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ENDP - Q4 2017 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 4Q17 GAAP net loss from continuing operations of $272m and GAAP diluted loss per share from continuing operation of $1.22. Expects 2018 total revenues to be $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 Q4 2017 Endo International plc Earnings Conference Call. (Operator Instructions) I would now like to turn the call over to Steve Mock, Senior Vice President, Investor Relations and Corporate Affairs. Please go ahead.

Stephen J. Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Aiella. Good morning, and thank you for joining us to discuss our fourth quarter and full year 2017 financial results as well as our 2018 outlook. Joining me on today's call are Paul Campanelli, President and Chief Executive Officer of Endo; Blaise Coleman, Executive Vice President and Chief Financial Officer; and Patrick Barry, Executive Vice 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 www.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 - CEO, President and Director*

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

Beginning on Slide 2, here's a brief agenda for today's call.

Moving to Slide 3, I plan to provide only a brief recap of our fourth quarter and full year 2017 performance and instead focus the majority of my comments on our strategic priorities and what Endo plans to achieve as we continue to execute against our multi-year plan. In his remarks, Blaise will offer some additional insight on our fourth quarter and full year 2017 results and will also provide our 2018 financial guidance.

Once again, Endo is pleased to report a solid quarterly operating performance. The company reported full year 2017 revenue in line with our most recent revenue guidance range and exceeded the upper end of our adjusted EBITDA and adjusted EPS respective guidance ranges. And consistent with our past few quarters, the fourth quarter benefited from strong growth in our Sterile Injectables and Branded Specialty portfolios.

Moving to Slide 4, you will see a snapshot of our segment revenues for the fourth quarter. As was expected, our U.S. Generic Pharmaceuticals business faced a challenging comparison with the prior year when, in the fourth quarter 2016, we launched 2 very significant first-to-file products: the ezetimibe tablets, the generic version of ZETIA; and quetiapine extended-release tablets, the generic equivalent of SEROQUEL XR. U.S. Branded Pharmaceuticals overall performance was impacted by continued generic competition for established products and our ceasing shipments of OPANA ER. International Pharmaceutical reflects, of course, the divestitures of Litha and Somar at the beginning of the third and fourth quarters of 2017, respectively.

Now moving to Slide 5. The decline in the U.S. Generic Pharmaceuticals resulted in large part from the loss of marketing exclusivity in the first half of 2017 for ezetimibe and quetiapine ER. This loss of exclusivity is also reflected in the significant decline in revenues you see in new launches and alternative dosages. The decline in our base business resulted in part from the annualization of 2016 competitive events, 2017 competitive events as well as product discontinuations. For the year, our base generics business declined approximately 33% compared to 2016, in line with the guidance we provided last February.

Our assumptions for 2018 are included in the guidance we are providing today. In terms of the generic industry and our positioning, we will always work to be a stable source of high-quality product that our trade partners have come to know and rely on over the years. However, when it no longer makes sense in terms of profitability, we have to make tough decision as to whether we will continue to offer a product or consider discontinuing it as we have done with certain commoditized drugs.

Although some level of product discontinuations will always occur in normal course, we're cautiously optimistic in our expectation that the level and frequency of product discontinuations going forward will be meaningfully lower than experienced over the past 18 months. We will work closely with our direct customers to maintain reliable supply at acceptable levels of profitability for us.

Finally, Sterile Injectables once again achieved strong double-digit growth in the fourth quarter. Powered by the continued growth of ADRENALIN, Sterile Injectables grew 16% versus prior year. For the full year, Sterile Injectables revenue grew 23%, again, in line with our previously provided revenue guidance. VASOSTRICT and ADRENALIN achieved full year 2000 sales of -- 2017 sales of $400 million and $77 million, respectively.

Regarding VASOSTRICT, as you know, last month, Endo agreed to a request by the FDA to seek a temporary stay of the litigation initiated against the FDA last October by the company. Endo concluded that a temporary stay of its litigation against the FDA was appropriate given the FDA's recent public statements, including its recent issued 2018 Compounding Policy Priorities Plan, along with discussions amongst the parties' counsel.

We believe the FDA is taking steps to comply with the Drug Quality and Security Act and we are closely monitoring the FDA's announcement of further details, which we expect by the end of March 2018.

Endo agrees with the FDA's recent public comments that by ensuring that outsourcing facilities do not compound using a bulk drug substance when an FDA-approved drug can be used to meet patient medical needs, the patient health and the drug approval process can best be protected. Endo will continue to take whatever actions are necessary or appropriate to defend the intellectual property related to our VASOSTRICT product franchise.

Now turning to Slide 6, let's briefly discuss U.S. Branded Pharmaceuticals. We continue to be pleased with the solid growth across our Specialty Products portfolio. Branded Specialty Products revenues grew 8% in the fourth quarter, driven primarily by XIAFLEX. As expected, Branded Established Products were impacted by the cessation of shipments of OPANA ER that took place on September 1, 2017, as well as generic competition adversely impacting the remainder of the company's Established Products portfolio.

