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ENDP - Q4 2016 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 4Q16 GAAP net loss from continuing operations of $3.3b and GAAP loss per share of $14.96. Expects 2017 revenues to be approx. $3.45-3.60b and reported diluted GAAP EPS from continuing operations to be $0.04-0.34.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International plc fourth quarter 2016 earnings conference call.

(Operator Instructions)

As a reminder, this call may be recorded. I would now like to introduce your host for today's conference, Mr. Steve Mock, SVP, Investor Relations and Corporate Affairs. Please go ahead, sir.

Steve Mock *- Endo International plc - SVP of IR & Corporate Affairs*

Thank you. Good morning, and thank you for joining us to discuss our fourth quarter 2016 financial results. Joining me on today's call are Paul Campanelli, President and Chief Executive Officer of Endo, and Blaise Coleman, Executive Vice President and Chief Financial Officer. We have prepared a slide presentation to accompany today's webcast, and that presentation as well as other materials, are posted online in the investor section at www.endo.com.

I would like to remind you that any forward-looking statements made by management are covered under the Private Securities Litigation Reform Act of 1995, and Canadian Securities Litigation Act, and are subject to the changes, risks and uncertainties described in today's press release, and in our US 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. I would now like to turn the call over to Paul.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you, Steve. Good morning, and thank you for joining us for today's call. I presume that most of you have had an opportunity to review the Company's earnings press release that we issued earlier this morning. Let me now turn to our fourth quarter 2016 earnings presentation.

On slide 2, we begin with a brief agenda for today's call. Now before we commence with the review of Endo's fourth quarter performance, I will first address the activities we have been engaged in, since I assumed the role of CEO in late September. As many of you know, over the past few months Endo has undertaken an overall assessment of our Company's strategy, and its asset and product portfolios. Through this assessment, our management team developed a multi-year plan for our Company.

This necessitated a realistic examination of Endo, our current industry environment, and where we are headed over the next several years. In conjunction with our annual goodwill and in-process R&D impairment testing, we developed a revised company-wide long-term forecast, taking into consideration the realities of our current external environment. The revised plan reflects a lower estimated fair value for certain reporting units and intangible assets.

This change in estimated fair value ultimately led to significant impairment charges being recorded during the fourth quarter. Blaise will address these charges in greater detail, later on this morning's call. While the impairment charges reflect an accounting evaluation of assets acquired in the past, our multi-year plan represents our forward-looking strategy.

Importantly, we've already begun to execute on a number of our plan's underlying initiatives and priorities. In this regard, moving to slide 3, we have defined three key priorities. The first is to reshape our organization for success.

We've put in place a new executive leadership team that possesses a demonstrated track record of success. We have centralized and streamlined Endo's global supply chain, quality, and compliance organizations, in order to create a more cohesive and efficient structure to support both our generics and branded businesses. Additionally, we announced the restructuring of our corporate and branded pharmaceutical R&D functions.

Importantly, we named Terry Couglin to be Endo's Chief Operating Officer. As a result, we now have an operating leader with visibility into all of our business units, which we believe will allow us to achieve greater efficiencies, and to capitalize on synergistic opportunities between the businesses. We also believe our new operating model will help enable a new Endo culture, focused on execution and accountability.

Our second priority is to build our portfolio and capabilities for the future. In doing so, we identified assets and businesses that were no longer core to us and divested them, or plan to in the near future, as they no longer align with our go-forward strategy. We divested non-core assets such as BELBUCA, and restructured Endo's pain franchise to become a highly focused specialty branded business. And today, we announced the divestiture of the South African Litha Healthcare Group. We are investing where we can win, and divesting non-core assets.

In this context, we have also identified Somar as non-core, and we'll be conducting due diligence on divesting Somar, in order to focus on regulated markets in developed countries. Both Litha and Somar are good businesses with talented teams, and we appreciate all the contributions they have made to our Company. However, they are no longer a good strategic fit for Endo, and they are better placed with companies that can provide the attention and resources they deserve.

Lastly, our third priority is to drive margin expansion and delever. We will look to drive margin improvements through a culture focused on smart product selection, operational execution, and continuous improvements. In addition to driving margin improvement, delevering is a priority, and we do aspire to delever back into the 3 to 4 times range over time. We are not going to put a specific time frame on when we expect to achieve this goal, due to the number of uncertainties in the near-term that could impact the timing of achieving it.

We are committed to taking a highly disciplined approach to capital allocation, with the repayment of debt as a top priority, after investing in our key growth drivers. Through the actions we have already taken to date, we are achieving cost savings that will ultimately result in lower operating expenses, solid EBITDA generation, and a significantly improved EBITDA margin percentage, starting in 2017.

Moving to slide 4. Today it is Endos' intent to be a highly-focused generics and specialty branded pharmaceutical Company, delivering high quality medicines to patients through excellence in development, manufacturing, and commercialization. Endo will focus on its core assets, a generics business which is the fourth largest in the US based on sales, with a growing sterile injectable unit, and a promising pipeline of almost 120 ANDAs, and a revamped specialty branded business focused on our flagship product, XIAFLEX, as well as products like SUPPRELIN LA, TESTOPEL and AVEED.

Now moving to slide 5. We'll begin the review of our financial results. Driven by a strong fourth quarter performance, Endo placed at the high end of our guidance range for both revenue and adjusted diluted earnings per share for the quarter and the year. This performance was driven by our generics business which benefited from important product launches, as well as the continued growth of our XIAFLEX franchise.

