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ENDP - Q1 2018 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 1Q18 net loss from continuing operations of $498m and GAAP diluted loss per share from continuing operations of $2.23. Expects 2018 revenues to be approx. $2.6-2.8b and adjusted diluted EPS from continuing operations to be $2.15-2.55.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the First Quarter 2018 Endo International plc Earnings Conference Call. (Operator Instructions) As a reminder, this call is being recorded. I would now like to turn the call over to Nina Goworek, Senior Director of Investor Relations.

Nina Goworek

Thank you, Michelle. Good morning, and thank you for joining us to discuss our first quarter 2018 financial results. Joining me on today's call are Paul Campanelli, President and CEO of Endo; Blaise Coleman, Executive Vice President and Chief Financial Officer; and Patrick Barry, Executive Vice President, President and Chief Commercial Officer, U.S. Branded Pharmaceuticals.

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 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, Nina. Good morning, and thank you for joining us for today's call. I hope that you'd have a chance to review the company's earnings release that we issued earlier this morning.

Let me now turn to our first quarter 2018 earnings presentation. Beginning on Slide 2. Here's a brief agenda for today's call.

Moving to Slide 3. Endo is very pleased to report another solid quarter of adjusted operating results. Revenue growth in our core areas of focus, XIAFLEX and the Sterile Injectables accelerated in the quarter, and our first quarter adjusted results reflect the continued progress we are making against our strategic priority to drive meaningful margin expansion.

We are off to a very encouraging start to the year and are affirming our previously provided full year 2018 revenue, adjusted EBITDA and adjusted EPS guidance. Blaise will discuss our financial guidance in greater detail later in our presentation.

Moving to Slide 4, you'll see a snapshot of our segment revenues for the first quarter. The quarter's performance versus the same period last year was primarily attributable to the loss of exclusivity of ezetimibe and quetiapine ER, the annualization of 2017 competitive entries and the product discontinuations in the U.S. Generic Pharmaceuticals segment, the divestitures of Litha and Somar, and the voluntary withdrawal of OPANA ER.

This was partly offset by a continued strong growth in our U.S. Branded - Sterile Injectables segment, as well as continued growth on our U.S. Branded Pharmaceuticals segment's Specialty Products portfolio.

Now moving to Slide 5. As I just mentioned, our Branded Specialty portfolio continued its growth momentum, with 7% growth year-over-year. This was largely driven by the strong 15% growth of our XIAFLEX franchise. As mentioned, Branded Established products were impacted by the voluntary withdrawal of OPANA ER and the generic competition amongst several other established brands.

As we've indicated over the last 1.5 years, we've transitioned our portfolio to focus on our specialty brands, and most importantly, XIAFLEX in CCH life cycle strategies.

Branded direct-to-consumer advertising and disease awareness campaigns for both Peyronie's disease and Dupuytren's contracture continue to yield results, as demand for both indications showed strong growth in the quarter.

Turning to our CCH cellulite treatment development program. We continue to be pleased with the ramp-up of our 2 pivotal Phase III trials in botox, and recruitment for both trials is progressing as planned. We currently expect to share top line results from these Phase III trials by the first quarter of 2019.

More recently, an encore presentation of our Phase IIb results was presented during the Hot Topics Symposium at the American Society for Aesthetic Plastic Surgery, commonly known as ASAPS. Having our data presented at one of the most popular and prestigious sessions of ASAPS demonstrates that there is a great interest in the aesthetic community for an innovative injectable treatment for patients with cellulite.

We will continue to have a presence at major aesthetics conferences as we advance our cellulite treatment development program and data generation plan. I'm very pleased by the progress we are making with our prelaunch planning efforts as our commercial team prepares for success.

Turning to Slide 6. Our U.S. Branded - Sterile Injectables segment continued its strong momentum in the first quarter, growing 25% versus fourth quarter of 2017. This growth was largely driven by ADRENALIN, with sales of $30 million in the quarter, as unapproved sources begin to vacate the market in the second quarter of 2017.

Adding to the strong growth was VASOSTRICT, which benefited from some favorable buying patterns in the quarter, with sales of $114 million, growing 15% year-over-year.

Speaking of VASOSTRICT, we are extremely pleased we were able to obtain a preliminary injunction during the first quarter, preventing QuVa Pharma from marketing and releasing a compounded version of vasopressin using bulk substance until the conclusion of the trial. A trial date has not yet been set.

Additionally, as you are aware, the FDA made public statements in January regarding the bulk compounding of essentially copies of approved drug products under Section 503B of the Federal Food, Drug and Cosmetic Act. The FDA also issued draft guidance in March on clinical need determinations for purposes of establishing a 503B bulk list.

These developments, together with further discussions amongst our and FDA's counsel, resulted in our agreeing to a temporary staying our pending litigation against the FDA, which stay has now been extended by the court until September 26, 2018 to provide the FDA additional time to implement its new compounding policy.

It is important to note that we retain the ability to lift the stay if we believe an entity has commenced or is likely to commence bulk compounding of vasopressin under the FDA's prior policy, and we intend to seek preliminary injunctive relief.

