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ENDP - Q4 2015 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 4Q15 results. Expects 2016 revenues to be $4.32-4.52b and adjusted diluted EPS to be $5.85-6.20.

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PRESENTATION

Operator

Good day, Ladies and Gentlemen and welcome to the Endo International fourth-quarter and full-year 2015 earnings conference call.

(Operator Instructions)

As a reminder this conference is being recorded. I would now like to introduce your host for today's conference Ms. Keri Mattox. You may begin.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Good morning and thank you for joining us to discuss our fourth-quarter and full-year 2015 financial results. With me on today's call are Rajiv De Silva, President and CEO of Endo; Suky Upadhyay, Chief Financial Officer; and Paul Campanelli, President of Par Pharmaceutical. We have prepared a slide presentation to accompanies today's webcast and that presentation is posted online in the investor section at www.endo.com.

I would like to remind you any forward-looking statements 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 accord an with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used other companies.

Investors are encouraged to review Endo's current report on Form 8-K furnished with the SEC today for Endo's reasons for including those non-GAAP financial measures in today's earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in our earnings press release issued prior to today's call. With that I'd now like to turn the call over to Rajiv.

Rajiv De Silva - *Endo International PLC - President & CEO*

Thank you, Keri. Good morning, everyone, and thank you for joining us for today's call. I hope that you have all had a chance to review the Company's earnings press release that we issued earlier this morning.

Let me now turn to our fourth-quarter and full-year 2015 earnings presentation. On slide 2, you will see our agenda for today's call. We will start with an overview of Endo's transformation in 2015 and we will move to review the highlights of our fourth-quarter and full-year 2015 financial results, walking through our US Branded, US Generics and International Business.

We will then turn to our full year 2016 outlook and financial guidance. After our prepared remarks we look forward to taking your questions.

Moving on to slide 4. 2015 was a year of transformative growth for Endo as we work towards our goal of improving lives while creating value. We made significant progress in our US Branded Pharmaceuticals business segment completing the acquisition of Auxilium and revitalizing our product portfolio and R&D pipeline. We also secured FDA approval for BELBUCA and extended our VOLTAREN Gel licensing agreement.

In addition, we received a favorable IP ruling for Opana ER and are continuing to advance that product with the recently submitted data package to the FDA that we feel could support an abuse deterrent formulation label expansion. The FDA has accepted the submission and set an action date of July 29, 2016. Collectively, these efforts and our continued execution across our full branded portfolio of products, resulted in full-year 4% underlying revenue growth for 2015.

Next, 2015 was a year of transformation and achieving critical mass for our US Generics business. In September, we acquired Par Pharmaceuticals, expanding our portfolio with higher barrier-to-entry and alternative dosage products, tripling our R&D pipeline and creating a top four US generics Company. After beginning full scale integration in the fall, we have continued to optimize our Generics Business operations and product portfolio, ultimately driving 11% underlying revenue growth in 2015 in this segment.

Our international segment was also re-based in 2015, positioning our emerging market businesses strongly for growth in 2016 and beyond. For example, in our Litha business, we focused on core pharmaceuticals acquiring a product and R&D portfolio from Aspen and divesting non-core asset like devices and vaccines. Overall we drove 6% underlying revenue growth in our international segment in 2015.

Finally, we continued to evolve Endo's corporate structure and strategy. We divested our AMS Men's Health business to further sharpen our focus on specialty pharmaceuticals. We continue to build out and enhance our Irish infrastructure.

We generated strong underlying cash flow from operations in line with expectations. In short, we have established a platform that, even if we pursue no additional M&A, positions us for future double-digit underlying growth and expanding margins. 2015 was indeed an important and transformative year in Endo's evolution.

Moving to slide 5. You will see that evolution reflected in our solid financial performance in the fourth-quarter and full-year. Suky will provide more details about our results in just a few minutes.

Next, on slide 6, let's talk about US Branded pharmaceuticals. In 2015, our rebuilt Branded portfolio drove underlying revenue growth in the mid single digits. Key drivers of that growth included XIAFLEX which continued to perform in line with our expectations.

We have also officially launched BELBUCA and expect that product to be an important growth driver moving forward. The kickoff for this differentiated schedule 3 product took place at our national sales meeting earlier this month and I can personally attest to the excitement and enthusiasm of our significantly expanded pain field force.

All of us at Endo believe that this first and only currently approved buprenorphine buccal film for chronic pain does offer an important new treatment option for patients. Also, in December, we executed a new agreement to extend our commercialization for the market-leading VOLTAREN Gel through 2023 and secured rights to any future authorized generic for that product.

Moving on to slide 7. Let's look at a snapshot of how XIAFLEX performed for the year. While XIAFLEX US revenues represent approximately 12% of our branded full-year reported revenues and only 5% of overall Endo full-year reported revenues, the product continues to be a very attractive growth opportunity and we are excited about the potential in its currently approved indications as well as in the R&D pipeline.

Overall, XIAFLEX for Peyronie's disease saw strong 72% full-year demand growth with vials totaling nearly 30,000 in 2015. We continue to expand our physician-base and are increasing our efforts to broaden clinical awareness. We believe the PD patient base can also expand.

Our broader DTC campaigns, including a comprehensive disease awareness program with celebrity spokesperson Dr. Jerry Punch, a long time ESPN commentator and M.D., are formally kicking off next week. In Dupuytren's contracture, we saw steady 12% full-year demand growth in 2015 which is especially encouraging given that we are five years post-launch. Our continuing efforts in this indication are focused on expanding the physician user-base, educating patients about an effective non-surgical option and, with the multi-cord label expansion, building the average number of vials per patient over time.

Next, let's talk about our US generics business on slide 8. Overall, we were able to drive an underlying growth rate in the double digits for the full-year despite increasing pricing pressures across the sector. We are very pleased with the strong contribution provided by the legacy Par business in the fourth quarter, which exceeded our internal expectations.

The legacy Qualitest business, while diversified and historically insulated from a challenging pricing environment, did experience a volume loss and pricing pressure in the fourth quarter due to increased competition in multi-player categories. While we have seen volume decline in some areas of this business, it is important to note that 80% of Qualitest's extended unit loss in the full-year 2015 versus prior year was driven by only a handful of products that correspond to approximately 20% of Qualitest's reported net sales in 2014. The fourth quarter also saw a more mild cold flu season that we believe contributed to lower than expected overall generic sales performance.