On slide 6, you will see a snapshot of our segment revenues for the fourth quarter. Owing to two significant product launches, our US generic pharmaceutical unit represented about 70% of our Company's revenue in the fourth quarter.

Turning to slide 7, our generics business delivered a very strong performance in the quarter, driven by the first-to-file launches of quetiapine ER, the generic version of Seroquel XR in November, and ezetimibe, the generic equivalent of Zetia in December. The successful launches of ezetimibe and quetiapine achieved combined sales approaching $300 million for the quarter. Ezetimibe represented the largest product launch in Par's history.

Our sterile injectables business continues to grow, led again by Vasostrict. In 2016, Vasostrict achieved sales just over $340 million, and is Endo's largest selling product. Going forward, sterile injectables will continue as one of Par's areas of strategic focus. We are developing an impressive roster of ANDAs for sterile injection and infusion, having filed 5 ANDAs for sterile products just in the fourth quarter. We also received approval for our mycophenolate injection ANDA, and launched the product in November.

In new launches and alternative dosages, the strong performance was driven by the two product launches we just reviewed. Alternative dosages specifically benefited from the increased sales of potassium chloride liquid and powder. Based on our generics business decline approximately 300 -- I'm sorry, our base generics business declined approximately 23% compared to fourth quarter of 2015, and approximately 30% for the full year of 2016, compared to pro forma 2015, which is in line with the guidance we provided last November.

As we've discussed before, the base business has been impacted by consortium pricing pressures, an evolving consortium structure, and additional competitive generic entrants in certain product categories. The fourth quarter base business revenue increased sequentially from the third quarter of 2016. The increase was due to the expected restocking in the quarter.

Slide 8. Finally, as we said last month at the JPMorgan Healthcare conference, we expect our 2017 base business revenue decline to be similar to what we experienced in 2016, or in the low 30% range. In 2017, the underlying rate of base business price erosion is likely to be high single-digit, when we exclude the impact of product discontinuances, the full year impact of prior year competitive events, and the impact of expected new competitive events in 2017.

With that said, we expect our total generic segment to decline in the high single to low double-digit percentage range in 2017, due to what I just described, partially offset by growth in our sterile injectables and new launch revenues, respectively. It is important to note, that we expect modest growth in gross margin improvement versus prior year, with margins in the high 50% range.

Now moving to slide 9. You will see that in 2016, Par launched approximately 20 new products representing approximately $11 billion in market value according to IMS Health. In addition, we made 27 regulatory submissions, including 21 ANDAs.

We also successfully rationalized our generics product portfolio, with approximately 70 products that provided no profit identified for discontinuance. In addition, we restructured our manufacturing network, including the divestiture of our Charlotte manufacturing facility.

As a result, we are on track to realize approximately $75 million in annual net savings in 2017. These savings are higher than previously communicated, as we have been able to accelerate and increase the net savings expected to be realized through our restructuring efforts. These savings are contributing towards the expected year-over-year improvement in our 2017 adjusted gross margin.

On slide 10, we highlight our full year 2017 product launch expectations. We expect to file a similar number of ANDAs as we did in 2016. We also expect to launch at least 20 new products in 2017, although none will be of the same magnitude of quetiapine and ezetimibe.

Year-to-date, we have already launched three products, the 25 milligram and 35 milligram strength of dexmethylphenidate ER capsules for which Par was first-to-file, itraconazole capsules, and most recently our 505(b)(2) NDA ephedrine sulfate injections.

We also received news from the FDA that we can now expect [unapproved] sources of adrenaline to vacate the market by the second half of the year. In addition, we continue to have 100% share of the potassium chloride liquid market, and have been growing our potassium powder market share nicely. Including Vasostrict, our 505(b)(2) strategy has yielded five products for Par, that are all significant contributors to our businesses.

On slide 11, we'll discuss our branded business. Revenues in our US branded pharmaceutical business declined 24%, compared to fourth quarter 2015. The decrease in sales was due primarily to the impact of generic erosion on Endo's pain and established products portfolios, as well as the divestiture of STENDRA. Brands impacted by continued generic erosion included VOLTAREN gel, LIDODERM and FROVA.

Specialty pharmaceuticals increased 14% in the fourth quarter versus prior year, powered by strong performances from XIAFLEX and SUPPRELIN LA. Sales of XIAFLEX, our flagship branded product, increased 11% compared to fourth quarter of 2015, driven primarily by double-digit demand growth for the product, particularly in Peyronie's disease. Meanwhile, sales of another core specialty product, SUPPRELIN LA grew 23%, driven in part by continued demand growth.

In 2017, we expect our branded revenue to decline in the low to mid-teen percentage range year-over-year, based on the annualized erosion for the products previously discussed, as well as the continued decline of the legacy pain portfolio, partially offset by the growth of XIAFLEX and our other specialty brands. We expect gross margins for this segment to remain in the high 70% range.

Turning to slide 12. For the year, XIAFLEX achieved US sales of $190 million, a 14% increase from 2015, on a pro forma basis. We expect our 2017 specialty business to grow in the high single-digits, driven primarily by expected high single- to low double-digit growth for XIAFLEX.

Only a small portion of the diagnosed patient population for each of the XIAFLEX indications have actually been treated. This represents a very promising opportunity to Endo to increase awareness among patients, and extend the product's growth in each of its on-market indications. Our Q4 2016 branded speciality business performance demonstrates an initial proof point that Endo can win in those strategic core areas that we focus upon and invest in appropriately.