Lastly, as you are aware, we received a Paragraph IV notification on VASOSTRICT on April 17, alleging invalidity and noninfringement with respect to 5 of our patents. Procedurally, under Hatch-Waxman, we have 45 days to assess the details of the notice letter and, if appropriate, initiate a patent infringement lawsuit. If that occurs, filing a lawsuit triggers an automatic 30-month stay of FDA approval. We intend to vigorously defend our intellectual property.

Now on to some recent and exciting news. In late April, we announced we received definitive agreements to acquire Somerset Therapeutics and the business of its Indian-based affiliate, Wintac, in an all-cash transaction for approximately $190 million. We believe that this bolt-on acquisition in Sterile Injectables is in line with our strategic priority of building our product portfolio and capabilities for the future, and that our strong sales and marketing capabilities will add great value to their 8 commercial products. Additionally, we will gain an extensive pipeline of over 40 products, along with production and development capabilities that augment our existing Rochester sterile facility.

We believe that this acquisition will strengthen and expand our product offerings in the hospital setting, an important step for us in achieving our aspiration of becoming a larger player in the sterile injectable market. We expect the transaction to close towards the end of this year. Separately, we have signed an agreement to become the exclusive distributor of Somerset glycopyrrolate injection, the generic version of ROBINUL, effective May 1.

Turning to our U.S. Generic Pharmaceuticals on Slide 7. The performance for the segment during the first quarter versus the same period in the prior year reflects the loss of exclusivity of a large first-to-file products ezetimibe and quetiapine ER, which contributed sales of approximately $200 million in first quarter 2017. Also contributing to the performance versus prior year was the annualization of 2017 competitive entries, as well as the previously announced product discontinuations.

With regard to overall generic retail market conditions, the downward pressures we have previously discussed appear to be stabilizing. We view this trend as positive and believe the hard decisions and actions that we have taken over the last 18 months, in combination with our efforts to build relationships with the real line consortiums, are helping contribute to these developments. We will continue to compete in this dynamic generic retail market by focusing on launching first-to-file, first-to-market retail products, along with our emphasis on difficult-to-produce products.

On Slide 8, let's briefly discuss International Pharmaceuticals. As expected, our International performance reflects the divestitures of Litha and Somar in the second half of 2017. Excluding these divestitures, our International business grew 18% year-over-year.

Paladin grew 10% year-over-year, which is better than expected, due to new product launches and delayed competition on certain products. We are pleased with Health Canada's approval of XIAFLEX for Peyronie's disease, giving us the opportunity to launch this indication.

Paladin also recently launched Unisom Snore Relief, the only natural health product throat spray indicated to help release symptoms associated with snoring. We are continuing to build our portfolio in Canada, with 2 sterile injectable product filings pending approval with Health Canada, one of which could launch this year; and continued business development efforts with the in-licensing of Envarsus XR, for which we are currently seeking approval in Canada for the prophylaxis of organ rejection in kidney transplant patients.

Turning our attention towards scorecard for the year and select disclosure on our pipeline on Slide 9. I've already touched on U.S. Branded Pharmaceuticals, U.S. Sterile Injectables and International Pharmaceuticals with their business results.

The U.S. Generics segment launched 3 new products year-to-date: sodium phenylbutyrate powder and praziquantel tablet, which were first to market, and memantine ER being shared first to market. We've made 2 regulatory submissions year-to-date and continue to expect to make a similar number of filings in 2018 as we did in 2017. We continue to be enthusiastic about our pipeline, including the large disclosed opportunities to come in the second half of 2019 and beyond.

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

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

Thank you, Paul, and good morning, everyone. First, on Slide 10, you'll see a snapshot of the first quarter GAAP and non-GAAP financial results. Paul covered company and segment revenues earlier, so I will not review that again.

On a GAAP basis, we had a diluted loss per share of $2.23 from continuing operations in the quarter versus $0.74 in the first quarter of 2017. GAAP net loss from continuing operations in the first quarter of 2018 was $498 million compared to a GAAP net loss from continuing operations of $165 million during the same period in 2017.

This was primarily due to the after-tax impact of goodwill and intangible asset impairment charges related to the U.S. Generic Pharmaceuticals segment during the first quarter of 2018 as compared to the same period last year.

On an adjusted basis, first quarter results were solid. Adjusted operating income of $299 million and adjusted diluted earnings per share from continuing operations of $0.67 exceeded our expectations for the quarter and reflects significantly improved adjusted gross margin and lower adjusted operating expenses versus prior year.

The greater than 800 basis point improvement in adjusted gross margin in the first quarter was due to favorable business mix, primarily driven by increased revenue growth in Sterile Injectables and Branded Specialty products, and benefits from our ongoing cost efficiency initiatives.

Turning to Slide 11. In light of our first quarter performance, we are affirming, with increased confidence, our 2018 full year revenue, adjusted EBITDA and adjusted diluted EPS financial guidance.