As you will note, actual full-year underlying generics growth was lower than preliminary estimates shared earlier this year. This was due to fourth quarter actual sales of our legacy Qualitest portfolio versus our previous expectations, part of the shortfall was driven by the number of non-recurring net charges recorded as part of our year-end processes.

While these types of customary charges -- while these types of charges are customary in any given quarter, we did see a higher level in the fourth quarter of 2015. Also, the shortfall is driven by a combination of higher than anticipated rebates and chargebacks that came through on fourth-quarter sales identified during our year-end close processes in January and February.

These shortfalls were offset by better than expected results in our branded business bringing the total Company performance in line with our 2015 preliminary expectations, once again highlighting the value of our diversified revenue base. We will talk more about our expectations for the generic pricing climate in 2016 and beyond when we discuss our full-year guidance later in this call.

Next, on slide 9, you will see that 2015 was a year of re-basing for growth and increasing profitability for our International Pharmaceuticals segment. Paladin continues to be a steady, high-margin contributor with recent launches providing potential upside for the business over time. In the fourth-quarter, the impact of these launches were offset by the loss of exclusivity on select products leading some modest non-cash impairments.

Our Somar business continues to grow driven by-products across its broad portfolio. It was also a year of transformation for Litha with the Aspen portfolio acquisition and our divestiture of non-core product lines which closed earlier this month. That business is now more sharply and strategically focused on higher growth and higher margin pharmaceutical products.

I should note that, similar to what we've seen across the sector and broader markets, a stronger US dollar did impact our reported performance for the quarter and full year. On slide 10 you will see how our reported segment revenues continued to grow in 2015. Now, for a more comprehensive look at our financial results, let me turn the call over to Suky. Suky?

Suky Upadhyay - *Endo International PLC - CFO*

Thank you, Rajiv, and good morning, everyone. As Rajiv mentioned, the full-year 2015 financial results are solid and characterized by a diversified and profitable business. On slide 11 you'll see that we achieved robust performance in 2015 with increased revenues, adjusted margins growing faster than revenue, progress on our tax planning strategies and adjusted earnings per share growth.

Moving to slide 12, let take a more detailed look at our underlying cash flow from operations in 2015, which remained strong throughout the year. We view this as a quality measure of our overall results and our ability to deliver long-term shareholder value. What you will see on this slide is that our 2015 reported cash flow from operations was impacted by a number of non-core cash outlays that are centered around product liabilities and non-recurring costs related to M&A transactions completed in 2015.

If you neutralize these items, cash flow from operations has a high correlation to adjusted net income. We expect this profile to continue into 2016. As a note, you will see -- also see more information on our cash conversion cycle related to working capital in the appendix of today's slide presentation.

Next, on slide 13, we would like to provide you more background around the mesh product liability accrual in the fourth quarter and how that is projected to impact future financial results. The environment around mesh product liability has evolved rapidly with an influx of claims having been presented to the Company in late 2015. We believe these additional claims are primarily the result of increased advertising by plaintiffs' attorneys, a lack of meaningful settlements by other mesh manufactures and higher-value verdicts awarded against other manufactures.

That said, we've taken the approach to strategically settle higher-value and quality case inventories with key plaintiffs' lawyers and certain individual cases. Also, we plan to shift our strategy to vigorously defend and, if appropriate, litigate remaining cases and seek relief from the Federal Court in the ongoing mesh multi-district litigation. I note that our accrual is based on claims that are settled or are considered probable and estimate.

We currently are aware of approximately 8,000 purported claims that have not been accrued for because, based on the analysis by the Company and outside Legal Counsel, we believe this portfolio could be of lower value and lower quality as almost all of the claims are lacking medical records and or basic demographic information. We've also recently become aware of what we believe may be fraudulent or other wrongful activities relating to the generation of certain mesh claims. While we do not yet know the scope of such activities, we plan to fully investigate them and, if appropriate, will vigorously pursue all available remedies against each responsible party and cooperate with law enforcement authorities, other mesh manufactures and the court.

Importantly, we have seen the rate of purported cases decrease substantially in the early part of 2016 as we continue to make progress in the narrowing the mesh liability tail. We are also reducing the potential for product liability related to future mesh implants through our decision to shutdown our ASTORA Women's Health business, which we announced earlier today.

Now turning to the accrual. Our pretax product liability accrual as of the end of the third quarter was approximately $1.4 billion. In the fourth quarter about $150 million was paid out of qualified settlement funds or QSFs.

During the fourth quarter 2015, we recorded an $834 million pre-tax charge to increase the estimated product liability accrual for mesh cases. Reflected in this increase as a conservative measure based on the lack of any meaningful reduction factor observed to date, we have removed the

reduction or kick out factor resulting in a $401 million impact. Total increase also reflects a $433 million impact primarily related to the execution of additional Master Settlement Agreements in 2016.

It is important to note that we believe these recently settled cases represent a higher value and quality portfolio of cases with a higher mix of ex-plant surgeries or revisions and are not representative of overall settlement per case averages. At the end of the fourth-quarter 2015, the amount funded in the QSF was $579 million. This brings us to a total remaining mesh liability pre-tax cash call of approximately $1.5 billion.

Our total remaining mesh liability post-tax cash call based on the current accrual is projected to be approximately $575 million through 2017 with about $150 million to $250 million paid in 2016 and approximately $325 million to $425 million paid in 2017. The overall pretax cash call is mitigated by an expected tax refund of approximately $700 million that is expected in the first half of 2016. With these post-tax cash call projections and our robust underlying cash generation, we have the confidence we can continue to de-lever into the 3 to 4 times range in the second half of 2016 and expect further de-levering into 2017.

Next, on slide 14, let's talk briefly about the announcement we made this morning regarding ASTORA Women's Health business. As you know we successfully divested the AMS Men's Health business and launched a strategic sale process for AMS Women's Health, now ASTORA Women's Health, in 2015. That process did result in formal bids for ASTORA, however Endo has now determined the best strategy is to wind down ASTORA business operations.