As I briefly mentioned earlier, BELBUCA has been returned to BDSI. The pain opioid market has changed significantly, and BELBUCA no longer aligned with Endo's US branded strategy and portfolio prioritization. A portion of the cost savings from the restructuring of our pain business will be redeployed in 2017 to support our core franchises including XIAFLEX, SUPPRELIN LA and other core branded franchises.

On slide 13, let's now discuss XIAFLEX further. We are very excited about the prospects for XIAFLEX, and recognize it to be a very valuable asset. We'll focus our efforts and resources behind XIAFLEX in its approved indications, and in pursuing an indication for cellulite, following the announcement of positive Phase 2b data last November.

Endo is fully committed to obtaining the necessary aesthetic capabilities to be prepared to successfully launch and commercialize XIAFLEX for cellulite. We are, in fact preparing for success. As part of the preparation, we intend to maintain what I refer to as our optionality with regard to the cellulite opportunity, in its potential commercialization. We will examine and consider all options, in our efforts to maximize the value of this opportunity, and increase the long-term shareholder value.

Moving to slide 14, let's address international pharmaceuticals. As part of our product by product and business by business assessment, we made the determination that Litha Healthcare Group and Somar are no longer aligned with the Company's strategy, and do not represent a core area of focus for Endo. Accordingly, we have entered into an agreement with Acino to divest Litha, and have started due diligence efforts for the potential sale of Somar.

Fourth quarter international revenues of $70 million declined 18% compared to prior year. Paladin's fourth quarter performance actually exceeded our expectations, due to delayed competition on certain products. In the fourth quarter, Paladin began to promote XIAFLEX and Nucynta in Canada. Paladin also retains Canadian market rights to Seralaxin, and looks forward to the results of a Phase 3 clinical trial later this year.

The decline in emerging market revenues from Litha and Somar were attributable in part to a decrease in Litha revenue, as the result of the divestiture of non-core assets in the first quarter of 2016. Somar revenues were impacted by lower demand for certain products in Mexico, and the unfavorable impact of foreign exchange. In 2017, we expect international revenues to decline in the mid to high 20% range, reflecting the divestiture of Litha, as well as the competitive pressure discussed earlier for Paladin, and the impact of foreign exchange on Somar.

With that, let me turn the call over to Blaise Coleman to further discuss the financial performance of the Company in the quarter, and our 2017 financial guidance. Blaise?

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

Thank you, Paul, and good morning, everyone. First on slide 15, you'll see a snapshot of the fourth quarter GAAP financial results. Paul covered Company and segment revenues earlier, so I will not review that here.

On a GAAP basis, we had a loss per share of $14.96 in the quarter, versus diluted earnings per share from continuing operations of $1.97 in the fourth quarter of 2015. GAAP net loss from continuing operations in the fourth quarter of 2016 was $3.3 billion, compared to GAAP net income from continuing operations of $444 million during the same period in 2015. The $3.3 billion net loss resulted from the $3.5 billion goodwill and intangible asset impairment charges recorded during the fourth quarter 2016.

Moving to slide 16, as Paul mentioned, during the fourth quarter, the Company conducted its annual goodwill and in-process R&D impairment test, and tested several other finite-lived intangible assets that had triggering events during the quarter. To test these assets for impairment, the Company utilized estimated future cash flows developed, as part of our fourth quarter company-wide forecasting process.

The Company's revised forecast reflects a change in [outlook], primarily for its generics reporting unit, reflecting the quickly evolving new realities of the US generics external environment, as characterized by increased buying power from the continued consolidation of its customer base, increased levels of competition due to the new low cost competitors, and accelerated FDA ANDA approvals, and a change in the value derived from estimated future pricing levels.

All of these factors, coupled with increases in the risk factor included in the discount rate used to calculate the discounted cash flows, have driven a material decrease in the estimated fair value of our generics reporting unit, and certain intangible assets. This change in the estimated implied fair value led to the majority of the impairment charges recorded in the fourth quarter.

In addition to the impairment charges related to our generics reporting unit, we also had impairment charges related to our international pharmaceutical segment, driven by the change in the expected future cash flows from those respective reporting units.

Turning to slide 17, as Paul mentioned on an adjusted basis, both revenue and adjusted diluted earnings per share are at the high end of our guidance range for the quarter and the year. To summarize the points Paul made earlier, revenue was strong due to the launches of ezetimibe and quetiapine extended release, the continued growth our sterile injectables business, and double-digit growth for XIAFLEX. Adjusted net income of $396 million and adjusted diluted earnings per share from continuing operations of $1.77 increased versus fourth quarter of 2015, due to higher revenues and lower operating expenses, especially when viewed as a percent of sales.

Moving to cash flow and liquidity on slide 18, in fourth quarter 2016, cash flow from operations totaled approximately $81 million. We've also highlighted some of the material items that impacted our cash flow from operations on a quarterly and annual basis.

On slide 19, you will see highlights of our full year 2017 guidance. We expect revenues to be approximately $3.45 billion to $3.6 billion, a low double-digit decline versus 2016, reflective of the pressures in our generics brand and international businesses Paul described earlier. Excluding the impact of divestitures and product discontinuations, our forecasted total enterprise revenue decline would be high single-digits.

Reported diluted GAAP earnings per share from continuing operations are projected to be between $0.04 and $0.34, and we expect adjusted diluted earnings per share from continuing operations to be between $3.45 and $3.75. More importantly, we expect adjusted EBITDA from continuing operations to be between $1.5 billion to $1.58 billion, representing a significant increase in adjusted EBITDA margins year-over-year, reflective of the impact from our ongoing margin enhancement initiatives.

