraph IV settlement on teduglutide that we -- that we're able now to talk a little bit about. That's where you're going to see us focus a little bit more on a go-forward basis. And Blaise?

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

Yes. Sure. So on the competitive landscape question, our guidance takes into account 2 things: one, the competitive events that happened in 2018, and the analyzation of that into 2019. It also, as we stated, takes into account potential competitive events that we continue in 2019. We're not going to get into product-specific assumptions around that, but our guidance takes both of those into account.

Operator

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

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

First, on CCH for cellulite. What sort of prelaunch activities do you plan on doing this year? Have you been talking to potential partners, whether in the U.S. or outside the U.S.? And are you looking to bring other derm products in to try and maybe build some infrastructure ahead of the CCH launch? And then just quickly on NASCOBAL. Based on IQVIA, it accelerated significantly in 4Q, continued in January. You called that out, Paul. So what drove that? And is that sustainable going forward?

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

Yes. Sure, Gary. Maybe I'll take maybe the first part of that question, and I'll hand it over to Pat. In terms of -- well, Pat will talk about the prelaunch activities. In terms of partnerships, I think we've been pretty clear that we -- that we're always listening, we're always out there in the case of optionality. If there's somebody that wants to partner with us in the U.S., we certainly will always listen if that's the way that we can maximize the asset. I've got that fiduciary responsibility to do so. But absent of that, we are planning for success. And in a second, Pat can tell you a little bit about what we're doing in 2019 and as we lead towards the expected launch and success in 2020. That said, we do have international rights. We've talked about that in the future that when appropriate, we would look to partner. We've had initial discussions with certain companies that could maximize it from an ex-U.S. standpoint. But clearly, the focus is preparing for the regulatory success in the U.S., and then we would parlay that into the potential territories in Latin America and hopefully, Europe as well. And with that, I'll pass it over to Pat to talk a little bit about the commercial activities.

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

Yes. Now great. Thanks, Paul. As Paul mentioned, I mean, it's exciting time in 2019 as it relates to the CCH and cellulite. The R&D team is working very hard to ready ourselves towards the submission of a BLA in the second half of 2019, so that's a major milestone for us. As far as commercially and what we're doing both commercially and scientifically, we're continuing to expand our introduction of Endo aesthetics. We'll be attending probably approximately 25 major meetings similar -- in similar fashion to the AAD coming up this weekend. We feel like, given the disruptive innovation at CCH and cellulite represents, that will garner a lot of podium time. And so we're excited about Joely Kaufman releasing the Phase III results this weekend. So we've got an aggressive publication strategy in 2019 where we can begin to disseminate data. We'll also be continuing to work with our key opinion leaders to generate real-world data, and that's generating a lot of excitement. We've made the right strategic hires with medical aesthetics experience that you would anticipate from company that you would recognize. So we've got our commercial head onboard. We've got our head of marketing with strong consumer background onboard, which will be important to CCH, and we've made a couple of other strategic hires. So we're really building out the commercial infrastructure from a sales and marketing perspective. That also -- we benefit from the fact that we also have an internal structure to draw on from our existing branded specialty organizations. So we're excited about having this other channel that we can build off of. As far as key activities, obviously, beyond building out the commercial plan from a marketing perspective, we've done a lot of segmentation work. We're sizing the market. Obviously, a pricing decision will be a big one for us, and we'll begin to zone in on the right price point. We'll be finalizing our branding and packaging work. The brand naming we're excited about is right on track to complement our regulatory submission. And then we will be building out our framework around both our branded positioning and our unbranded positioning in the marketplace and really putting ourselves in the position to really accelerate that build-out in 2020.

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

And then, Gary, maybe just to add a little color. We get asked the question on NASCOBAL. When you look at what past commercial team has done just with XIAFLEX with the Dupuytren's indication launching in really 9 years ago and the Peyronie's launching 6 years ago, NASCOBAL launched 10 years ago, in 20 -- in 2009. So it's just an amazing position that we can continue to grow these older assets. But maybe we'll talk a little about the zero copay?