This decision was a difficult one as it impacts our dedicated employees, the physician community and importantly the patients for whom ASTORA products are important treatment options. Key factors that drove our own decision include the evolving product liability landscape around vaginal mesh has been challenging and continues to evolve for all manufacturers including ASTORA and, second, by shutting down the business as opposed to selling it, we're able to reduce the potential for product liability related to future mesh implants which would not have been achievable in the event of a sale of the ASTORA business.

So we will now work to support physician transition plans to alternative products. We expect to cease business operations for ASTORA by March 31, 2016. On other balance sheet matters, as noted in our press release, we took non-cash impairment charges totaling approximately $140 million in the quarter.

These charges are on a total goodwill and intangible balance of $15 billion, as of December 31, 2015. The majority, or about $86 million of the charges, were related to Paladin and is driven by the loss of exclusivity of certain products. As we noted at Q3, we finalized our goodwill testing in Q4 and guided that there could be modest changes to impairments in the fourth quarter.

I would like to emphasize that 2015 was another year of transformation for Endo and one that positions us for future growth and profitability. Specifically, it was a year where we further diversified and expanded our revenue base. We delivered solid underlying growth in a challenging market.

We expanded margins, improved our underlying after-tax cash flow conversion, we built a strong branded and generics product pipeline, we improved our operating model and execution, and made continued progress on narrowing the tail of the Companies mesh-related product liability. Now let me turn the call back over to Rajiv to discuss our key priorities and growth drivers for 2016. Rajiv?

Rajiv De Silva - *Endo International PLC - President & CEO*

Thank you, Suky. Let me first echo your comments about our dedicated ASTORA employees and Management Team and take a moment to thank them for their contributions and commitment to the business. We would also like to thank the physician community which has been so supportive of ASTORA and its products.

Now moving to slide 16. As we enter 2016, we have set out a number of strategic and operational priorities. First, we are focused on value creation, including a strong commercial launch of BELBUCA, continued growth of XIAFLEX in DC and PD, and the seamless integration and continued growth for our generics business.

Second, we are executing using our differentiated operating model. We are advancing our de-risked R&D pipeline and moving key XIAFLEX programs into clinical trials this year, and we are continuing Par's R&D pipeline momentum and productivity.

Third, Endo is achieving sustainable growth. As Suky mentioned, we expect to de-lever back down to the 3 to 4 times net debt to adjusted EBITDA range this year, and, in our continuing efforts to diversify our revenue base, we expect to drive underlying growth in our Emerging Markets with our re-based Somar and Litha businesses.

Next, on slide 17, we are very pleased to have launched BELBUCA last week. We believe BELBUCA is well differentiated as it combines schedule 3 status, proven efficacy and established safety and tolerability profile of buprenorphine with a novel delivery system that adds convenience and flexibility for patients. To support our launch into the nearly $5 billion long-acting opioid market, we have more than doubled our pain field force and have been working to insure broad patient access.

We believe BELBUCA is strongly positioned for growth and are projecting sales to be greater than $250 million in 2019, which while significant, represents only a small proportion of the existing current market. Turning to slide 18.

You will see the scope and size of the chronic pain burden that we are looking to address with BELBUCA. More than 30% of all Americans, or about 100 million people, are suffering from chronic pain. This is more than diabetes, coronary heart disease and cancer combined.

On slide 19, let's discuss where we are positioning BELBUCA within the chronic pain treatment paradigm. We see a prime opportunity for BELBUCA to serve those patients who are transitioning from short-acting opioids to a long-acting opioid treatment.

We also see potential for BELBUCA and its differentiated product profile to make an impact by capturing patients switching from other long-acting opioids or those who are opioid naive and are going directly to a long-acting opioid product. In short, we believe the opportunity for BELBUCA is exciting and significant and our early feedback from customers on the launch has been very positive.

Next on slide 20, let's talk about our progress with XIAFLEX. XIAFLEX continues to perform in line with our internal growth expectations. We continue to aspire to build a billion dollar franchise around this molecule.

We are projecting continued momentum into 2016 and double-digit growth for this product over our planning horizon. This growth will be filled in part by our multi-pronged sales and marketing campaigns designed to increase physician and patient awareness. In terms of the R&D pipeline, XIAFLEX continues to exceed our internal initial expectations and are continuing to move new programs into the clinic this year.

Next on slide 21, you will see the considerable market expansion opportunity for XIAFLEX. While it was launched more than five years ago and has seen steady growth and increasing traction over time, we believe there's a significant opportunity for us to grow market share for XIAFLEX for Dupuytren's contracture using our DTC campaigns and to continue building traction for the multi-cord indication.

In Peyronie's disease, we are seeking to expand the market to an unbranded disease awareness campaign, while a large number of diagnosed patience are currently untreated, XIAFLEX is showing very strong penetration amongst those patients that are treated. We believe that by continuing to capture those patient treatments and expanding the base of patients seeking a treatment option, we can continue the robust double digit growth in this indication.

In summary, across our branded business in 2016, we expected to drive growth with BELBUCA, XIAFLEX and other products including our long-acting TRT portfolio with some offset by continued erosion in our legacy products. As a result, we project low single-digits underlying growth for this business.

Moving to slide 22. Our focus on value creation also includes our US Generics business. This 2015 and 2016 break out of our pro forma generics revenue illustrates key segments of our Par business as well as how those segments are growing. Most importantly, the segments that are growing substantially are also those that represent our highest value products.

In fact, we project that in 2016, more than 40% of our generics revenues will come from revenues in our highest value and highest growth categories. First, new launches and alternative dosages will be a key growth driver this year as it includes the introduction of first to file products like the generic versions of Zetia and Seroquel XR which we expect to bring to market at the end of 2016. This category also includes differentiated higher barrier-to-entry and higher margin products like patches, powders, ophthalmics and other alternative dosages.

Next, sterile injectables have tripled in net sales since Par acquired JHP in 2014 and these products have high barriers to entry, high margins and strong competitive positioning and growth potential. We project significant continued double-digit growth with gross margins well above the Company average for this segment in 2016. In summary, across our Generics business in 2016, we project underlying growth in the mid to high teens.

Moving to slide 23. You will see that the effect of our collective efforts and our acquisition of Par in 2015 are not only increasing the size of our portfolio and Generics pipeline but also growing revenue and improving our gross margins. We expect to meaningfully continue this expansion into 2016 and beyond.