The Company's financial guidance is based on the following assumptions, adjusted gross margin of approximately 62% to 63%, adjusted operating expense as a percentage of revenues to be approximately 22.5% to 23%, adjusted interest expense of approximately $470 million to $480 million, adjusted effective tax rate of approximately 13% to 14%. And adjusted diluted earnings per share from continuing operations assumes full year adjusted diluted shares outstanding of approximately 224 million shares.

Additionally, it is important to note that we expect our 2017 cash tax rate to be in the low single-digits as a percentage of adjusted pretax income. Our guidance assumes that the Litha divestiture announced today closes in the second quarter of 2017. From a P&L phasing perspective, we also expect approximately 53% of our total enterprise full year revenue to be realized in the first half of the year, mainly due to the exclusivity period of quetiapine and ezetimibe.

We also expect our gross margin percentage in first quarter 2017 to be broadly in line to slightly below fourth quarter 2016, with a meaningful improvement during the course of the year based on favorable shifts of product mix, and increased realization and net savings from our recently completed generics manufacturing restructuring initiatives. Lastly, we anticipate our first quarter 2017 operating expenses to be largely in line with fourth quarter 2016, due to the timing of certain expenses, and as our recently announced corporate and R&D restructuring initiatives begin to yield meaningful savings in the second quarter of this year.

Finally, on slide 20. We provide our 2016 actual, and 2017 estimated cash flow prior to debt payment. We generated approximately $585 million in cash flow prior to debt payment, and repaid approximately $330 million in principal in 2016.

Fourth quarter 2016 cash flow prior to debt payment was higher than expected, primarily due to a lower use of cash from changes in working capital, and a favorable shift in timing of payments into the mesh qualified settlement funds. As noted in our press release, we ended the fourth quarter with approximately $517 [million] in unrestricted cash, approximately $276 million in restricted cash, and a net debt to adjusted EBITDA leverage ratio of approximately 4.6 times. As we look forwards 2017, we expect cash flow prior to debt payment in the range of approximately $200 million to $280 million, and estimate ending net debt to adjusted EBITDA leverage ratio to be in the high 4 times range.

With regards to funding Endo's existing mesh obligations as of September 30, 2016, approximately $930 million of the mesh liability accrual remained to be paid into qualified settlement funds. In the fourth quarter, Endo paid approximately $240 million into the qualified settlement funds. We expect to pay the remaining balance of approximately $690 million in 2016, with the vast majority being paid in the first half of the year. We did not increase our mesh product liability accrual during the fourth quarter, and we believe that the current accrual includes all known claims, risks, liabilities, probable and estimable.

More broadly, we continue to execute our legal strategy of litigating claims that are invalid, for which settlement is not able to be reached, or that are in excess of the maximum claim amounts under our master settlement agreements. I note that we recently received varying levels of information supporting an increase in our estimate, from approximately 8,000 to 9,700 filed or asserted claims, or claims that we believe are likely to be asserted. We have not accrued for these claims, because we lack sufficient information to determine if any potential loss is probable.

I'd point out that the possibility of additional claims has been disclosed by Endo in multiple public filings, and I reiterate today, the potential of other claims to be filed or asserted in the future. This is currently not possible, however, to estimate the number or validity of such claims, and Endo will not speculate in that regard, or with respect to the overall outcome of the mesh litigation and its impact on our business, financial condition, results of operations and cash flows.

This update will be included in our 2016 Form 10-K and we will continue to update our disclosure as additional information becomes available. Now let me turn it back over to Paul. Paul.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you, Blaise. Moving to slide 21, I want to reiterate and close with our three key priorities. Our 2017 financial guidance clearly reflects that Endo is entering a period of transition. From a Company that grew through debt-fueled M&A to one that will primarily focus on organic growth, and driving margin improvements through a new Endo culture focused on operational execution.

It will take some time to successfully address the challenges that our Company faces today, and it will take time to reposition Endo for long-term success. We are ready, and we have already begun to meet these challenges, and are very excited about our future. We have a management team with a track record of success. We have the people, products, and pipeline in place that we believe will enable us in time to achieve success, and create value for our shareholders.

There are several reasons why I believe Endo represents an attractive opportunity for long-term investors. First, we reshaped the organization and have a new execution-focused culture built for sustainability in the future. And finally, we will maintain a highly disciplined approach to capital allocation, with a commitment to delever over time that has the potential create value for equity holders.

I remain excited and enthusiastic about the opportunity to be leading the new Endo. I want to thank all of our employees for their hard work, dedication, and commitment to the Company. This has not been an easy period for them, and I am proud of how they've fully embraced the new Endo culture and priorities. We continue to believe that this is a time of significant opportunity for Endo, our employees, the patients we serve and our shareholders.

That concludes our prepared remarks. Let me now turn the call back over to Steve to manage our question and answer period. Steve?

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Paul. We'd like now to open the lines to your questions. In the interest of time, if you could limit your initial question, to allow us to get in as many as possible within the hour, we would appreciate it. Christie, may we have the first question?

QUESTIONS AND ANSWERS

Operator

Thank you. Our first question is from the line of Louise Chen of Guggenheim. Your line is open.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Hi, thanks for taking my questions here. So first question I had here, was how we think about sales growth longer term? Just curious, given the fact that you've got some exclusive launches in 2017, and then also Vasostrict is a very big product for you. How do we think about growth in 2018 and beyond, and any risk to those sales going forward?