Specifically, we continue to expect revenues to be approximately $2.6 billion to $2.8 billion. We also continue to expect adjusted diluted earnings per share from continuing operations to range between $2.15 and $2.55, and continue to expect adjusted EBITDA from continuing operations to be between $1.2 billion and $1.3 billion. The company's full year financial guidance is based on the assumptions noted on this slide.

In terms of quarterly phasing, we've previously communicated we expected total enterprise revenue and adjusted gross margin to be fairly balanced on a quarterly basis over the course of the year. Given the better-than-expected first quarter of 2018 revenue and adjusted gross margin, mainly driven by our Sterile Injectables segment due to favorable customer buying patterns on VASOSTRICT, we do expect to see lower total enterprise revenue and adjusted gross margin in the second quarter versus first quarter. We also expect to see higher adjusted operating expenses in the second quarter versus first quarter, mainly due to timing of certain legal and development expenses.

Lastly, in terms of projected cash flow on Slide 12. We had $2 million in cash flow prior to debt payment in first quarter 2018, and now expect the use of cash prior to debt payment for full year 2018 to be in the range of approximately $415 million to $315 million, reflecting the expected funding of the Somerset Therapeutics and Wintac acquisitions in late 2018.

It's important to note that these acquisitions are fully aligned with our stated intent to delever over time. A key enabler to delever is adjusted EBITDA growth, and we believe that this bolt-on acquisition will contribute meaningful adjusted EBITDA growth in the short to medium term.

As we progress through the year, we will continue to evaluate our capital allocation priorities, including optional debt paydown. We ended the first quarter 2018 with $980 million of unrestricted cash. And at quarter-end, our net debt to adjusted EBITDA leverage ratio was approximately 5.1x.

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

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

Thank you, Blaise. We are off to a very encouraging start to the year. I truly believe that the actions we have taken over the last 18 months and the further work we have planned for 2018 will help reposition Endo for long-term success. We will continue to focus on the things that we can control and be relentless in executing on our strategic priorities.

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

Nina Goworek

Thank you, Paul. (Operator Instructions) Michelle, may we have the first question, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Ami Fadia of Leerink Partners.

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

My question is for Paul. And I wanted to get your thoughts on the Somerset acquisition. What particularly about the asset got you most excited? And if you could provide us any visibility into the type of products they have in the pipeline. And does that pipeline help change the cadence of meaningful new product launches over the next year or 2?

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

Thanks, Ami. Obviously, we're incredibly excited. I think as we've been communicating over the last 18 months, we have a high focus on -- in Sterile Injectables. I think what excites us is the ability to bolster our portfolio and bringing more high-value products that are more challenging to make to patients. This acquisition is going to infuse us and, in essence, more than double our existing footprint in injectables. So when you look at the history of what we've created in less than 4 years, in essence, we started this journey in 2014 with $110 million revenue company from JHP, and we've created a nearly $775 million company last year. These are products that have stability. This is an area that we want to continue to grow in. That's why we wanted to acquire a company that has meaningful injectable products. And we have a track record with the former principal of Wintac, Veerappan Subramanian. We had a very good track record historically at par. So a known entity, good track record, sterile products having longevity. And now we're building our portfolio, so it's something that we're very excited about.

Operator

Our next question comes from Andrew Finkelstein with Susquehanna Financial.

Andrew Jay Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

I was hoping you could talk a little bit more about your views on the VASOSTRICT and any updates on the ADRENALIN IP situation. You're still pursuing additional IP, but any comments you can give on the strategy of copying an older formulation, and your views on why it will be inappropriate for FDA to approve a product that had some of the nonclinical characteristics of the older version. And then just on the upcoming product launches. You mentioned an authorized generic product for the 2019 launches, if there's any more detail you can give there.

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

Sure. Thank you, Andrew. I think the starting point on VASOSTRICT, as we've indicated, we have a Paragraph IV that we received on April 17. That said, we -- I think, as you know, we have 6 Orange Book patents, 5 tied to the 1 ML. We're very, very bullish on our intellectual property. When we look at the formulations, our view is that the FDA is going to be focusing on the most current RLD, and that's going to be -- I think to us, we view that as a very high barrier to overcome from an approvability standpoint. So I think we look at VASOSTRICT from 2 different angles. We have our intellectual property and the fact that the FDA typically makes ANDAs focused on the current RLD. So I think from that standpoint, we're pretty bullish. And then we also have about another 5 to 6 Orange Book patents that are pending, and that will also bolster VASOSTRICT. Regarding ADRENALIN intellectual property, I don't believe that we have any follow-on patents that I'm aware of on the ADRENALIN side. That said, I think we had some positive news with respect to the existing Paragraph IV that, that is going to continue, and we should expect a 30-month stay. So from that standpoint, it's really running itself at this point. I think your last question was with respect to a product that we put on our slide. From a generic standpoint, we have, under an agreement with Takeda, we have the right to launch an AG version of Colcrys come July 1, 2017 -- I'm sorry, 2018. My apologies.

Operator

Our next question comes from David Buck of B. Riley FBR.