I'm especially pleased by the performance of our flagship branded product, XIAFLEX. Fourth quarter XIAFLEX revenue increased 10% to $61 million, driven by strong demand growth. For the year, XIAFLEX revenue grew 12% to $213 million as increased demand in both Peyronie's disease and Dupuytren's contracture was driven by our continued strong execution, including the effectiveness of our consumer activation and marketing initiatives. This performance was consistent with our 2017 guidance that full year Branded Specialty Products and XIAFLEX revenues were expected to grow in the high single- to low double-digits range.

Now moving on to Slide 7. Let's take a look at International Pharmaceuticals. Fourth quarter international revenues of $41 million declined from prior year due primarily to the divestiture of the company's South African Litha business at the beginning of the third quarter and the sale of Endo's Mexican business, Somar, in October 2017. Our Canadian Paladin business was broadly in line with prior year.

Turning to Slide 8. A year ago, we outlined a strategic vision for Endo and laid out our key strategic priorities, setting out to focus on those things that we can control. We articulated a clear vision in which we aspire to be a highly focused generic and specialty branded company, delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization.

We told you that Endo was in transition from a company that relied upon acquisitions for its growth to one whose future growth would be primarily organic. Importantly, we also told you it would take time for us to get where the company wants to be and that this would represent a multi-year turnaround. Over the past year, we have made significant progress executing against those priorities, and we believe we will continue to do so in 2018.

Since we have implemented a new leadership team, we have undertaken a series of significant measures to reshape our organization for success and create a new culture at Endo. In doing so, we have created a unified culture that values integrity and collaboration amongst our colleagues, a culture that is customer-focused and performance-driven with a relentless commitment to flawless operational execution.

We have simplified our company through commercial -- through centralization and unification, and these actions have also served to drive productivity improvements. We centralized and streamlined Endo's global supply chain, quality, compliance, medical affairs and R&D organizations. Endo now has one unified R&D organization with the technical capabilities needed to deliver our portfolio of the future. We are agnostic in our product selection and development process and instead simply pursue what we determine to be the most promising product opportunities available within our core areas of focus.

We have restructured our corporate functions as well as our branded and generic pharmaceutical R&D functions. In doing so, we simplified and unified each of these organizations. We believe that our approach will result in greater efficiency, permitting us, in some cases, to spend less with the same productivity through a better integrated process.

In 2016 and 2017, we made very tough decisions that impacted our generics and manufacturing network. These manufacturing rationalizations over the past 2 years have resulted in the sale of our Charlotte, North Carolina facility and the closure later this year of our Huntsville, Alabama location. In addition, we discontinued a total of approximately 85 generic products that were not significant contributors.

Although we believe we have substantially optimized our generic product portfolio, we continue to examine our product roster on an ongoing basis, always seeking to be more efficient and operationally sound. In consolidating our manufacturing network and tech transferring products to our remaining sites, we have further simplified and unified our company. Today, for example, we manufacture both generic and branded products at our Chestnut Ridge, New York facility as well as at our Rochester, Michigan Sterile Injectables site. All of these actions I've outlined have been taken to reshape our organization for success.

In undertaking all of these actions, our goal has been to simplify our organization to make it as efficient and effective as possible. Achieving this has not been easy and has necessitated difficult decisions. In 2016, Endo had more than 6,000 employees worldwide. Today, there are approximately 3,000 employees at Endo. However, importantly, the savings generated from these actions are being used to build our portfolio and capabilities for the future and to drive margin expansion.

Building that product portfolio and those future capabilities remains a critically important priority for all of us at Endo. We began this mission by undertaking an overall assessment of our company's strategy and its assets and product portfolios. We identified assets and businesses that were not core to us and divested them. We withdrew OPANA ER from the market, ceased promoting pain products to physicians, disbanded our pain sales force and terminated our opioid development programs. We divested other noncore assets, including Litha and Somar. We redirected those resources behind key areas that we have identified as our core areas of growth, namely, Branded Specialty Products and a generics pipeline of hard-to-produce products.

Speaking of our pipeline, as you know, it is always difficult to provide visibility into our generics pipeline without running the risk of placing ourselves at a competitive disadvantage. Nevertheless, permit me to share what I can.

On Slide 9, in 2017, Par launched 17 products, including ephedrine injection, neostigmine injection, and a first-to-market product, vigabatrin for oral solution. We also submitted about a dozen regulatory filings in 2017.

For 2018, we again expect to launch in the neighborhood of 20 products and submit at least as many ANDAs as we did in 2017. To date, we've launched 2 products, sodium phenylbutyrate powder and memantine ER capsules. We all recognize the significant challenges that have been impacting the retail sector of the U.S. generics industry over the past few years. The continuing consolidation of our retail trade partners into essentially 3 customers, together with the FDA approving ANDAs at a record pace and primarily for products in existing generic categories, have combined to heighten already intense competition. Quite frankly, today, the number of ANDAs a company files has become less relevant as it is the quality of those filings that now matter more than ever.