And the second question I had, was on Litha and Somar. Can you confirm whether or not those have been removed from the 2017 guidance? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

Okay. So Blaise will start with --

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

Yes, so Louise, on your second question, Somar is included in the guidance. Litha is included, for essentially the first quarter, and then we've removed it.

Paul Campanelli - *Endo International plc - President & CEO*

Yes. And Louise, in terms of how we look at the business on a go forward basis, unfortunately at this time, we're not going to be able to guide beyond where we are in 2017. We have a series of uncertainties, in essence we've got to get through. When you look at 2017, with the launches of ezetimibe and quetiapine, those are going to be tough comparators, as we look out into 2018. So with that, we're just going to have to ask for some patience here, and we're just focused on 2017 at this point in time.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Okay. Thank you.

Operator

Thank you. Our next question is from David Amsellem of Piper Jaffray. Your line is open.

David Amsellem - *Piper Jaffray & Co. - Analyst*

Thanks. I wanted to get your thoughts, Paul, on the upcoming panel on OPANA ER, what do you make of it? What ultimately, do you think is the end game for the FDA, and really your level of concern, or how should we be concerned about a potential, that the product is removed from the market? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

Yes. So David, I think, right now as you know there's an Ad Comm on March 13 and 14. It is in fact a joint meeting to discuss the risk and benefit of all oxymorphone products. So it's not just OPANA ER. It includes any generic forms of oxymorphone as well.

As you can imagine, Endo is always going to be focused on patient safety. That's a top priority, and we are committed really to provide patients, to have a commitment to provide patients, with safe and efficacious products for their intended use. So right now, the Ad Comm is focused on risk benefit from abuse. So it's a little bit difficult for us to opine, in terms of what the end game is with the FDA.

I think at this point in time, we can say is that our studies to date support the safety and efficacy for the intended use of OPANA. We'll know on March 13 and 14, what the potential outcome is. So really at this point in time, we're prepared to discuss all aspects of our trials, but we're in a wait and see game until March 13 or 14.

David Amsellem - *Piper Jaffray & Co. - Analyst*

Okay, thanks.

Operator

Thank you. Our next question is from Elliot Wilbur of Raymond James. Your line is open.

Elliot Wilbur - *Raymond James Limited - Analyst*

Thanks. Good morning. Just two questions on the generic business overall. First, Paul, in your deck, I think it's slide 8, the waterfall chart, you talk about 2017 price erosion, sort of a high single-digit impact. And basically what I'm looking for is commentary, on the actual rate of price erosion exiting 2016, and then what you have embedded in 2017, in terms of just the pure price erosion metric?

And obviously, we talk or -- base business down 23% year-over-year, and then you -- sort of your earlier commentary, that it would be down 30%. Obviously, there's a fairly big volume impact included in that as well. Just trying to get a sense of what the actual price erosion on the portfolio may be?

And then secondly, with respect to new product launch expectations, I think you talked about approximately 20 launches. How many of those do you actually have a relatively high degree of visibility on, in terms of either specific, date certain patent expiration, or a settlement? Obviously, the FDA hasn't been doing favors for any companies in terms of specialities generics. Just want to get a sense of, the degree of confidence we can have around that level of launches? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

So Elliot, what I'll do, is I'll give you some visibility really on the new product launches, and Blaise will give you a little bit more color on the base erosion, which has about four components of the composition here. But moving back, to like new product launches. As we say, I'm going to go through this pretty slowly, so there's no confusion. When we look at new product launches for 2017, we say we have about 20 products.

I would tell you that we have a fairly high degree of confidence that those are all products that we'll be able to deliver on. Now, there's always some degrees of uncertainty, but in this case when we talk about the 20 products, I have pretty good certitude that we're going to execute, and we've already launched a series of products up to this point. When we look at -- maybe I'll be put a little color on the value, I think that's probably important.

When we look at these 20 new products, the value that we should be looking at is about $100 million of true pure new product launches, from a revenue standpoint. So we want to get that out there. But I think it's also important to talk maybe just a little bit of the carryover for our Zetia and quetiapine, because they're so big contributors to what we're doing. So when you look at those two products, there's going to be a carryover value of about $360 million of those two products.

So you've got $100 million of new product launches, true, pure new product launches, about $360 million of carryover products that are Zetia and quetiapine. And then, you should look at about another $100 million of carryover 2016 products into 2017, that are excluding Zetia and quetiapine. So that should give you full color on how we're looking at 2017. Now I'll turn it over to Blaise to give you some color on base erosion.

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

Yes, Elliot, so just to pick up on your question, when we think about 2016 in terms of, from a price volume standpoint, overall we had about 13% price erosion in that 30%. There's two components of that, there's a normal course sort of price erosion. There's price erosion due to new competitor events.

And so, for normal course, it was sort of in the mid single-digits, and then the delta was due to competitor events. When we show it now for 2017, on the slide there, you see that 9% price erosion is -- that's very much our normal course price erosion. And included in that, is obviously our expectations around some additional pressure from consortiums through the course of the year.

There's another element that's embedded in the other blocks, in terms of the competitor events that also has a price element to it. And again, that -- so from a total price erosion standpoint year-over-year, when you take the normal course, and then the impact from competitor events, we would also have that in sort of that low double-digit, mid-teen range.

Operator

Thank you. Our next question is from Marc Goodman of UBS. Your line --

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Marc Goodman - *UBS - Analyst*

So Paul, once we get rid of the international business, okay, we understand that's happening. And then, should we assume that you're done taking a look at the branded products, and that what we see today, is what we're going to keep? So that's really the first question.