Next, on slide 24. Let's talk about our differentiated operating model. Specifically, our de-risked XIAFLEX R&D pipeline.

As I mentioned earlier, we anticipate that we will initiate new clinical programs this year. Beyond that we see a broad range of potential aesthetic and therapeutic indications with significant unmet needs with large patient populations and market potential that we believe will drive the long term value of XIAFLEX.

Moving to slide 25. Let me take a moment to provide you with an overview of our recently initiated Phase IIb clinical trial in cellulite. Cellulite affects nearly all women and there is little evidence that current treatments effective.

Moving to slide 26. Our differentiated operating model and de-risked R&D approach also drives our Generics activities. Par brought with it some of industry's strongest Paragraph IV, first to file and first to market R&D capabilities.

Those capabilities are fueling the projected stream of potential high-value, high-margin product launches in 2016 to 2019 time frame. Specifically, we project more than 100 potential product launches over the horizon including 20 first to files.

Next on slide 27, let's talk about our Emerging Markets International business as another driver for sustainable growth. Overall, we expect our International business segment, including Paladin in the more established Canadian market, will demonstrate a high [to] single digit underlying growth rate in 2016 driven by Emerging Markets businesses. That said, we believe international reported revenues will decline in 2016 due to a stronger dollar versus 2015, increased generic competition for the Paladin portfolio and divestitures of low margin device and vaccine products from the Litha portfolio.

However, importantly, we expect that our 2016 operating income from this business segment will be in line with 2015 due to our successful re-basing of our Emerging Markets businesses. You will see here the expected impact of this rebasing on Somar and Litha revenues and operating margins in 2016. We expect a significantly improved margin profile in the International segment and lower double-digit underlying growth across Somar and Litha this year.

With that, let me turn the call back over to Suky to talk about our full financial guidance for 2016. Suky?

Suky Upadhyay - *Endo International PLC - CFO*

Thank you, Rajiv. On slide 29, we have outlined the key considerations built into our 2016 financial guidance. First, our guidance incorporates a risk-adjusted range of scenarios around potential 2016 generic and competitive entrance for select products including VOLTAREN Gel, LIDODERM HE, FROVA, Valganciclovir and low dose hydrocodone APAP.

Second, while our diversified portfolio insulated us for most of 2015, as Rajiv mentioned, we do expect pricing headwinds in US generics to continue across the sector and for there to be a more challenging pricing environment for commoditized products. And third, we assume current exchange rates for foreign currency conversion.

So, on slide 30, you will see the highlights of our full-year 2016 financial guidance are as follows. We expect total net revenues to be in the range of $4.32 billion to $4.52 billion. We project adjusted gross margins of 63% to 65% this year, which is in line with 2015 despite a higher mix of Generics revenue in 2016.

This is primarily driven by the continued growth of XIAFLEX, the launch of BELBUCA and our continued shift towards high-value products in our Generics business. Each of our segments is expected to maintain or improve their gross margin profile in 2016 versus 2015.

Despite increases in branded promotional spending across XIAFLEX and BELBUCA, and higher R&D expenses to support the branded and generics pipelines, total expenses are growing below the rate of sales as we leverage G&A and capture the full synergies from the Par transaction. This translates into a projected adjusted operating expense to revenue ratio of 19.5% to 20% which is more than 150 basis point improvement versus 2015. Under these assumptions, we expect adjusted EBITDA margins in the mid 40%s which is better than our 2015 EBITDA margin profile.

Adjusted interest expense is expected to be approximately $455 million. This estimate includes approximately $34 million of the amortization of deferred financing fees in 2016 and also assumes debt pay down of about $500 million in 2016 versus ending gross debt balances in 2015. Given our continued progress on building out our infrastructure in Dublin, leveraging deal attributes and executing on our tax strategy as observed through 2015 we expect an adjusted effective tax rate of 9% to 11% for the full year of 2016. These moving parts translate to an adjusted diluted earnings per share range of $5.85 to $6.20 with approximately $224 million weighted average diluted shares outstanding.

As expected, our results will be lumpy through the year driven by a number of factors including the early investment and corresponding ramp of BELBUCA, the timing of potential market events around key products in the Branded and Generics portfolio that Rajiv mentioned earlier, the cyclical nature of some of our businesses, including fluctuations in stocking levels, and the anticipated launch of our generic versions of Seroquel XR and Zetia in the fourth quarter of 2016. Using the mid-point of our revenue and EPS ranges, we expect about 54% of revenues and about 57% of EPS to be in the second half of 2016. This weighting is heavily influenced by the expected timing of the Zetia and Seroquel launches.

Again, using mid-point of our revenue and EPS ranges, we expect 22% of revenues and 18% of EPS to be in the first quarter of 2016. This is driven by normal cyclical trends and destocking that we historically see in the first quarter. Also, investment for BELBUCA in the first quarter more than offsets revenues for that product as we will book revenues based on demand until we see a normalized pattern of shipments versus demand trends.

So, in summary, we believe that 2016 financial profile will be a continuation of 2015, which was marked by solid underlying revenue growth, margin expansion, and attractive tax rate, and strong underlying cash flow conversion. Now to close out the call, let me turn it -- the call back over to Rajiv. Rajiv

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Rajiv De Silva - *Endo International PLC - President & CEO*

Thank you, Suky. Moving to slide 31. In summary, we see the Endo story as one marked by significant growth, increased profitability and value creation in 2016 and beyond.

We are building a leading global specialty pharmaceutical company with three diversified and strongly positioned businesses. Our focus is on value creation which we plan to drive through our priorities including a strong commercial launch of BELBUCA, continued growth of XIAFLEX and continued growth for the Par portfolio. We utilize a differentiated operating model that is based on a diversified product portfolio and a strong de-risked R&D pipeline across our businesses.

And finally, we are achieving sustainable growth with a projected double-digit underlying growth rate, increasing operating margins, strong cash flow conversion and the ability to de-lever rapidly. 2015 was a year of transformation and continued evolution for Endo. We see 2016 as a year of execution, of delivering on the promise and potential of our business and of creating significant value for our shareholders.

We look forward to achieving these goals and to your continued support. That concludes our prepared remarks. Let me turn the call back over to Keri to manage our question and answer period. Keri?