I mentioned the first-to-market launch of vigabatrin for oral solution, which took place last August. I'm very pleased that we've been able to achieve a significant market presence. Vigabatrin represented a complicated new product introduction for a generics company. The product has an extensive shared REMS Program, is available to patients only through certified health care providers and specialty pharmacies and requires a dedicated patient assistant resource. Our successful vigabatrin launch required the collaboration and shared expertise of our U.S. Generics, U.S. Sterile and Branded Specialty sales and marketing teams. This experience reinforced to me the value of our hybrid business model. The successful launch of vigabatrin further reinforced my view that Endo is a company with strong experience in specialty pharmacy distribution.

To help maintain a continuing flow of new product introductions, we have more than 70 products in development and more than 100 ANDAs pending with the FDA. These ANDA submissions represent approximately $30 billion of combined annual sales for the corresponding branded products in 2017. Of these pending ANDAs, approximately 40 represent first-to-file or first-to-market opportunities. The 2017 launches of vigabatrin and sodium phenylbutyrate tablets, the generic equivalent of BUPHENYL, both represented first-to-market product introductions made available through specialty pharmacies. Among our pending ANDAs are several first-to-file or first-to-market opportunities that also will require marketing through a specialty pharmacy distribution network. Furthermore, we are focusing on hard-to-produce products that include a number of peptides and polypeptides such as teduglutide, the generic version of GATTEX, which are very challenging products that take years to successfully develop.

The patent litigation surrounding several of our filed ANDAs has been settled with market entry dates determined. In most cases, the litigation has been settled pursuant to confidential terms. Some examples of these date-certain assets include generic versions of DEXILANT, AFINITOR, CIPRODEX,

AMITIZA, KUVAN and MITIGARE. The portfolio of products in which we have been investing can be expected to begin contributing around 2020 and beyond.

Now turning to Slide 10, Branded Specialty. The big news is, of course, the initiation earlier this month of 2 pivotal Phase III clinical trials of collagenase clostridium histolyticum, or CCH, for the treatment of cellulite. In early February, we enrolled our first patients. The multi-center, randomized, double-blind, placebo-controlled release studies will evaluate the safety and efficacy of CCH in reducing the appearance of cellulite. These studies will be conducted in the United States and are expected to enroll a total of 840 women with 420 in each trial. The women will be 18 years or older with moderate to severe cellulite. Each subject will receive up to 3 treatment visits of CCH or placebo with each treatment visit occurring approximately 21 days apart. 12 injections will be administered into cellulite dimples during each visit across each of the 2 treatment areas, the left and right buttocks. At both the outset and conclusion of treatment, cellulite severity will be assessed by each patient and clinician using 2 validated Photonumeric Cellulite Severity Scales developed by Endo and third-party psychometric experts.

The primary endpoint is a composite responder analysis demonstrating at least a 2-level composite improvement independently reported by both patient and clinician on a Photonumeric Scale of Cellulite Severity. in addition, there are several key secondary endpoints.

We expect top line results from the study in the first quarter of 2019 and look forward to sharing those results with you. The entire Endo team is very excited about (inaudible) and our prospects for success.

Moving to Slide 11, cellulite is a contour abnormality of the skin resulting in dimpling and continues to affect about 85% to 90% of postpubertal women in all races. Despite the high incident of the condition, there is still much debate around the cause of cellulite. The most recent literature and consensus amongst aesthetic physicians indicates the fibrous septae as being the primary ideology of cellulite. The dimpling mostly located on the buttocks, thighs, lower abdomen and arms is caused by the tethering of this fibrous septae with fat cell volume as the secondary cause.

When injected, CCH lyses, or enzymatically disrupts, the septae, releasing the dimple and permitting the skin to return to its normal contour. To date, there has been no FDA-approved product to address this new understanding. We believe the core mechanism of action for CCH will be to treat the root cause of cellulite, which is the fibrous septae. As a result, we believe there is significant unmet need for an effective and safe noninvasive treatment for cellulite.

That brings us to Slide 12. With no FDA-approved injectable for the treatment of cellulite, it's an especially exciting time to be potentially entering into a market with such opportunity. The total U.S. aesthetics market is a $15 billion growing market when you include both surgical and nonsurgical procedures. The U.S. aesthetics injectable market is a $3.5 billion market and is growing at more than 7% annually. According to the 2017 American Society for Dermatologic Surgery Consumer Survey, body sculpting is the #1 procedure that consumers are considering.

You can also see on the right-hand side of the slide results from a survey in which both plastic surgeons and dermatologists were shown the CCH for cellulite product profile. Over 70% of both dermatologists and plastic surgeons were either excited or extremely excited to potentially offer this treatment to their patients upon regulatory approval. It is very unusual to see health care professionals score a new potential pharmaceutical product so high, suggesting that CCH could represent true innovation for the market.

In addition, Endo is pleased to have international marketing rights for the product since there are numerous countries that represent attractive potential markets for CCH.

As a result of a collaborative process with the FDA, we have designed a robust Phase III development program and data generation plan to observe the treatment effect of CCH on fibrous septae in the buttocks and thighs. We look forward to submitting all data in buttocks and thigh in 2019, and we will be seeking an indication for the treatment of cellulite. We view the approach we have outlined to be the simplest and quickest way to market with a treatment to address this significant and unmet need.