Second is, can you just give us a flavor for generic gross margins in the quarter? And then, a third, that was a great explanation for the previous answer. Is there any way you could tease out, just how much of the consortiums is adding to the pricing pressure? I mean, is it an extra 2% in the year, 3%? Is there any way you could do that, Paul, just for us to understand? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

High level, Marc, we'd say the consortium pricing pressure is probably adding 3% to 4% -- about. About -- yes, that would be generally.

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

And Marc, maybe I'll handle your gross margin question. So our generics gross margin for the segment in the fourth quarter 2016 was around [55]%.

Paul Campanelli - *Endo International plc - President & CEO*

Yes. And then Marc, in terms of the big question, really in terms of how we're looking at our businesses, I think we've proven and we've shown, that we've taken a lot of action here over the last four, five months here, with decisions that we've made on the portfolio, on facilities in BELBUCA, amongst many other things. And really doing this with a new leadership team that's been in place for really, probably three or four months.

As we take a step back, and look at our total businesses, your question was specifically on the branded side, I think what we're -- how we're looking at it is, we are considering optionality, across really the entire business. Ultimately, we'll need to do what's right for Endo. We are prepared for success, both on the generics side and the branded side. So we are putting resources into R&D, both from pure generic play, and obviously we're preparing for success on XIAFLEX.

But we also have to keep our optionality open, if we can place Endo in a better position down the line. We would just have to always consider that, and I think you would expect that from us as normal course. So that's pretty much where we are. We want to keep our options open.

Marc Goodman - *UBS - Analyst*

Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you.

Operator

Thank you. Our next question is from Randall Stanicky of RBC Capital Markets. Your line is open.

Randall Stanicky - *RBC Capital Markets - Analyst*

Great. Thanks. Paul, I just have a couple of quick follow-ups. If the 4Q generic gross margin was 55%, I think you pointed to high 50% for 2017. What's driving that, and how does some of this base business erosion factor into that -- I guess, that increase in margin outlook, if that is correct? And then, secondly, do we have timing around McKesson Walmart, the bid cycle there, and can you just provide some comments on expectations? And then, I have one really quick follow-up after that.

Paul Campanelli - *Endo International plc - President & CEO*

Okay. So I would say, the gross margin that's driving up into the mid-50% -- now Blaise, I would point to the 505(b)(2)s. I think part of that is, you look at the sterile injectable unit, the margins there are very healthy. We had success with the potassium liquids and powder product. Adrenaline is another product that we've had great success with. So those are for the most part, the drivers of positive gross margin.

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

The other thing I would add, Paul, is the -- Randall, as we mentioned in the slide, we'll see about $75 million of savings related to the generic restructuring. That's an incremental $50 million of savings from what we had in 2016. So that's also contributing heavily to the gross margin favorability. So both the product mix that Paul talked about, as well as the cost savings initiatives that we have been driving.

Paul Campanelli - *Endo International plc - President & CEO*

Yes. And then, in terms of the Claris One impact right now, I would tell you it's a little hard to totally pinpoint the implementation of Claris One. But I would probably -- my instinct is telling me somewhere around Q2, maybe Q3.

Randall Stanicky - *RBC Capital Markets - Analyst*

And that's built into the 3% to 4% impact that you talked about from consortium pressure?

Paul Campanelli - *Endo International plc - President & CEO*

Yes. When we talk about base erosion similar if in 2017 as 2016, we are including the impact of Claris One.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Great. And then, just one clarification. So we talked about on the mesh side, 8,000 cases last year or earlier in the year. Can you update us, what is that outstanding number now, in terms of total outstanding mesh cases? And what's the trend been, in terms of settlement, just so we can try to get some better visibility, or handle around where, and what really when that's going to resolve?

Paul Campanelli - *Endo International plc - President & CEO*

Okay. So I'm going to pass it over to Blaise, but you're referring to the 8,000 claims, that we've increased to 9,700? So maybe Blaise can talk a little bit?

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

(Multiple speakers) Yes, so Randall, the 9,700 of the non-MSA claims that we've been filed, asserted, or we believe likely to be asserted, that we haven't accrued, for because we can't assesses probability of loss at this time. And there's a number of reasons why that can increase. Some of those -- and many of those are outside of our control.

It has to do with a number of factors, including the receipt of new information, and then, some of that comes in as they -- there's the end of the tolling agreements are lifted, which really causes the statute of limitations to be in running, and requires claimants to file, in order to avoid dismissal. There's also the additional advertising by plaintiff attorneys, as well as other factors. So all of those things are contributing to us receiving new information, that's really leading to the increase, to the 9,700.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. I mean, you don't expect that to -- is that 9,700 kind of where you expect that to max out at, or are we still seeing claims coming in?

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

Yes, I mean, Randall, at this time, we don't have any way to assess that.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Thanks a lot, guys. That's helpful.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you, Randall.

Operator

Thank you. Our next question is from Greg Fraser of Deutsche Bank. Your line is open.

Greg Fraser - *Deutsche Bank - Analyst*

Good morning, guys. It's Greg Fraser on for Gregg Gilbert. Thanks for the additional color on how to think about the generics business in 2017, that was helpful. I was wondering if you could comment on how much growth you expect for the injectables business this year, or is that sort of embedded in the other comments that you made?

Paul Campanelli - *Endo International plc - President & CEO*

It's embedded. We'll see if we can -- just bear with us for a second, and we can give you a little bit of color on growth --

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

Yes, I mean, in terms of growth, we would expect that to be sort of in the high single to low double-digits growth in 2017, for the overall sterile injectables.