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

Yes. No, I apologize I missed that one. Yes, so we've seen strong growth of NASCOBAL, as Paul said. We've got a focus in the bariatric segment, and we put a zero copay offering for our commercial payer patients, and that's been really well received to remove any patient out-of-pocket barriers. And our (inaudible) sales team has done a terrific job of executing really strong messaging around NASCOBAL, and what we're really proud of the fact that we grew that product at 14% year-over-year.

Operator

Our next question comes from Gregg Gilbert of SunTrust.

Gregg Gilbert

First, for Blaise, I was hoping you could quantify the effects of the shipment timing that you called out on VASOSTRICT -- I'm sorry, on XIAFLEX and whether that affected other products. And then, Paul, a strategic question. When you first announced the Somerset deal, you pointed to a filed application for injectables as well as a sterile injectables facility in India. So I'm wondering if those are still key strategic priorities for you, and do you see opportunities out there to address those externally? Or have you just turned those efforts inward? Or will it be a mix of both?

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

Yes. Sure, Gregg. I'll take the latter question. So sure. I mean, while we're disappointed with Somerset, we remain incredibly excited with the Nevakar deal, and there's always potential to expand that existing relationship. In terms of small injectable deals, there are -- there certainly are a series of other companies and products that we could potentially acquire. So that strategy is going to remain intact. We're excited about that. And then the comment about injectables, we are -- we have a robust and an aggressive injectables program that we want to continue to invest in. As I said, it's a core part of our growth. So I don't see any change in that regard. So maybe a bump in the road with Somerset, but we remain pretty excited with Nevakar and other potential acquisitions that we -- that we're evaluating currently. And I'll pass it over to Blaise.

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

Sure. So Gregg, in terms of the stocking question, we had noted on the call, during the script, that we expect to see about a $15 million to $20 million drag in Q1 related to that item. And of that, about $5 million we expect to be related to XIAFLEX.

Operator

Our next question comes from David Amsellem of Piper Jaffray.

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

Just a couple. So I wanted to drill down on business developments, and you talked about focusing on specialty and injectables. But within specialty, can you elaborate on what areas you're looking at? And I apologize if I missed this before, but what areas are you looking at? What you're prioritizing? And then also, what your wherewithal is given the capital structure? And then secondly, with injectables, I know you've talked about toggling more to -- towards 505(b)(2) as a more complex product. Can you talk about your capabilities now and kind of aspirationally what you're thinking about in terms of what you want to add in terms of the capabilities within Sterile Injectables going forward?

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

Sure. So Dave, maybe the first question, with respect to business development and focus, I mean, think I started the question by indicating that we are agnostic. And when I say agnostic, we also have to be a bit true to ourselves in terms of our strengths and where we are today. So clearly, on the specialty side, having indications for men's health would be a -- clearly a focus that would make sense. We have, obviously, other indications that we can pursue with XIAFLEX. That's an R&D question. So it's a balance between men's urology from in-licensing. We also have to think about potential R&D that we can do with XIAFLEX for the future. I also get a lot of questions about, would we aggressively go after another -- a medical aesthetics product for the portfolio? And I think the way Pat and I really look at it is at an appropriate time, we will or consider it. I think we've got a lot to execute on the current CCH path. We'd like to prove success, right? We have the expectation of filing. We have the expectation of launching. We have to get that behind our back, under our belt, that would clearly be a [on the com] area of focus. A couple of other points. In terms of your question on the cap structure, I'll leave that to Blaise in a second, maybe I'll just move over to the 505(b)(2) capabilities. I think when you look at our company, we have unified and centralized our R&D groups. We have a lot of talented individuals that have shown success, both on our specialty and our injectables side. Long history, when you look at the portfolio, Megace ES, NASCOBAL, ADRENALIN, VASOSTRICT, these are all 505(b)(2)s.

The Nevakar is all 505(b)(2)s, right? So when you look at the internal capabilities -- and again, we have the same team that's helping us develop BLA. So I think we have a lot of in-house capabilities to bring the right type of products forward. So if there's a 505(b)(2) that we want to file, whether it's on a solid oral dosage side, the injectable side or the BLA side, we're going to be agnostic. But we have the talent to be able to develop and file those with our own in-house talent. And with that, I'll pass it to Blaise with the cap structure.