We are preparing for success as we continue to build our aesthetics commercial team. I am pleased to say we have been able to attract top aesthetic talent with substantial prior experience at best-in-class aesthetics companies. These key additions are already contributing to and shaping our

preliminary launch planning. Although we are excited about our cellulite opportunity, please do not interpret that to suggest we are taking our eye off of the current or in-line indications for XIAFLEX, which I mentioned earlier.

The success we achieved this year in both Peyronie's disease and Dupuytren's contracture was the result of great attention to detail and flawless operational execution of our marketing initiatives, including consumer activation via digital direct-to-consumer outreach. Furthermore, the 12% growth we recorded for XIAFLEX full year revenue could not have been achieved without the efforts of our talented sales professionals and the effective management of our specialty pharmacy network relationships.

In 2018, we will continue to invest behind these in-line indications as we continue to believe that there is further opportunity to increase disease state awareness as well as diagnosis and treatment rates for both indications.

Now let me turn the call over to Blaise Coleman to further discuss the company's fourth quarter financial performance and to provide our detailed 2018 financial guidance. Blaise?

Blaise Coleman - *Endo International plc - CFO and EVP*

Thank you, Paul, and good morning, everyone.

First, on Slide 13, 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 read that again.

On a GAAP basis, we had diluted loss per share from continuing operations of $1.22 in the quarter versus diluted loss per share from continuing operations of $14.96 in the fourth quarter of 2016. GAAP net loss from continuing operations in the fourth quarter of 2017 decreased to $272 million compared to GAAP net loss from continuing operations of $3.3 billion during the same period in 2016. This decrease includes the impact of lower asset impairment charges and intangible asset amortization in the fourth quarter of 2017.

The company recorded an aggregate increase of approximately $200 million to its legal reserves in the fourth quarter 2017 related to LIDODERM antitrust matters and the testosterone or TRT-related product liability matters after determining that a loss is probable and reasonably estimable.

The LIDODERM reserve includes an estimated loss for, among other matters, a settlement in principle of all remaining claims filed against the company in the multi-district litigation pending in the U.S. District Court for the Northern District of California. This settlement is subject to court approval, and if approved, will be paid out between 2018 and 2020.

The TRT-related reserve includes an estimated loss for, among other matters, all product liability cases filed in the multi-district litigation pending in the U.S. District Court for the Northern District of Illinois and in other courts.

On an adjusted basis, fourth quarter adjusted net income from continuing operations of $174 million and adjusted diluted earnings per share from continuing operations of $0.77 exceeded the upper end of our implied fourth quarter financial guidance range provided in November and reflects the significantly improved adjusted gross margin and lower adjusted operating expenses versus prior year.

The more than 500 basis point improvement in adjusted gross margin in the fourth quarter versus prior year was primarily driven by cost-savings initiatives and a favorable business mix. The favorable business mix reflects greater sales of higher gross margin products such as Sterile Injectables and Branded Specialty Products and reduced sales of lower gross margin products such as the partner products ezetimibe and quetiapine extended release and discontinued generic products.

The lower adjusted operating expenses were primarily due to lower sales and marketing costs that resulted from the restructuring of our commercial pain business.

Earlier, Paul discussed certain strategic priorities that we identified a year ago. One of those priorities is to drive margin expansion through operational execution and continuous improvement. In addition to a meaningfully improved adjusted gross margin for the fourth quarter and full year 2017, our adjusted EBITDA margin improved by almost 360 basis points in 2017 to just over 45%. This improvement reflects the cumulative benefit of many of the initiatives we have undertaken that Paul described earlier. In addition to these strategic actions, earlier in 2017, we successfully refinanced our secure debt to provide the company with additional operating flexibility.

Additionally, last August, we announced an important milestone at Endo, reaching settlement agreements to resolved virtually all known U.S. mesh product liability claims.

Turning to Slide 14, before I provide 2018 guidance, I want to take a moment to address the change we have made in the way we report our segments. As of December 31, 2017, the 3 reportable business segments in which the company operates were U.S. Generic Pharmaceuticals, U.S. Branded Pharmaceuticals and International Pharmaceuticals.

During the first quarter of 2018, we changed our reporting -- our segment reporting to reflect the manner in which we now manage our business, including resource allocation and performance assessment. Our Sterile Injectables product portfolio, which was part of our U.S. Generic Pharmaceuticals segment as of December 31, 2017, will be presented as a new segment name, the U.S. Branded Sterile Injectables. Additionally, our current U.S. Branded Pharmaceuticals segment will be renamed U.S. Branded Specialty & Established Pharmaceuticals.

Subsequent to this change, we will have 4 reportable business segments: U.S. Generic Pharmaceuticals, U.S. Branded Specialty & Established Pharmaceuticals, U.S. Branded Sterile Injectables and International Pharmaceuticals. This new presentation of our business segments is aligned with how Endo now evaluates its businesses. In addition, it serves the purpose of separating sterile products that are generally longer-duration assets from those in our U.S. Generic Pharmaceuticals segment.