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Thank you, Rajiv. We would like now to open the lines to your questions. In the interest of time if you could limit your initial questions to allow us to get in as many as possible within the hour we would appreciate it.

Operator, may we have the first question please?

QUESTIONS AND ANSWERS

Operator

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

Randall Stanicky - *RBC Capital Markets - Analyst*

Great, thanks. Rajiv, or maybe this is better for Paul, can you just expand on the pricing headwinds you're seeing and factoring in? Most of your larger peers are talking about a similar erosion level this year to last year despite with -- an expectation of greater approvals. So can you help us understand the Qualitest impact from Q4, how -- if that's likely to continue and what type of erosion are you expecting in the business for this year?

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure. And what I'll do, maybe I'll just pass it to Suky first, just to comment on the financial aspect of it and Paul can comment on the more qualitative aspects and what he's seeing from the consortia and how that's changing our view on pricing in the sector.

Suky Upadhyay - *Endo International PLC - CFO*

Good morning, Randall.

The first thing I would say is, into the forth quarter when we gave preliminary results around 2015 that did imply some softness in 2015 fourth quarter around generics. We did start to see the early signs of volume erosion in our more commoditized parts of our business. And then as we closed out our final processes for the year, we did recognize higher level of chargebacks and rebates coming through, specifically around our more commoditized portfolio, as well as pain franchise.

That in tandem with one-time charges that occurred in the fourth quarter led to a lower than expected fourth quarter. I should say that those one-time charges, we do not expect to continue in forward-looking quarterly results, but there is some underlying pressure on around pricing that will extend into 2016.

Having said that all of that is baked into our forward-looking estimates for 2016, and as Rajiv noted earlier in scripted remarks, we still see very strong generics growth in the mid teens to high teens, primarily driven by our injectables business, continued growth across the base, as well as our launches on base certain products. I don't know if Paul you want to add anything on the price erosion, please?

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

I think that's right. Suky hit the nail on the head. When you look at the consortiums, et cetera, really it started back in the full impact of the consortium really resulted back in Q2 of last year when you saw Red Oak and One Stop in full operation. I think on a go-forward basis, to Suky's point, we are prepared for it. It's part of our 2016 forecast.

And really, when you look at the commodities business it's going to be very, very challenging to take price increases like we had historically seen over maybe the past couple of years, but that, again, is all planned for. Our focus is clearly on our pipeline, it's all on execution. Rajiv touched on it in his opening comments that this year is going to be a year of execution. We've got to get our products out of the FDA.

That's our defense. That's our strategy on a go-forward basis. It's our portfolio and getting our products approved.

Randall Stanicky - *RBC Capital Markets - Analyst*

Can I just confirm there's no pricing increases built into the 2016 guidance? Thanks.

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

So from that standpoint on the Generics side, we have not taken any real price increases that are material. Clearly, the plan is driven on volume. Maybe we have to point out a few brands in the injectable portfolio that we can selectively and very appropriately increase. But to answer your question on the generic commodities business, it's a volume game for 2016.

Randall Stanicky - *RBC Capital Markets - Analyst*

Great thanks.

Operator

Our next question comes from the line of Louise Chen from Guggenheim.

Louise Chen - *Guggenheim - Analyst*

Hi, thanks for taking my question.

So first question I had here was on gross margin expansion and operating leverage in 2016. How should we think about that in light of your results in the fourth quarter? And then second question is on the Generics business, how should we think about the underlying growth outside of Seroquel and Zetia and the sales progression quarter-over-quarter? Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Let me have Suky cover the gross margin question, Louise, and then Paul and I will come back and talk about the Generics question.

Suky Upadhyay - *Endo International PLC - CFO*

Yes, so actually a little bit better than expected from the closing of Par. Our initial expectations going into 2016 was with the higher mix of generics products versus branded. We might see some dilution into our gross margin. As we actually work through our plan and our portfolio prioritization we're actually moving to a higher mix of higher value products which is ultimately expanding our margins.

So as Paul talked about, or as Rajiv talked about in scripted remarks, the growth of the injectable franchise is one that is characterized with a gross margin profile well above the overall Company average. As we think about the launches of some of our dates, certain products, those are also products that have gross margin profiles well ahead of the overall gross margin average. But then when you add in continued growth of XIAFLEX, as well as BELBUCA, both of which have gross margin profiles above the Company average, you start to form a picture of where we're going to see this gross margin expansion into 2016 and one that we're very pleased and confident in. And then from about operating margin perspective, as I said we are going to spend more against advertising and promoting, promotion against XIAFLEX and BELBUCA.

We are going to spend more this year around R&D for generics and for branded, full stop. However we are getting operating leverage through G&A, as well as through the full realization of the Par synergies some time in mid-2016. So not only do we get operating margin expansion -- excuse me, gross margin expansion, but we'll see operating margin expansion, as well. And also on top of a very favorable tax rate.

Rajiv De Silva - *Endo International PLC - President & CEO*

Thank you, Suky, and just to touch on your growth question, Louise, let me take a crack at it, and then Paul will add. While you mentioned Zetia and Seroquel, keep in mind what Par has over the 2016 to 2019 time frame is 100 possible product launches, so certainly Zetia and Seroquel stand out because of the magnitude but, as we talked about in the past, they are also partnered products.

So as you look out over this entire horizon we will have many, many more launches most of which are not partnered where the bottom line accretes entirely to Endo. So from that standpoint we do see new launches being the primary driver of growth in this business in 2016, as well as into the future. I would also say that the injectables business has been a great performer for Par.

It has tripled in size since JHP was acquired by Par, and we expect to see that momentum continue in 2016, as well as beyond. I don't know, Paul, if you'd like to add anything to that?

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

Yes, sure. Thanks Rajiv. I think that's right. When we look at 2016, we all know that Zetia and quetiapine are clearly large drivers coming out at the end of Q4. And not apologizing for that. Those were hard to develop products, hard to partner products and we're very proud of that relationships. That said, we have about 20 products we should be launching in 2016, albeit maybe not major, major drivers.

But in the generic industry you never actually know what product could outperform. And as some examples, when we look at what we achieved in 2015 that carrying us into 2016, we had a handful of carryover products, like pramipexole, dutasteride/tamsulosin. These were relatively smaller type products that ultimately had limited competition. They are going to carry us into the first part of 2016. Again, hard to make but from a brand sales standpoint, maybe not the largest products, but good drivers.