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

Yes. So David, just in terms of your question around our wherewithal, I would just first say, our ultimate path to success lies in our ability to grow EBITDA, and that's really building the portfolio we need for the future. And our capital allocation priorities are aligned to that goal. Now just in terms of funding our capital needs and our ability to achieve that goal, we ended the year with about $1.1 billion, $1.2 billion of unrestricted cash. Based on our cash flow guidance, we expect to see use of cash somewhere between $75 million to $175 million in '19, and that's fully funding the remaining cash call on our mesh liability. So based on this outlook, we would expect to exit 2019 with somewhere around $1 billion of unrestricted cash. We'll be in a position to generate meaningful positive cash flow as we enter 2020, and we also have available secured capacity. So we feel good about our current level of operational flexibility. We're always assessing to see if there are other ways to increase that flexibility, but we feel good about where we are and the things we're targeting.

Operator

Our last question comes from Louise Chen of Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

One question I have is we got a lot of thoughts on people on this opioid litigation trial that's coming up. I don't know if the date has been changed, but last we checked, it was September 3. So just curious, what are your expectations here? And how can you help us think about the potential liability to you? And then second question on CCH and your data presentation this weekend, maybe if you could give us a little bit more color on what you plan to present. And then one of the pushbacks that we've gotten is that it looks like the data were not as strong as some people had expected. And just curious if that will be enough of a data to drive uptake and also for people to come back for their additional treatments.

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

Sure, Louise. So this is Paul. I'll take the opioid question, and I can then maybe pass it over to Pat. So clearly, the -- so what had previously been communicated was that there were -- there was a bellwether case that was scheduled for September. The judge, in fact, did push that out to, I believe, October 21. So that is a change. That is track 1. I think it's important to note that in track 1, the defendants are not yet known actually who is going to be specifically in track 1. So to answer your question, bellwether case got pushed from September to October. We still do not know whether Endo or who any of the defendants are going to be in track 1. And that's pretty much the -- we're not going to be able to quantify. We're -- that's something that we're not going to do. We always like to say that we've had discussions. And if there's a way to settle, that's always something that we would consider. But at this point in time, we need to be prepared to go to trial if we are a part of track 1. With that, I'll pass it over to Pat to talk about CCH.

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

Yes. Sure. Thanks, Paul. We're very excited about the AAD, and we'll be -- we anticipate a lot of play at subsequent meetings throughout the year. So again, it will be a comprehensive review of the Phase III data, making sure people understand the differences between Phase III and Phase II, which you mentioned, so I want to definitely address that and some of the subanalysis that we've seen. Maybe taking on the question of the data, in fact, the data has been remarkable. I mean, again, it's important to understand that it's a largest cellulite trial ever, a very stringent endpoint, and despite that, it didn't meet that endpoint. So the main differences between the Phase III and the Phase II, on the Phase III, there were no restrictions on BMI or no restrictions on cellulite severity. So it's an all -- really, an [all comer] trial with a very difficult patient population. Yet it still met its

primary endpoint in 15 of 16 as a -- 15 of the 16 secondary is truly remarkable. When you look at patients within the normal BMI range, which is the stratified data that we'll be able to disseminate going forward, in fact, those patients did much, much better and actually did slightly better than the Phase II results. So the Phase III results and those normal targeted BMI patients, the result was actually slightly better than the Phase II. So that's the type of nuances that you'll see going forward as we disseminate data. In relation to your KOL question, based on the discussions today with our investigators on our KOLs, they're very excited about the data, especially when they look at the 1-grade and 2-grade improvements as characterized by the before and afters. And we've consistently heard that it's a -- they believe it to be an impressive result. And they feel like there's a lot of patients that would line up quickly for it, probably likely the aesthetically experienced women within a normal BMI active lifestyle who have cellulite and spotted by cellulite, happens to be a lot of patients, by the way, they feel like those would be first in line for us. So we feel like there's a big market potential for CCH and cellulite once approved.

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

Thank you. I guess that's our last question.

Operator

At this time, I'd like to turn the call back over to Mr. Paul Campanelli for closing remarks.

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

Thank you. Simply said that we truly appreciate your continued interest and support of the company. And we look forward to providing you with updates as we move forward. Thank you for joining us this morning, and goodbye.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. You may disconnect. Everyone, have a wonderful day.