Under the new reporting presentation, newly launched products will go into their respective segments. For example, newly launched sterile injectable products will be included in the U.S. Branded Sterile Injectables segment instead of being classified in the previous new launches and alternative dosages category.

On Slide 15, you will see highlights of our full year 2018 financial guidance. We expect total revenues to be between $2.6 billion and $2.8 billion. This decline versus 2017 results primarily from the annualization of 2017 events, anticipated competition for several of our U.S. Generic products and continued underlying pressures on our U.S. Generic Pharmaceuticals segment. I'll provide more color on the revenue moving pieces on the next slide.

We expect adjusted diluted earnings per share from continuing operations to be between $2.15 and $2.55 and expect adjusted EBITDA from continuing operations to be between $1.2 billion and $1.3 billion, which represents continued improvement in adjusted EBITDA margin year-over-year, a key priority for Endo.

The company's financial guidance is based on the following assumptions: adjusted gross margin of approximately 67% to 68%, adjusted operating expenses as a percentage of revenues to be approximately 25.5% to 26.5%, adjusted interest expense of approximately $530 million to $540 million, adjusted effective tax rate of approximately 11% to 12% and adjusted diluted earnings per share from continuing operations assumes full year adjusted diluted shares outstanding of approximately 226 million shares.

Although we're not going to give specific quarterly guidance, we expect total enterprise revenue and adjusted gross margin levels to be fairly balanced on a quarterly basis over the course of the year. However, we expect adjusted operating expenses to be significantly higher in the first half of the year and more heavily weighted to the first quarter due primarily to the timing of certain legal spend.

Prior to moving to the next slide, let me spend a moment providing an update with regards to the implications of the recently passed U.S. tax reform. While the new stricter interest limitations and anti-base erosion provisions of the act will have an unfavorable impact given our capital structure and global operations, in the midterm, we expect to maintain a relatively modest level of cash tax due to the amount of favorable tax attributes such as net operating loss carryforwards arising from product liability matters that we expect to be able to utilize over this period. From

an adjusted effective tax rate perspective, we expect to maintain a low teens rate in the midterm assuming a static jurisdictional mix of pretax adjusted earnings.

Now let's take a look at Slide 16, which will provide some additional insight into our 2018 revenue guidance. Our fourth quarter 2017 was a substantially clean or de-noised quarter as most 2017 events that impacted revenues occurred in the first 9 months of the year. This slide presents a reconciliation that explains the difference between our annualized fourth quarter 2017 revenue and the midpoint of our 2018 revenue guidance range. As you can see, the major impact is being felt in our U.S. Generic Pharmaceutical segment where we could encounter new generic entrants in 2018 that could have a significant impact on a number of key products with no or limited competition. Just as we provide limited visibility into our pipeline for competitive reasons, we also have limited visibility into our competitors' pipelines for the same reason. Our guidance is based on certain competitive assumptions.

For the full year 2018, we expect U.S. Generic Pharmaceuticals revenue to decline to the mid- to high 30s percent range versus prior year. This decline includes the impacts from the ezetimibe (inaudible) extended loss -- extended-release loss of exclusivity, product discontinuations and competitive assumptions.

U.S. Branded Specialty & Established Pharmaceuticals revenue is expected to decline in the low teens versus prior year, primarily due to continued pressure on the established products portfolio, which includes the stopping of shipments of OPANA ER in the third quarter of 2017. These established product-driven declines are expected to be partially offset by the expected low to mid-teens percentage growth for XIAFLEX revenue.

U.S. Branded Sterile Injectables revenue is expected to grow in the low double-digit percentage range versus prior year.

And lastly, our International segment revenue is expected to decline in the high 40s percentage range, primarily due to the previously announced divestitures.

Advancing to Slide 17. In terms of cash flow, we had $474 million in cash flow prior to debt payment in 2017, 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 and slightly lower net mesh payments due to timing. We ended 2017 with $987 million of unrestricted cash, and at year-end, our net debt-to-adjusted EBITDA leverage ratio was 4.6x.

As we look towards 2018, we expect a use of cash prior to debt payment in the range of approximately $225 million to $125 million. This assumes approximately $400 million in payments into the mesh Qualified Settlement Fund; $140 million in non-mesh legal payments, including an estimate for the portion of the expected LIDODERM antitrust litigation payment and the expected TRT product liability settlement payments in 2018; $120 million in capital expenditures; and approximately $520 million in interest payments.

We have not assumed any optional debt repayments in our 2018 financial guidance. We will evaluate our capital allocation decisions, including optional debt repayment, as we progress through the year and gain more clarity on a number of key uncertainties. We will update our plan as appropriate through the course of the year.

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

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

Thank you, Blaise.

2017 was an extremely ambitious year for the Endo team and we anticipate no letup in 2018. While much of our effort in 2017 was directed at reshaping and rightsizing our organization, our work in 2018 will focus on further building our portfolio and capabilities for the future.

In closing, I just want to say how excited I am about 2018. Years from now when we look back, we will view 2018 as a pivotal year in Endo's development, marked by the CCH Phase III studies in cellulite, which we expect to facilitate our entry into a new and promising market.