Greg Fraser - *Deutsche Bank - Analyst*

Got it. And then, a question on cash flow, and the $975 million of cash distributions you expected to settle mesh claims in 2017. Will there be a tax refund related to those payments? It wasn't clear.

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

Yes, so Greg, the way you should think about modeling cash taxes, is not to do it at any specific line item, but do it at an enterprise level. So the guidance we gave is that we anticipate that our cash tax rate will be in the low single-digits as a percentage of pre-tax adjusted net income, and that's how we would recommend that you model cash taxes.

Greg Fraser - *Deutsche Bank - Analyst*

But will there be a specific refund related to the -- ?

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

There will -- but not specific to that, no.

Greg Fraser - *Deutsche Bank - Analyst*

Okay. And then, just a last quick one. How do we think about R&D spend for the cellulite study that you're going to be starting in the second half? Thank you.

Paul Campanelli - *Endo International plc - President & CEO*

Well, we are preparing for success. The actual number is about $30 million-ish around -- about $30 million for the clinical trial portion.

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

In 2017.

Paul Campanelli - *Endo International plc - President & CEO*

In 2017, for the clinical trial portion of cellulite. Okay? Thank you.

Operator

Thank you. Our next question is from Chris Schott of JPMorgan. Your line is open.

Dana Flanders - *JPMorgan - Analyst*

Hi, thanks is Dana Flanders on for Chris. Just my first question, can you just talk a little bit more about your outlook for your potassium chloride products, and I know you mentioned the incremental opportunity to gain share on the powder. Maybe you can help frame that? And then, what are your assumptions around competition in guidance for 2017, on both the liquid and powder? And then, I have a quick follow-up.

Paul Campanelli - *Endo International plc - President & CEO*

Well, regarding both of those products, there's no intellectual property holding anybody back from filing it or launching into those products. So I think you just have to assume, that generic competition is able to come back into both the liquid and the powder.

That said, anyone filing an [ANDA], would have to go through the standard regulatory process, and you'd have to assume probably about a 24 month review, knowing that these [ANDAs] have been approved for more than a year. So I'd just caution you on the longevity. So these products have been approved, I believe since 2014, maybe even 2015.

Anybody that would file an [ANDA], I would not have visibility to that because they would be filing Paragraph probably II. There's no patents associated with these 505(b)(2)s. But at this point in time, we have 100% of the liquid market, and we have greater -- much greater than 50% share in the powder market.

Dana Flanders - *JPMorgan - Analyst*

Okay. Great. And my quick follow-up, just can you talk about the interest expense for 2017? I know that came in, I think a little bit higher than what we were expecting. So just what's the average blended interest rate for the Company, and just, I guess help frame your exposure to rising interest rates? Thank you.

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

Yes, so that's right. We do -- just to remind you, about 45% of our debt is variable-based debt, and we have factored into our guidance increase -- a rate increased environment, have factored that into our thinking. And that's what's really driving the impact you're seeing year-over-year, from an interest expense standpoint.

Paul Campanelli - *Endo International plc - President & CEO*

Okay.

Dana Flanders - *JPMorgan - Analyst*

Thank you.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

The next question?

Operator

Thank you. Our next question is from David Risinger of Morgan Stanley. Your line is open.

Thomas Chiu - *Morgan Stanley - Analyst*

Hi. Thanks. This is [Thomas Chiu] for -- on behalf of Dave. We just have one question. Regarding the XIAFLEX for cellulite, can you please disclose how you plan to you address the pricing, given the high price for medical conditions and [JCAOH] pricing restrictions? Thank you very much.

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

Yes, so Thomas, thank you. At this point in time, we do have a strategy, but we're not going to -- at this point in time, we just -- we're not going to elaborate. We acknowledge the challenge, and we do have a plan to address it. When it's finalized, we'll be pleased to communicate it. So we're just going to ask for some patience in this regard. Thank you.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Next question.

Operator

Thank you. Our next question is from Gary Nachman of BMO. Your line is open.

Unidentified Participant - - *Analyst*

Good morning, this is Nicole on the line for Gary. Just going back to XIAFLEX. Could you describe the Phase 3 program, and are you looking to partner that out, or could you ultimately just market it out yourself?

Paul Campanelli - *Endo International plc - President & CEO*

Sure. So in terms of the Phase 2 program, it, the trial had about 375 patients enrolled in it. And just from a very -- to try and address the question from a very high level, it utilized a primary endpoint that had a -- what was called a 2 point improvement in severity from baseline.

So it was an internally-developed metric with external consultants, that if you, as a patient or clinician had seen more than a 2 point improvement from baseline that, that would ultimately provide clarity, in terms of the direction of the results. This study is really kind of referred to as a photo numeric cellulite severity scale. And the results were discussed with the FDA probably about two, three weeks ago, in our end of Phase 2b discussions with the FDA.

That meeting went reasonably well. We're pretty excited, and we are preparing for success, as we move into Phase 3. We try not to get too deep into the results, because ultimately, we want to publish the results of the trial, so stay tuned.

But we, again, we're planning for success. We're very excited about the outcome of Phase 2b, and we should be preparing for Phase 3 in the Q4 time frame.

Unidentified Participant - - *Analyst*

Thank you.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you.

Operator

Thank you. Our next question is from Andrew Finkelstein of Susquehanna. Your line is open.

Paul Campanelli - *Endo International plc - President & CEO*

Andrew?

Operator

Please check your mute button.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Christie, maybe we want to go on to the next question?