David George Buck - *B. Riley FBR, Inc., Research Division - Analyst*

Maybe just a follow-up on the first -- the last comment. The Colcrys agreement, is that exclusive and no AG during the -- after July 1? And maybe for Blaise, can you talk a little bit about what the additional buying may have been in the first quarter for VASOSTRICT? And how would you expect the phasing of gross margin going forward? And maybe how does the -- some of the divestiture news, including the Lannett deal, affect gross margin for the rest of the year?

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

Okay, David. I'll take the AG question. I think the way you should look at that, I would view that as just a typical AG. We will be stepping in the shoes of a company that's already there, so I think it would be a limited disruption in normal course. But the way you should look at the deal would be as a standard authorized generic relationship with the brand company. I'll pass it over to Blaise on the financial.

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

Yes. Thanks, David. So just in terms of the VASOSTRICT impact, the favorable buying patterns was about $10 million at top line. And then as maybe you heard in the prepared remarks, in terms of cadence for the rest of the year, from a gross margin step-up standpoint, we will see a -- expect to see a decrease in Q2 mainly due to the VASOSTRICT favorable buying patterns. And as we move through the rest of the year, in the Q3 and Q4, at this point, we would expect the gross margin to be fairly balanced between those 2 quarters. So that's sort of the cadence in the rest of the year on the gross margin side.

David George Buck - *B. Riley FBR, Inc., Research Division - Analyst*

I guess maybe a follow-up. The divestitures of products from -- including the one to Lannett, any impact that we should be expecting in second half or into '19 on gross margin?

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

No. No, David. They were a part of -- mainly a part of our discontinuation program that we previously announced.

Operator

Our next question comes from Liav Abraham of Citi.

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

Paul, can you talk a little bit more about the dynamics in the U.S. generics market? And in particular, are you seeing any ability to take price on a discrete basis? And then secondly, on your CCH pivotal trial for cellulites, can you make comments on how enrollment is progressing? You've guided the headline data in Q1 '19. However, given the rapid enrollment in the Phase II trials, would it be possible to see data in the latter part of 2018?

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

Yes. Sure, Liav. So in terms of the generic environment, again, I've used this term last quarter and I'll stick with it, that we are -- we remain cautiously optimistic. And what that really means to me is that we still see erosion, but it's erosion that we have forecasted. And I hate to characterize it like this, but it's not worse than what we've anticipated. So we're starting to see some normal course and some stability. Regarding the CCH enrollment, obviously, we're incredibly excited. I'll pass it over to Pat in a second. But we're actually pretty excited about staying -- I'm sorry, bringing forward cellulite. While enrollment may be going a little bit quicker than anticipated, I think for now, we'll stay with our top line results for first quarter 2019. Pat, I don't know if you've got anything you want to add.

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

No. Paul, I think that's well said. We did see our Phase IIb trial enrolled incredibly fast. We think that sort of speaks to the fact that there's a large unmet need here, so that's why we're excited about this development program. We think we're incredibly well positioned to address an unmet need, and we're really excited about having those topline results. And as Paul stated, we're looking at some time during Q1 2019. Anything is possible, of course, but we stand by our statement of Q1 of 2019. To have with our hope of great data. Again, I think why we're excited is, to date, there is not an innovation like this where it's an injectable product that treats the underlying cause of cellulite, that's the fibrous septae. And so we believe that the market is ready for this type of innovation, that's why we stand ready to speak to those results when we're ready.

Operator

Our next question comes from Randall Stanicky of RBC.

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

Just looking strategically at the business. You're growing your brand business, you're shrinking the generics business, getting bigger in the hospital and set to add a footprint with the CCH in probably 2020. Can you just comment, what percent of your overall business goes through the big 3 consortiums now? And where does that go in 3 years? And then a related question, when you think about the retail generic comments that you made, is that stabilization, do you think, due to the consortiums now realizing that they pushed as hard as they can push? Or is that more related to the fact that there's been broad-based pruning and just the supply-demand equilibrium is better than it was a year to 2 ago?

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

Yes. So Randall, I would say about 1/3 of our revenue goes through the 3 large wholesalers right now. So it's an incredibly important part of our business. And I want to be clear that we're not walking away from retail, it's just we need to be focused on the areas of growth, right? So -- now the retail segment continues to be an area that is going to be a material contributor for the years to come. But our areas to grow, as we've mentioned, comes from cellulite and from our sterile business. And hence, the recent acquisition of Somerset Therapeutics. And Randall, I apologize, can you just maybe help me with that second question again? If you could repeat it, please?

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

Yes. Just the comments on the retail generic environment stabilizing, do you think that's more driven by the big 3 consortiums realizing they've pushed as hard as they can push? Or is that related more to there's just fewer products out there because there's been so much pruning and pulling back on some of the unprofitable products?