The many initiatives and extensive efforts we have outlined this morning all share one underlying purpose: to ultimately create value for our investors. I remain confident that if we continue to execute against the key priorities that we have identified, Endo will enjoy a successful future, and we will reward those investors who have placed their trust in us.

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

Stephen J. Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Paul. We'd now like to open the lines to your questions. (Operator Instructions) Operator, may we have the first question?

QUESTIONS AND ANSWERS

Operator

Our first question comes from Marc Goodman with UBS.

Marc Harold Goodman - *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

I guess, one thing is can you just clarify the discontinued products, what the revenues were on those? And then really my question, Paul, is if you could just give us a flavor for just the lay of the land in generics over the past several months. I think we're all just curious to hear your thoughts on has Red Oak gotten any tougher? Have there been any new rebids that have come in that have been surprising or new for many of these 3 consortiums? Obviously, the big 4 went to the big 3. Not that long ago, I think we're all still trying to figure out the impact from that. So maybe just a kind of a big picture thoughts on those.

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

I'll try, Marc. I'll take that first question and maybe we can pass the second -- the first question back over to Blaise on discontinued product. I think, Marc, at this point in time, we need to be real cautious. There certainly seems to be a more stable market environment, but it's very early in 2018. So I think we always started the conversation by saying as long as there is movement within consortiums, there's always the challenges of further requests coming back on the portfolio. We saw that towards the end of 2017 with what I kind of refer to as the equalization of the portfolio with Eikon just moving into WBAD. So that is -- that's behind us, I would say that's built into our guidance. But we just need to be a little cautious at this point in time, Marc, it's still very, very early in the year. Blaise?

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, and Marc...

Marc Harold Goodman - *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Yes, I was just going to ask, Paul, on that last comment you made about Eikon just moving into WBAD at the end of the year, was that a significant change? Can you just give us a sense of how that was relative to some of the others?

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

At this point in time, I would say -- as I mentioned, it was really a harmonization and equalization of the existing 2 portfolios. That's where it -- that's where it started. That's where it ended. But we've got to be very cautious, Marc. It's early.

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, so Marc, in terms of your question on the impact from product discontinuations, in Q4 '17, it was worth about $20 million, and on a full year basis, it was between $80 million and $85 million.

Operator

Our next question is from Randall Stanicky with RBC Capital Markets.

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

As we think about the industry and the pruning that seems like it's been fairly broad based over the last year, you've certainly done your fair share. Teva had a very big announcement, as we all know, earlier this year. Has there been enough? And then do we need to think about ongoing pruning for efficiencies as a kind of a cost of doing business, in other words, a component of price erosion going forward? And then, Blaise, if you could just provide the amount of R&D you're expecting to spend on XIAFLEX that's built into the number this year, that would be helpful.

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

Yes. So Randall, on the pruning side, obviously we had a significant culling of the portfolio in 2016 and 2017. I think one of the ways that we had looked at is that we need to build our portfolio out for the consortium environment on the retail sector, and I think that's something that we had talked about in the last earnings call. I think we've done a very good job of that. On a go-forward basis, I think you're always going to see, at least at the Par side of our business, you're going to always see a handful of rightsizing and culling of the portfolio as normal course. Hopefully, our new product introductions, obviously, would offset that. But I think that's just the wave of the future, at least for Par, that you're going to see products that are culled, our facilities are rightsized to handle the volumes that we are projecting from a launch standpoint and I think I would call it normal course. So with that, I'll pass it...

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, and Randall, we expect to spend about $50 million in 2018 for the development of cellulite and CCH.

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

And total cost of the program?

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, Randall, we're only going to provide what we're spending this year in 2018, okay.

Operator

Our next question is from Chris Schott with JPMorgan.

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

Just 2 here. Maybe, first, just building on this kind of generic dynamics. When we get past this generic portfolio optimization, just interested in your perspective in your ability to grow your generic portfolio over time. I guess, do we see -- should we think about 2017 as representing a bottom for the generic business as we kind of balance this more focused portfolio and pipeline relative to some of these ongoing industry challenges that are still out there? My second question was just on the testosterone and LIDODERM legal reserve. Just give us a little more perspective here how much clarity you have around these issues at this point? I know with mesh, your ultimate exposure ended up being much higher than your initial reserves, so maybe just walk through a little bit of any differences or similarities in that situation relative to what we should think about with these more recent reserves.

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

So Chris, maybe on the generic side, I mean, the way we're looking at it is, we've said this for the past year that we look at this company's growth as -- it's a multi-year approach, right, so we had to cull many products within the portfolio. The return to growth, it's going to take a multi-year process. While we have about 100 products at the FDA and we have, as I indicated, some attractive products that we indicated are going to start to provide contribution in the realm of 2020 time frame, but we are going to be looking a little bit out to the future, as we indicated, when we indicated products that are material to us such as -- like CIPRODEX and DEXILANT and MITIGARE. These are all products that are hard to make. They're technically challenging. But it will take a multi-year process.