Operator

Our next question is from Liav Abraham of (inaudible). Your line is open. Oh.

Liav Abraham - *Citigroup - Analyst*

Hi.

Paul Campanelli - *Endo International plc - President & CEO*

Hi, Liav.

Liav Abraham - *Citigroup - Analyst*

Hi. Thanks. Good morning. Firstly, could you please just outline the exact contribution from generic Seroquel and Zetia in 2016 in the fourth quarter? And then secondly, just a question on your path to delevering, which is understandably a stated goal. I understand that you don't want to provide specific commentary or time lines on how you'd get there, but perhaps you can help us think about the pushes and pulls, as it relates to cash flows, in at least post-2017, as you aim to get to the 3 to 4 times range? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

So the exact was what, [280]

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

So the exact combined for ezetimibe and quetiapine for Q4 was $293 million, Liav.

Liav Abraham - *Citigroup - Analyst*

Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

And in terms of the push and pulls, I mean, I think at this point in time, we're not -- we're just not in the position to give specifics. As I mentioned earlier, we made tremendous progress in a short period of time, but there is still a degree of uncertainty, that we need to get our hands wrapped around. So we're just going to ask for some patience.

Clearly, it's a primary focus, and you can see the moves that we're making to put ourselves in a better position for efficiencies, and growing really at the end of the day, growing EBITDA margins. Just give us a little bit more time, and when we're ready, we'll come back, and communicate where we stand on our strategy for delivering in 2018.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thank you.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you.

Operator

Thank you. And now we'll take Andrew Finkelstein's question of Susquehanna. Your line is open.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much for taking the question, that Paul, just (inaudible) away. I was just hoping you could talk a little bit more -- the slides mention a stocking impact in generics in 4Q. I noticed the generics base was up quarter on quarter, so if you could talk a little about those dynamics?

Second, on potassium, you note the lack of exclusivity, but do you have any views on the citizen petition that one of your competitors submitted recently, regarding elemental impurities? And then, just for the generics business more broadly, are there any pipeline products in particular, that should be a focus for people, as opportunities either in the second half of this year, or as we go into next year? Thanks.

Paul Campanelli - *Endo International plc - President & CEO*

Sure. So there's three questions there. I'm going to let Blaise answer your first one.

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

Andrew, just in terms of stocking in Q4 in generics, so if we look at total generics -- and we're going to exclude quetiapine and ezetimibe, because they're just -- we had the major launches -- excluding those two products, the overall stocking in our generics business was around $25 million. And then, particularly in the base (inaudible) business, in fourth quarter, we saw about $12 million of stocking.

Paul Campanelli - *Endo International plc - President & CEO*

And then, Andrew, your question regarding the citizens' petition, we believe that ultimately that citizens' petition is not going to have any impact on our ability to sell, in terms of opening up competition. And as I mentioned earlier, there isn't anything stopping anyone from filing ANDAs. So when that occurs, and the FDA approves somebody, we'll defend our share, as you would expect as a Par-based product.

Regarding the pipeline focus, I think really if you go back in some of the questions -- sorry, some of the commentary around ephedrine and adrenaline, the fact that the FDA's taken action to take the unapproved sources off the market in several months, that's probably where I would focus my attention to, in terms of drivers for 2017, ephedrine and adrenaline.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Okay. Go ahead. Next question, please?

Operator

Our next question is from Annabel Samimy of Stifel. Your line is open.

Esther Hong - *Stifel Nicolaus - Analyst*

Hi, this is Esther Hong on for Annabel Samimy. Just a quick question on Vasostrict. Can you provide any updates on any potential competition for that product? Thank you.

Paul Campanelli - *Endo International plc - President & CEO*

Sure. Thank you. At this point in time, as you know, we have intellectual property, we have an orange book patent. And to the best of our knowledge, we believe at this point in time, that we have not been noticed from any Paragraph IV filers. So I think that's probably maybe the best way to communicate that. At this point in time, we have not been noticed of any Paragraph IV applicants.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Okay, Christie, we'll take one more question, please?

Operator

Our last question is from the line of Ken Cacciatore of Cowen and Company. Your line is open.

Ken Cacciatore - *Cowen and Company - Analyst*

Hey, thank, guys. Just a real quick question, just looking forward to the cellulite Phase 3, just kind of counting out how long it would take, sounds like it could be on the market around 2020. So just wondering, can you review for us the XIAFLEX intellectual property, when we should expect you have durability for this product to? Thank you.

Paul Campanelli - *Endo International plc - President & CEO*

So Ken, your assumptions are in the ballpark, in terms of timing, assuming success, so I probably won't go any deeper than that. In terms of the intellectual property surrounding XIAFLEX, there are a number of -- there's a number of patents that are -- that have been granted. I would say, most notably, there's a 560 patent that expires in 2026.

But on top of that, as you would expect, we have -- our team is working towards additional patents for in-market, as well as potential future indications, so a work in progress. And then just keep in mind, that it is a BLA, and with that comes a series of defacto challenges.

This is not something that is easily developed. So we're pretty excited about potential indications, and -- okay. All right.

Steve Mock - *Endo International plc - SVP of IR & Corporate Affairs*

All right. That concludes the Q&A session.

Paul Campanelli - *Endo International plc - President & CEO*

Okay. So with that, thank you, Steve. As I said, this is an important time for Endo. We appreciate your continued interest in and support of the Company, and we look forward to providing you with updates as we move forward. Thank you all for joining us in the call today. Thank you, and good-bye.

Operator

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