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

Yes, and I think it's a combination of both. And it depends who you're asking, too, and what the companies' motivations are. I mean, I think when you look at the consortiums, there's been enormous pressure placed back on companies that have been forced to make tough decisions and -- on products. And in essence, may have exposed certain inefficiencies on generic manufacturers. But as a result, you're seeing product discontinuations in that pressure. You're not going to see these products coming back. And I think that will possibly result in certain types of drug shortages on a go-forward basis. There's been an enormous amount of pressure, right? So from that standpoint, that's somewhat concerning. I think when I say stability, I kind of speak for the Par portfolio because we made those tough decisions 18 months ago, where we discontinued products where we had no meaningful gross margin dollars or weren't even contributing to, say, even planned absorption. So from that standpoint, we already made those tough decisions. And I think, ultimately, it's kind of where -- it's kind of led us to where we are today. And I think a couple of companies have clearly followed suit on further difficult decisions. But I think, ultimately, the pressure started with the consortiums and exposed certain inefficiencies

in making tough decisions. But I think for the near term, we will probably see some normal course erosion as we have Par start to focus on first-to-file and first-to-market products on a go-forward basis.

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

And Randall, if I could just add on to Paul's earlier comment on the 1/3 of the revenue. The 1/3 of the revenue is -- that's going through the 3 wholesalers, is related to generics retail business. Just to qualify that a bit.

Operator

Our next question comes from Elliot Wilbur of Raymond James.

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

Paul, I just want to go back to some of your earlier commentary around Somerset. Trying to figure out this was just a sort of a unique opportunity, maybe identified based on a past relationship. Or whether or not we should, in fact, not be surprised if you continue to make kind of these small tuck-in, bolt-on acquisitions going forward, kind of go back on offense. It certainly seems with kind of the balance sheet limitations that maybe that surprised folks a little bit, but I'm just not sure if that's going to be part of the regular game plan here in the next couple of years. And just quickly in terms of follow-up. If you're thinking about new products expectations for the year, number now 15 to 20. And I know, kind of beginning of the year, it was around 20. It seems like that's one area where industry is still having a little bit of difficulty in terms of getting the real good line of sight in terms of timelines coming out of the FDA. And I'm just wondering if you're thinking that's just more product-specific, company-specific issues, or still dealing with an agency that's kind of struggling to really honor its obligations under GDUFA.

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

Yes. Well, maybe I'll start backwards in terms of the qualifier around 15 products. So I think, right now, and you've characterized it well yourself in some of your reports, that you're seeing a lot of approvals but not necessarily first-time approvals. So I think we're seeing some pressures that the FDA is focusing on nonparagraph-related first to market types of products where there are certain types of delays. So I would say, this is the new FDA and we just need to be prepared for that. We still have a pretty robust portfolio of around 15 products. And as we indicated, we're actually pretty excited about the authorized generic product that we will be launching in July. Regarding the strategy on the injectable side, I mean, I think Blaise has characterized it really well. I mean, we are laser focused on delevering and debt paydown. This opportunity is one that we were just following for a very long time. And we are just so excited to be able to expand our sterile side. And again, right, at the end of the day, as Blaise characterized it, again, a way that we can delever is to drive EBITDA. So this is a -- while it's a small bolt-on acquisition, I would say, it's probably more towards a one-off. It's something that we're very, very excited about. We'd like to say, in our hands, we're more hoping that we can make it better. And I think we've got a history of certain acquisitions at Par over the last 7 or 8 years that we've been able to create value once we get a hold of it from a technical standpoint and from a sales and marketing standpoint. So we've got a couple months to go. Stay tuned. But we're really excited about this small injectable company.

Operator

Our next question comes from Louise Chen of Cantor.

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

So my question was on CCH. Just curious if you could talk about the Phase II trial design, what you saw there and how it differs from the Phase III trial design, and if there's any positive read-throughs from Phase II to Phase III.

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

Yes. Louise, I'm going to pass that over to Pat Barry. Pat, you can talk a little bit about the Phase II and III.

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

Sure. I mean, the Phase III clinical development program is designed based on the success of the Phase IIb results. So again, it's a composite endpoint, both a 2-point improvement for both patients and physicians. So it's a very high watermark that was achieved in Phase IIb, highly statistically significant results. And so it's based on that confidence that we designed the Phase III trial. It's focusing on our cellulite severity scales, which is a validated scale. So that was validated in Phase IIb and that's the central part of our Phase III. And so one of the things we're excited in Phase IIb was not only the statistically significant results from an efficacy and outcomes perspective, but also from a safety perspective as well. We saw a very, very low discontinuation rates. So again, as we go on to Phase III, we go into it with great confidence based on the Phase IIb results.

Operator

Our next question comes from Chris Schott of JPMorgan.

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

Just a couple of follow-ups here, maybe first on Somerset. Can you just -- what are current Somerset sales from these 8 products? And how much of an opportunity is there for growth from that currently marketed portfolio in your hands? Any color there would be appreciated. And then as I think about the -- just the generic business, you commented you're seeing some signs of stability in the broader industry dynamics. You mentioned that we've got launch opportunities particularly if you start looking at second half of -- I think you said '19. I guess, at this point, is it reasonable to think about 2018 as a bottom for that generic business that we can return to growth? Or is it too early to be able to make that statement?