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, and then, Chris, in terms of your question on the reserves, when with think about the LIDODERM matter, as we said, we had a settlement in principle for all the remaining claims filed against us that currently are part of the MDL in the Northern District of California. And once -- if that's approved and that's finalized, that matter would be final. In terms of TRT, again, we have a memorandum of understanding in principle with the parties involved and we are very optimistic that we'll able to achieve and get to final agreement on that settlement. In terms of the matter being final, there's always the possibility that future claims could be filed. We've contemplated that in our reserve. But again, as you know, that's an estimate and is subject to what happens in the future.

Operator

Our next question is from Liav Abraham with Citi.

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

Firstly, on the gross margin for 2018, can you provide some color on the drivers for the gross margin improvement and, certainly, it came in above our expectations? And then, secondly, just thinking longer term about your cellulite program, how you're thinking about marketing and commercializing this product. It seems, Paul, from your comments that you are -- your base case is to market this on your own or are you still open to partnering? Just interested in your thoughts on that.

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

So maybe the first question, Blaise, on the gross margin.

Blaise Coleman - *Endo International plc - CFO and EVP*

Sure. Yes, so just in terms of gross margin, we've been very clear about what our focus is in terms of driving profitability across the portfolio. You're seeing that play through in our guidance so we feel good about the progress we've made on those initiatives. What you're seeing is 2 things: you're seeing the benefit of the cost initiatives; and again, you're seeing the benefit of our product portfolio and the mix thereof where we're continuing to invest in the Specialty Branded area where we expect to grow as well as Sterile Injectables and you see lower revenue as a percentage of our total revenue in areas like our Generics Pharmaceutical business and in the International business.

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

And on the cellulite question, I mean, in this position here, I always have to start by answering it that we would always consider optionality, and I think you would hear that from any CEO in this type of position. That just comes with that responsibility. That said, today, we're here with Pat Barry, our Executive Vice President in charge of our Branded division. We are preparing for success. We're bringing in talent, we're recruiting talent, we're building out our plan. We plan to become an aesthetics company. I don't think I could be any clearer than that.

Operator

Our next question is from Irina Koffler with Mizuho.

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

I have 2 on XIAFLEX actually. One, can you help us remember if you've been able to decouple the aesthetic formulation of the drug from the J-Code of the therapeutic product? And then the second one is, how is this product going to be differentiated from other offerings in cellulite like the Cellfina, which also cuts these bands in the tissue?

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

Yes, I'll start by just simply saying on the pricing side, that's a regulatory question that we'll be dealing with in the future. But I'm going to pass the call over to Pat and Pat can add some color on both questions.

Patrick Barry - *Endo International plc - SVP of U.S. Branded Pharmaceuticals*

Yes, sure. Thank you, Paul. As Paul mentioned, it's really a regulatory question. We're not going to comment specifically on that, but what I can tell you -- that we're very confident in our regulatory submission strategy and we certainly look forward to discussions with the FDA at the appropriate point in time. In terms of innovation, frankly, this is an opportunity to bring new innovation. If you look at the current market today, there's really not a noninvasive injectable product that meets this large unmet need and so the market's really ripe for a product, an injectable product specifically, that addresses that primary underlying cause of cellulite. And so as the understanding amongst our KOLs and the research clearly shows that the fibrous septae is the primary cause of cellulite, to date, as Paul said in his -- on the call earlier, there's not an approved FDA product that addresses that. So we're jumping into a great space. The injectable space, in particular, is a $3.5 billion market and it's growing, and the market is ready for a new innovator and new innovation. So this is going to be something new to the marketplace and we're jumping into a large patient population where there's a high unmet need.

Operator

Our next question is from Gregg Gilbert with Deutsche Bank.

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

Yes, I have a couple. First, maybe a housekeeping question, but I'm confused about the Branded Injectables segment decision that you made. Should we assume that all injectables are in that segment, whether they're generic or not? Does it say anything about whether your injectables pipeline is more branded versus generic, a la more VASOSTRICTs versus more traditional generics, that's the first one. The second one is, Paul, in this challenging and consolidating environment, clearly, your eye's on the ball in executing at Endo, but where are you and the board on considering larger transactions potentially that could enhance your capital structure and achieve some other goals in this environment?

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

So Gregg, I would start by in terms of, again, when we look at optionality, it's something that we have. Since I've been the CEO in September of 2016, we have -- we've taken long and hard looks at different ways that we can shape the company. We also always have to remind folks that we've had a series of liabilities and complexities to the company. So with that comes things like mesh and opioids that we're dealing with. That complicates certain ways that we can look at the company. So while we're out there and exploring optionality, these are things that can impact the way others look at us and how we look at alternatives. Regarding the injectable question, I would just simply start out by saying when you look at the portfolio that comes out of our Rochester facility, the majority of those products in effect are our 505(b)(2)s or NDAs, products like VASOSTRICT, like ADRENALIN, Aplisol. These are all products that our branded products. I don't know, maybe, Blaise, if you want some color to that.

Blaise Coleman - *Endo International plc - CFO and EVP*

No, and the only thing, Gregg, just to maybe add on there is that when we think about how we're managing those businesses through that legacy Sterile Injectables business, which is now going to be its own reporting segment, we are managing that growth where the Generics Pharmaceutical segment we're managing for profitability.