When we look a little bit at the sterile portfolio, we are real proud of what we have in Rochester. I think it's a great time to have sterile facility on US soil. It continues to be a barrier-to-entry. Products like Vasostrict have continued to outperform, and that's on the branded side.

But additionally we have a handful of generic products that have had limited competition, products like dexmedetomidine and ethacrynic acid. These are all products that have been genericized, but limited competition. And again these factored in with some of our overlap and carryover products from last year, should give us a good basis for 2016.

Operator

Our next question comes from Liav Abraham with Citi.

Liav Abraham - *Citigroup - Analyst*

Good morning.

Just a couple of questions on the mesh liability. Can you confirm that this is pretty much the end of these charges that you'll be taking, or do you anticipate any more? And if so how meaningful could they be? And then secondly, related to that, how do you expect this liability to impact your cash flows going forward? That's it for now, thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure, we have discussed mesh over the course of the last two years and I think, as you know, with this mass start of litigation situations, it is very difficult to predict the end. Now that being said, what I would say is that we have come a long way. Although the environment has continued to be more challenging than we had thought when we did our initial settlements, which by the way I'm glad we did.

But the reality is that the rest of the industry at that time didn't follow with our additional settlements as we would have expected, and there was increased advertising, which is kind of what's led to this additional bolus of claims in the back end of 2015.

Now as we look at what we have done here though, I do feel good that the current settlements that we just announced this morning, ones that are focused on the high value claims, and effectively what is left is what we believe to be a much lower value set of a portfolio of cases, many of them could be spurious. And in addition there is a evidence of potential fraud among some of these cases, as well. So as we look at what remains, we do think it is a portfolio we can be a lot more aggressive in terms of how we approach it. Either in terms of taking some cases to trial, as well as potentially through our investigation of this fraud seeking to dismiss a chunk of it as well, right?

So and also keep in mind we've now put a significant time between us and the public health notice that the FDA issued in 2011. That again should also be another factor that drives to reduce the number of new cases. And then finally our decision to shutdown the ASTORA business also will contribute to reducing the potential for future liability. So as we stand here today, we do feel good about where we have taken the mesh liability despite the additional increment that we saw in 2015.

We do expect to resolve the remainder of it over the course of the next couple of years, And there's no guarantee that our accrual may or may not change but I would say is that we are confident given what we know now about where we have brought the situation. And fundamentally we're a different Company now, right? So we have an adjusted basis more than $2.5 billion, or roughly around $2.5 billion of adjusted EBITDA which allows us the ability to manage this over time and makes it a lot more manageable to call in our cash.

Suky Upadhyay - *Endo International PLC - CFO*

And, Liav, this is Suky. Good morning. Relative to your question on how it impacts cash flow, as we pointed out in the slides, at the end of fourth quarter we've got a pretax remaining cash call of about $1.5 billion after we make these additional accruals. So again pretax remaining cash call of $1.5 billion.

We expect that in 2016 to pay somewhere around $850 million to $900 million of that $1.5 billion on a pretax basis. But after you consider the tax refund that we would be getting as part of our structuring of the AMS sale, our post tax obligation for mesh in 2016 will be somewhere between $150 million to $250 million. So quite manageable in the back drop of $2 billion plus EBITDA in 2016.

As we move to 2017, as we put in the slide, we expect the post-tax cash call there for the residual of that liability that I talked about to be somewhere between $350 million and $450 million. And again that's going to be on a base of EBITDA from 2016 of $2 billion plus to one that's growing double-digits in the 2017. So again, very manageable cash call in the back drop of very robust underlying cash flow generation.

Liav Abraham - *Citigroup - Analyst*

Great that's very helpful, thank you.

Operator

Our next question comes from the line of Gregg Gilbert with Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thank you. Couple of quick ones.

First, can you quantify Par sales in the fourth quarter? Secondly, can you quantify the generic charges in the fourth quarter? And lastly, Suky, can you help us understand whether the 9% to 11% tax rate is sustainable longer term?

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure. I think the answer to the first question is very simple. It was $359 million of sales of Par in the fourth quarter. And then, Suky, do you want to?

Suky Upadhyay - *Endo International PLC - CFO*

Yes. The one thing I'd say is that $359 million was a little better than our expectation, primarily driven by the injectables business. We're also seeing good solid performance in the base business as Paul talked about a little bit earlier. That should carryover into 2016, as well. I will also say as we move forward into 2016, Paul was looking at this portfolio as one portfolio. So we will not break out Par versus legacy Qualitest sales. We treat this as one business and that's how we'll report on it.

The change in the fourth quarter were about $30 million that we consider to be one-time and non-recurring. It's really three factors that make this up. Well there's a number of factors, three of which are examples are around trade disputes in the fourth quarter. We have some changes and estimates around gross to nets.

And third, we had some charges higher than expected around the harmonization of our methodologies around gross to nets as we integrated Par and Qualitest. Again, we do not expect those to re-occur on a quarterly basis going forward.

Your last question, Gregg around the tax rate, again very pleased with where the tax rate is migrating. We expect our effective P&L tax rate in 2017 and beyond to be in the low double-digits to low teens, but there is, again, continued opportunity to improve that over time.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks.

Operator

Our next question comes from Annabel Samimy with Stifel Nicolaus.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Hi. Thanks for taking my question. Just wanted to understand a little bit the underlying growth in generics? I missed the first part of your call. Obviously, we see there was a hit from the commoditized business. What component of the Par business is commoditized, and what is the underlying growth of Par right now and how can we think about that going forward?

Rajiv De Silva - *Endo International PLC - President & CEO*

Annabel, this is Rajiv. Let me start and Paul will add.

I think I don't know if you were -- you said you were a little late for the call, you may not have heard us talking about the growth drivers for 2016. So there are two primary drivers for 2016, and frankly these will be the drivers going forward, as well. One are new launches, so obviously in 2016 you have the impact of Zetia and Seroquel, but just beyond that there are 100s of possible potential launches Par has in a time period of 2016 through 2019. So that is firstly the biggest driver of growth. It's all about volume and launch of those products.