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

Yes. Chris, I think it's just -- I think it's a bit early. I think a lot of the portfolio that you look at, it ebbs and flows. You've got a lot of Paragraph IVs. You've got settlement negotiations. So we've all been doing this a long time. So it's hard to kind of predict 2018 to 2019 when you're still negotiating certain types of settlement agreements and working with the FDA with respect to getting products out of FDA. I would tell you right now, as we said before, we feel pretty good about we're able to file about 20 products a year, and we're able to launch about, whatever it is, 15 to 20 products a year. That's our normal course. And I think when we look at 2018, it's just more of a year where we have our fair share of approvals, they're just smaller in nature. I think what we said in the last earnings call and we showed on the slide here that we've had our -- we've got our fair share of pretty exciting products in the future with CIPRODEX and DEXILANT and KUVAN, just to name a couple. So from that standpoint, I think it's just -- it's more of a timing issue. Regarding the Somerset question on revenue, we really haven't disclosed that yet, Chris. We're going to need a little bit more time. The deal isn't going to close for another 5 to 6 months. So I think we're just going to ask for some patience here. What we're excited about is that there's currently 8 commercial products. And actually, they just got dexamethasone approved a couple of days ago. This is a company that is very aligned to us on operational execution. They're executors, and that's something that excites us. What we can disclose is the IQVIA sales. From a commercial standpoint, they're doing about $28 million according to IQVIA, but that's over a 12-month period. So that's probably as far as we can go today.

Operator

Our next question comes from Irina Koffler of Mizuho.

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

Just in Somerset again. So I noticed in 2018, Endo moved some R&D operations to India. And we're just wondering if you could describe kind of a little bit more about Somerset. I mean, where various facilities are and also if there is an opportunity for additional synergies, cost synergies there.

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

Yes. So thanks, Irina. I would say it's a pretty lean operation and very cost effective. So I don't see a synergy play coming from Somerset. Now we've made some tough decisions on people here in the U.S. So I think right now, we are in a normal course process. And we're always evaluating people and facilities. That just comes with what we do today. But I think we have done an enormous amount of rightsizing over the last 18 months. With respect to Somerset Therapeutics, the Wintac operation that -- which is really referring to the manufacturer and the R&D center, that's in Bangalore, India. So we're in a very -- we're in an exciting city in India. It's very accessible. We have about 15 or 16 acres of property that comes with the acquisition. So it gives us a lot of flexibility as we look at our manufacturing and R&D footprint on a go-forward basis. If we so choose, we have a lot of flexibility at the Bangalore facility. Again, we have about 5 to 6 months before close. I don't want to get too ahead of ourselves, but a lot of optionality.

Operator

Our next question comes from Dewey Steadman of Canaccord.

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

On CCH, since you've got Pat there. Can you just remind us of the opportunity, the commercial opportunity there, in terms of sizing relative to XIAFLEX? And then your commitment to commercializing the product and the steps you're taking on that front.

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

Okay. So Dewey, this is Paul. I'll probably start with the commitment, and then I'll pass it over to Pat. I don't think we can be any clearer that we are preparing for success. We are bringing in people not only in the R&D side, but we are highly focused on the commercial side of sales and marketing. As Pat indicated earlier and what we said in our script today, that we are participating in ASAPS. So we are forging forward. We are 100% committed to the aesthetics indication. I would tell you that there's probably a lot of people here in Malvern on the third and fourth floor right now probably listening in to this call, and I will tell you we are incredibly excited to be locking arms with our colleagues moving forward to becoming an aesthetics company in the future. And with that, I'll pass it over to Pat who can talk about the exciting market as we see it today.

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

Thanks, Paul. Well, it's a great market, and we believe that we're really well positioned to jump into a market with a large unmet need. Maybe just a few comments on the U.S. market. And again, depending on what sources you go to, which side of the report you go to. They all say it's a large market. It's about a $15 billion market when you look at surgical and nonsurgical. What's really interesting and exciting for us is that you got a large injectable market, about a $3.5 billion injectable market. That is growing. It grew at about 7% in 2016 and again grew at 5% in 2017. When you look at the area that we're jumping into, when you look at what patients -- where patients' interests lie, body sculpting is the #1 procedure patients are considering. Buttock augmentation within the surgical segment is the second fastest-growing procedure. So you've got a lot of a positive energy around a space that we're going to be jumping into. When you look at cellulite specifically, 85% to 98% of host people are women have the conditional cellulite, and we have the opportunity to launch an innovative injectable. To date, there's not an injectable that addresses that underlying cause of cellulite, that being the fibrous septae. We have a clinical development program that is designed to prove the hypothesis of CCH lies in that fibrous septae. So we're extremely excited about that. You have a physician community, an aesthetics community that is well accepting of injectables. You have an aesthetic patient population as well, accepting of injectables as well. So we're really excited about this

opportunity. And as we go out and we speak to our investigators and we go out to the major meetings, as Paul stated, there's a lot of enthusiasm amongst our KOLs, and there's a lot of energy emerging around the opportunity to have an injectable in the space. So it's a large U.S. market we're jumping into. We're also excited about the fact that we also have global rights, which provides the potential for additional value for the organization.

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

And with the global rights, would you license that out or would you build a global commercial organization?

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

It's obviously a bit premature, but a high probability is that we're focused here in the U.S. I'll probably leave it at that for now.