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

But all injectables are in there, whether they're generic or brand, right?

Blaise Coleman - *Endo International plc - CFO and EVP*

Correct.

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

Okay. And one last follow-up, on VASOSTRICT, Paul, your comments and the company's behavior relative to the FDA litigation suggests that you're confident that there will not be compounded product available. Can you expound on that and agree or disagree with that comment? This is a case where you know more than the external world knows about that situation.

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

Yes. Gregg, again, as a reminder, the FDA requested the temporary stay. I mean, that was really -- that's based on public statements by the FDA and in discussions between both parties' counsels. I'm optimistic, but the stay is temporary and it's going to be in place until March of 2018. And I think that's -- it's kind of wait-and-see, and that's probably where I am right now.

Operator

Our next question is from Ami Fadia with Leerink Partners.

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

I have 2 questions. Firstly, on the U.S. Generics business, could you give us some more details around your guidance for the mid- to high 30% decline? And what you've assumed in there for either new product launches or product discontinuations? And then with respect to the outstanding legal cases, aside from the $200 million reserve that you're taking for the LIDODERM and testosterone litigations, what additional cases do you expect? Or have you provided for anything on top of the cases that have already filed?

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

Okay. Go ahead, Blaise.

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes. Yes, so starting with your first question on the Generics decline that we spoke about, the high 30s percentage range, again you're seeing a number of things there, one would be the loss of exclusivity on ezetimibe and quetiapine, which is a significant piece. We have the product discontinuations that are part of the restructuring initiatives, but we also had in its overall AG contract that was terminated, which you're seeing impact our outlook for '18. The other piece is that you have the annualization of 2017 competitive events and also our guidance does contemplate new competitive assumptions through 2018 that are impacting as well. Now in terms of the reserve question, as I mentioned earlier, we did for the TRT matter, there is the potential for future claims to be filed, and in our reserve, we did contemplate an estimate for what those future claims could be.

Operator

Our next question is from David Amsellem with Piper Jaffray.

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

Just wanted to follow up with you about some of the date certain launches in 2020 or later. I know that some of them are confidential, but can you give us a sense of how many of these are going to be at market formation? Any potential shared exclusivities? And also, are any of these situations where you could see limited competition for an extended period? AMITIZA is one that jumps out to me because that doesn't appear to be a crowded filing. But I just want to get a better sense of how impactful these could be and how -- and their relative attractiveness longer term.

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

Yes. So David, I would say the products that we talked about really are not subject to NCE Paragraph IV exclusivity so whereby you would expect shared exclusivity. So the ones that we mentioned, DEXILANTs, and the AMITIZAs, the CIPRODEXs. There's multiple on KUVANs. There's 2 products there. Those are products that we are either still first-to-file or we believe we'll be first-to-market. Now having said that, there's nothing stopping the innovator companies from putting in an Authorized Generic, I think that's something that you always have to at least think a little bit about. But we're pretty excited about the portfolio. It's a differentiating portfolio. They're hard-to-make products. And we do believe that there's limited competition. And some of these products, while they may be blockbuster in nature, some of them are even smaller and niche-ier products and sometimes with that we can get ourselves even into a longer de facto exclusivity. I'm not saying that, that's going to happen, but historically, when you look at the pipeline that Par has pursued, we can sometimes get even more than the standard 180-day exclusivity. So we feel pretty good about the pipeline that we disclosed here today. Thank you.

Operator

And our last question is from David Risinger with Morgan Stanley.

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

So I just wanted to ask about the testosterone settlement. So you described it as reflecting what's reasonable and estimable. Could you just remind us the number of cases, the dollar amount for those cases and I believe that you mentioned that you're also assuming future cases that haven't been filed. So I'm just trying to get my head around what the $200 million total reflects for testosterone and the numbers that you're looking at so we can better understand what you have booked as final for the testosterone litigation there.

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

So David, yes. So the total cases are about the 1,300 cases, right, and the settlement -- the accrual rather is expected to cover the settlement of all pending claims in the MDL and elsewhere. I think that's probably as far as we're going at this point in time. Blaise, I don't know if you...

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, David, we're not going to break out the charge we took between the 2 matters at this time. But as I said, we did contemplate in the reserve for TRT an estimate for future claims that are not filed today.

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

And may I just ask why not break out the 2? I don't understand. I haven't seen that before.

Blaise Coleman - *Endo International plc - CFO and EVP*

Yes, we're in an active matter right now that's still ongoing and it's in our best interest not to do that.

Operator

And I would now like to turn the call back over to Paul Campanelli for any further remarks.

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

Thank you. Before we conclude, I just want to thank our dedicated employees for their hard work and commitment to our company. I note that I attended Endo's national sales meeting last week, and the energy among our Branded and Generic talented sales professionals was incredibly remarkable. I could not have been more excited.

I'd also like to thank our investors for their patience and continued support.

We appreciate your continued interest in the company, and we look forward to providing you with updates. Thank you for joining us this morning.

Operator

Ladies and gentlemen, thank you for participating in today's conference. You may now disconnect. Everyone, have a great day.