And the second area of growth is the injectables, the sterile injectables portfolio, which will be a robust contributor to 2016, as well as beyond. Now outside of that, we have in the combined business, say, plus or minus a thousand SKUs. Now part of that [Paul] will continue to optimize, but among the remainder there will be certain molecules that do well for us and certain ones that won't.

So that's a benefit of having a diversified portfolio. But net-net, when you put all these three factors together on the back of those launch products and the sterile injectables business, we feel very good about the projectory in 2016, as well as beyond that.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Is there some underlying growth that we can assume for the Generics business at this point?

Rajiv De Silva - *Endo International PLC - President & CEO*

So yes, we've talked about mid to high teens for the Generics business for 2016.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay, great. Thank you.

Operator

Our next question comes from the line of Shibani Malhotra with Nomura Securities.

Austin Nelson - *Nomura Securities - Analyst*

Hi this is Austin Nelson on for Shibani. The first question, and I have a couple, was in one of the slides there was a point the Opana ER abuse deterrent label settlement has been resubmitted to the FDA. Wonder if you can give any color around your expectations on when we could hear from the FDA?

And then if Endo does receive the abuse deterrent labeling, would you expect the old formulation of generics would be removed from the market for safety? And then the other question was on the expectation for net debt to EBITDA guidance, you get back down into the mid three to four

times range. Does that include only restricted cash, or does that include cash that will be accrued -- for the accrual but not actually paid out in the year?

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure, on the -- let me grab the Opana question and Suky can talk about the debt question. So the Opana ER submission has gone in. It was a monumental effort because not only of the inclusion of data from our insufflation study but also a lot of epi-data. The FDA set an action date of July 29 of 2016, for the file, so there is the time frame in which we expect to hear back from them.

And now even if we are successful in getting the re-labeling, it will certainly serve to help remove all the generics from the market with the exception of impacts that are seen, per the license to the product. And therefore, to do so would require a longer path, including a Citizen's Petition, which we certainly would undertake but it would not be immediate. Suky?

Suky Upadhyay - *Endo International PLC - CFO*

Austin, relative to your question on EBITDA -- sorry, on our net debt leverage calculation, the way we think about that is the only cash we put in there is unrestricted cash. So restricted cash that is meant for the mesh liability is excluded from that calculation.

Austin Nelson - *Nomura Securities - Analyst*

Okay. Thank you very much.

Suky Upadhyay - *Endo International PLC - CFO*

You're welcome.

Operator

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

David Amsellam - *Piper Jaffray - Analyst*

Thanks, so a couple questions on Generics. So you'd mentioned Vasostrict earlier in the call. Can you talk about how much of the Par sales mix consisted of Vasostrict in fourth quarter, and what your thoughts are on the potential for that competition -- for that product to have competition down the road? So number one.

And then on the Seroquel and Zetia generics, given these are partnered, can you help give us a sense of how the margins on these will look like during exclusivity period compared to gross margins for the overall generics business, given that you've got shared economics there? Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Thanks, David.

So on the Vasostrict question, so we are not going to break out our guidance at a product line level and all the product revenues for the fourth quarter but certainly, suffice it to say that Vasostrict is a very important driver for us in 2016.

But maybe, Paul, you can comment a bit on your views on possible future competition for Vasostrict.

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

Yes, sure. Thanks.

So Vasostrict, remember is an NDA, right? So that was filed as a 505(b)(2), so it's not a generic product. Our goal will be to have proper and appropriate protection on a go-forward basis. That's something that we're working very, very hard and close with the patent trade office. Again but, at this point there's certain things that are unknown. But again, we are looking to protect that product as you would expect from an NDA standpoint.

David Amsellam - *Piper Jaffray - Analyst*

And Zetia and Seroquel?

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

So on Zetia and Seroquel question, we have two partners, but during the exclusivity period, there are certain mechanics that are contractual obligations. I would say that it behaves more like a balanced partnership for the exclusivity period. So I would just say it's more a 50/50-like relationship. Post day 181, I would say it behaves more like a standard three player partnership.

Suky Upadhyay - *Endo International PLC - CFO*

Yes, David, just to put a little bit more on what Paul just gave there, so Seroquel, we would expect to be slightly above the overall Company average during the exclusivity period. And Zetia we would expect to be in line with the overall Generics average during the exclusivity period.

David Amsellam - *Piper Jaffray - Analyst*

That's helpful, thank you.

Operator

Our next question comes from the line of Chris Schott with J.P. Morgan.

Chris Schott - *J.P. Morgan - Analyst*

Great. Thanks.

Just two questions here. First on BELBUCA, can you just talk about the launch expectations? I know you've talked about 2019, but just as we think about 2016, what type of ramp should we think about here as we're thinking about the initial modeling? And the second question is just a bigger picture one.

Over the last 18 months the Company has done two large acquisitions with Auxilium and Par. You've pursued publicly a third one, the Salix. As I think about the next 12 months and the evolution of the Company, is this just a fundamentally different environment from an M&A perspective, where we're not going to see these big deals or they are much less likely? Or do you see what's happening in the market now, just a temporary pause or slowdown and that eventually we're going to see the high level of consolidation that had been playing up the last few years returning to the sector? Thanks very much.

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure. Thanks, Chris.

So on BELBUCA, we're very pleased that we're able to launch the product as we had predicted in the month of February. I was personally at a national sales meeting. We are very excited and expanded pain pills growth. Also all the feedback on the product has been very good and all of our Managed Care conversations are going well.

That being said it's early days from a Managed Care contracting standpoint and it's also early days in terms of the actual launch of the product. And as we had indicated before, while we have every confidence in this product, which is why we put out an aspirational number for 2019 of $250 million, we do expect the ramp to be somewhat gradual in the first 12 months and that is reflecting unknowns, right? So this is a different format, a buccal patch, which while there are many advantages, patients and physicians need to get used to it.

For those patients on other LAOs that are being transitioned to BELBUCA, there needs to be down titration and up titration, so these things will take time for physicians to get used to. And also, as you well know, from a market access standpoint, while commercial covered lives you can contract early in the launch, when it comes to Medicare Part D coverage, which is roughly about a third of the coverage in this market, that usually waits for a full cycle, right? So we certainly would look to finish 2017 to have much more substantial ramp than in 2016, but all the early signs are well within our expectations of what we expected to see for the product.