Operator

Our next question comes from David Amsellem of Piper Jaffray.

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

So I just wanted to come back to the generics pipeline and also inclusive of the acquired pipeline from Somerset. So you've talked about DEXILANT and AFINITOR and CIPRODEX and KUVAN for a long time. Can you just give us a sense of which of these are going to be sole exclusivity or shared exclusivity opportunities, or just limited competition in general? And then also around Somerset, maybe help us understand how much of that 25-plus in the pipeline are going to be "limited competition" products, and how we should think about that.

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

So David, I'll start with Somerset. I think the way we're looking at Somerset, and it's always hard to predict out in the future, but their focus was -- is on areas that are not Paragraph IV related. So I don't see near-term exclusivities coming from that. What I do see coming out of Somerset is a meaningful pipeline volume with high-margin products with sustainability. So that, as we said, augments our existing operation, and that's something that excites us a great deal. With respect to products that have sole exclusivity, have we -- I'm not sure we've disclosed which -- have we? Right. So I think we have settlement agreements in place with certain companies that do not allow us to disclose the terms. So I think, at this point in time, we're going to have to be very cautious about disclosing whether or not we are sole or if you can expect an AG with these other companies.

Operator

Our next question comes from Greg Gilbert of Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Paul, with injectables becoming a bigger part of your business going forward, can you just briefly describe the differences between the power of the buyers in the injectable space versus that in the retail space? I realize a lot of consolidation occurred there years ago, but curious for you to compare and contrast there and see if the pricing erosion outlook is different there. And then secondly, on opioids, I know it's really tough to make any predictions here, Paul. But maybe you could point to some of the key mile markers that will eventually allow you to make some real decisions around it strategically and otherwise. Could those mile markers be this year or we're talking a few years away?

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

Sure, Greg. So on the opioids, as you rightly stated, we're not going to be able to go into any great detail. It continues to be very early in the process. What we can disclose, which is in the public domain, that Judge Polster did indicate, this is going to be a bellwether trial that's scheduled in Ohio for March 2019. That to me is going to be a -- it will be a meaningful point in time. And that includes, in essence, I believe, 2 counties in Ohio and as well as the City of Cleveland. So that, to me, would be a market that we're all going to be watching very closely. With respect to generics and consortiums on the retail side versus -- if I'm understanding the question correctly, Greg, versus the sterile side, what we -- what excites us is the fact that when you look at -- we're still dealing with these same 3 wholesalers as everybody knows. But in the case of Sterile Injectables, our contracts are negotiated with -- directly with the GPOs. So again, it's a nuance, but it's something that excites us. Keeping in mind that we have a sales force that goes out there and works with high-dispensing hospitals and the GPOs to ensure that our contracts are being maintained. So there's the nuance that with the injectable business, that our sales reps actually can enforce our contracts to make sure that they're being adhered to and being able to work directly with the hospital. On the consortium side, these guys are incredibly important. I mean, we -- I mean, these are our partners and they represent tens of thousands of pharmacies. They just have enormous buying and selling pressures, but we've learned to navigate through these rough waters at time. And it's on us. We ultimately are focused on our pipeline regarding tough-to-make Paragraph IVs on the retail side. So some of it, the nuances is that -- on the generic consortiums for retail, it's a little bit behind us and we've got to bring technically challenging products forward. And on the hospital side, we've got some control because the -- there's voluntary purchasing with the hospitals working with the GPOs and the ball is a little bit more in our control.

Operator

Our next question comes from Annabel Samimy of Stifel.

Andrew Abriol Santos Ang - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Andrew on for Annabel. So I just want to sort of -- you recently indicated that you'd be selectively divesting certain assets within generics and have done so already. So the sale of the products to LCI should come as no surprise. Should we expect -- continue to expect more? And with the separation of Sterile Injectables into a separate segment, is this a signal of any major future action to separate or spin the commoditized generics from the company? And secondly, on -- what are your long-term plans around debt paydown, if you have any clear goals given your current cash flow guidance?

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

Yes. So I would start by saying I think, from a products and facilities and a strategy standpoint, we made our tough decisions. There's not going to be any spin. We've divested products that are not core to us and, in essence, are not profitable to us. There may be a handful of products that remain, but we're all about going forward right now. As I said, our retail business is still very important to us, but when we look towards growth, it's clearly coming on the sterile side and our branded side focused on XIAFLEX. So I think that's probably as far as I can really shed some light. I'll pass it over to Blaise regarding debt paydown.

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

Sure. Yes. Thank you for that, too. As we've stated, our strategic priority is to delever back to 3x to 4x over time. We plan to achieve that through a combination of EBITDA growth, as well as reducing net debt reduction. And our 3 capital allocation priorities hasn't changed, which is investing in our portfolio, investing in complementary small bolt-on acquisitions and also paying down debt. And in that context, we're very aware of where our debt is trading at and we're very committed to paying down debt over time. We're ending the first quarter with about $980 million of unrestricted cash from the balance sheet. That's going to go towards funding our remaining mesh liabilities for the year, as well as the funding of the Somerset acquisition. That said, we'll continue to evaluate our capital allocation decisions throughout the year, and that includes optional debt paydown. And we'll provide updates as we move forward on what our plans are on that front.

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 here, can you just discuss in a little more detail just the XIAFLEX strength you saw this quarter? A very nice 15% growth. How much was driven by Peyronie's versus DC? And then is there anything in either of those underlying markets that just gives you confidence that this level of growth can be sustained? And then my second quick product question. On ADRENALIN, are you still picking up share in that market? Or has your share stabilized and we should think about growth similar to VASOSTRICT, which is more driven by price at this point?

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

Dana, it's Paul. I'll take the first question, and then I'll pass the XIAFLEX question over to Pat. ADRENALIN, I would say it's stabilized, right? I mean, at the end of the day, I think the market has converted. You've got 2 approved sources with the product as well as there's an ampoule on the market that's approved. So from that standpoint, I think we're in a stable environment. So all the unapproved sources are long gone. It's passed through the channel. And it's really just focused on the 2 approved sources. And I'll pass it over to Pat on XIAFLEX.

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

Yes. Thanks, Paul. We had another very strong quarter with XIAFLEX. We delivered $57 million in sales. As you -- as Paul stated in earlier in the call, 15% net sales growth. What we're really excited about is there's underpinning demand growth that's really supporting that. 11% of that growth was volume-driven. When we look at the split, both indications are growing. For example, Peyronie's disease indication is growing at 16% year-over-year, so that's really strong demand generation. Dupuytren's contracture, the more mature indication, is also growing, too. It grew at 4%. So across the board, we see really strong growth. We believe that that's sustainable growth. Last year, we made a concerted effort and commitment to invest in a strong sales and marketing effort. We made a commitment towards consumer activation with digital consumer activation. We're running unbranded television to create disease awareness. So we feel like there's a great opportunity to continue to grow XIAFLEX's online indications. We see strong market penetration for both indications. However, there's untapped potential in terms of diagnosis and treatment. And so for those reasons, that's why we continue to invest in terms of consumer activation, and we feel like we can continue to have durable growth with our online indications for XIAFLEX.

Operator

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

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

First, just an update on class action litigation. Any new mesh claims that have popped up? Or anything new on TRT to update us on? And then are you anticipating any other major rounds of discontinuations in generics going forward? Paul, just remind us what the normal course is for that in your business.

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

Yes. So Gary, I mean, just from a discontinuation standpoint, there's nothing major on a go-forward basis. I think, as I said, the heavy lifting is behind us. It's normal course. It's hard. I would say, it's a handful of products a year. Normal course, it could be 3 to 6 products a year. And at the same time, you're repopulating at a rate of around maybe 15 or so, 15 to 20, so that's the way we kind of look at it from a normal course standpoint. And then

question on mesh, to be honest with you, there's really not much to say. And frankly, I'm not spending nearly any time on mesh, and that should probably give you a pretty good indication as to where we are in mesh. And then on the TRT, I think all we can really say at this time is that we're pleased regarding that we've entered into a memo of understanding with respect to the potential settlement. So I think it's -- I think, right now, I don't have too much more to say on that as well. So it's -- I think we're really just waiting at this point in time.

Operator

Our next question comes from Rohit Vanjani of Guggenheim.

Rohit Govind Vanjani - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

On the 3 products you mentioned that were launched, the 2 first-to-market and the launched shared first to market, can you just give any details on the revenue opportunities there, or when you might see additional competition? And then secondly, you mentioned testosterone litigation. I thought last quarter, you had set aside a reserve of $200 million. I think $100 million was owed to LIDODERM, and then on the cash flow paid, there's a non-mesh settlement payment of $140 million. Could you kind of give any details of what buckets that falls into, or if that reflective of testosterone and all?

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

Okay. So maybe, Blaise, can take the...

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

Yes. So that's correct. We had recorded a total legal reserve in the fourth quarter of '17 for $200 million approximately, and $100 million of that does relate to the LIDODERM matter, which is now public, that settlement's in the public domain. So in terms of -- and also in terms of cash cadence on the Lido matter, that's also in the public domain. That's about $60 million that we'll be paying in the second quarter, and that is in that line item that you referenced in our cash flow guidance that we provided.

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

And then we're not giving specific revenue results on products. I think what we would say is that memantine ER is about a $1.1 billion brand product before we launched with limited competition. And I think there's 2 players in that market right now, 3 players at the most. So we feel pretty good about that. Praziquantel, we're exclusive. It's about a $10 million branded product, so there's no competition there. And then sodium phenylbutyrate, the brand sales were around $45 million, I believe. And again, we're exclusive. So you can probably run some math regarding sole exclusivity on those 2 products.

Operator

There are no further questions. I'd like to turn the call back over to Paul Campanelli, President and CEO, for any closing remarks.

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

Thank you very much. We really appreciate your continued interest and support of the company. And we do look forward to providing you with updates as we move forward. Thank you for joining us this morning. And we are pleased to report out in a couple of months on our second quarter results. Thank you all.

Operator

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