On your question on M&A, let me answer it from an Endo perspective and then see if you have any further need for clarification on it. For us, as you pointed out, 2015 was a very, very transformational year in terms of transactions, right? So we in particular, we concluded Auxilium, the Par transaction, at a smaller level the Aspen transaction in South Africa, which essentially gave us new platforms and a sense of critical mass particularly in our generics business. And in many ways we accomplished what we set out to accomplish, which is to get a set of assets, which even if you do no further M&A, gives us a path to double-digit growth.

And then you couple that with the market environment where the debt markets are weak as are the equity markets. But for us, leaving the market conditions aside, 2016 really is about execution, which is why we talked so much about BELBUCA, about XIAFLEX, the Par integration. Those are the things that are going to make us successful. So from that perspective M&A is not a key priority for us in 2016.

I have said in the past, I certainly we will continue to monitor opportunities. But realistically I think the types of opportunities that make sense for us in 2016 will be the small in-licensing or product acquisition here or there either for our branded business or international. But we are talking, really small call on our cash for doing those types of things if the opportunity come across them.

And in terms of larger transactions, it is not our anticipation to do -- to look for large acquisitions in 2016. I have, however, said that if there are eight days or larger merger which could be value creating that is done on the basis of relative value of two companies and those are the types of things we certainly will evaluate if they come our way. But certainly, it is not high on our list of priorities in terms of acquisitions as we look out over 2016.

Now back to your question about the nature of what's going on in the industry, I would say certainly the debt markets and equity markets have led to somewhat of a pause. But overall if you look over the last 20, 30 years this is still a highly fragmented industry. There are lots of -- its been a deal-rich industry for long periods of time. Obviously those deals are cyclical and my suspicion is that deals will continue to be an important part of this industry as you look forward. But 2016 is certainly likely to see a pause, at least from our perspective.

Chris Schott - *J.P. Morgan - Analyst*

Thanks very much.

Operator

Our next question comes from the line of Marc Goodman with UBS.

Marc Goodman - *UBS - Analyst*

Yes, morning. A few things. First, there were a couple of products, LIDODERM and VOLTAREN Gel, that seem to do much better than we would have expected. Can you just talk about if there was any inventory build there or what was going on? Second of all, you've talked about 2017 implying a $7 number which, now with VOLTAREN Gel back, seems a little low, especially given the way you're talking about tax rate now relative to before. I'd think that, that number of $7 is too low and needs to be brought up. So maybe you can talk about that a little.

And then third, I'm just trying to understand on the Generics business, the pricing that you're talking about, there's one aspect of it which is the commodity pricing, but then there's the other aspect, which is the pain products, which have been really important for you. The question is, we've heard from other companies in this space and they were complaining about new players coming back last year and they were complaining about pricing in that market and they were having some troubles there, and yet Endo was not complaining at all at that time and now there seems to be a delayed impact. So I'm trying to understand why is that?

Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Let's see if we can hit your questions in order.

With respect to V Gel it was a very good year last year. We had, I think, double-digit prescription volume growth and that was the driver of V Gel for the year. And the LIDODERM, I think we have been successful in holding some of our contracts through 2015, probably even better than we had expected on the branded Lido.

But as we enter into 2016, we do expect to see some drop off of those contracts and that will be seen when you see our 2016 results, but is already effected into our guidance. 2017, we aren't going to comment on 2017. Clearly, we made that comment against the back drop of the Par transaction.

First of all, I'm delighted to say what we committed to the outside world when we did the Par transaction, which was an accretion number for 2016, that is going out in our guidance, as well as the implied multiple that we put out there for the Par transaction, which was 10 to 11 times post-synergy EBITDA multiple that is also following through in the 2016 numbers.

Now as you said there are lots of other puts and takes in our business, certainly V Gel is one. We are very excited about the extension of the agreement. There's always the possibility and potential with generic on V Gel, which we also had to keep in mind. Which is somewhat offset in our new agreement by the fact we have the right to authorize generic, and a lot of 2017 will also depends on how well we're doing on BELBUCA and XIAFLEX. So we are very optimistic as we look at the 2016 and beyond time horizon for Endo. That being said, we aren't going to provide any specific further guidance on 2017.

On the generics question, I'll start and I'll bounce it to Paul. I think, what I would say is, if you separate the commodity -- the traditional commodity products from the pain products, and as you pointed out pain has been a traditional area of strength to us, we've often taken the approach of focusing on value versus pure volume on the pain business, right?

So although we've taken some substantial volume declines in our pain portfolio, they are somewhat anticipated based on the price increases we took and the approach we've taken. So net-net from a value standpoint, we are actually pleased with how the pain portfolio has performed. But is there pricing pressure in pain, as well as the commodity portfolio? The answer is, yes, because there are smaller players who tend to be aggressive even in the pain arena now, most of them have been in the past.

I don't know, Paul if you have any comments?

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

Yes, I think that's right.

At the end of the day you have product and you also have timing issues with the consortiums and our contracts with certain trade partners and I think that was part of what we've also saw. Again seeing the full impact of Red Oak really kicking in, in Q2 so you've got a timing issue that we were focused on. So to your point, to Rajiv's point, clearly, yes, there are more competitors in the narcotics space and we're seeing that. But we had our select wins across-the-board. So, to Rajiv's point, select wins yet we may have sacrificed certain pricing -- sorry, certain volume shortfalls. But ultimately I think the timing of the consortium was probably the main issue that we saw in 2015.

Operator

Our next question comes from the line of Jason Gerberry with Leerink Partners.

Jason Gerberry - *Leerink Partners - Analyst*

Hi, good morning and thanks for taking my questions. Just on first on XIAFLEX, a little stronger than we were forecasting into the quarter.

Was there any stocking, or is it the seasonal nature of the product, where it's a little bit stronger in Q4, coupled with heightened demand? And secondly, as we think about the consumer initiatives to drive awareness of the product in 2016 on the SG&A side, when can you expect to start to see that translate on the increased volume side? Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure. Jason, so we ended XIAFLEX in terms of inventories roughly where you would expect. This is not a product that has a lot of stock in the channel. (Technical difficulty) we expect to see it.

Now that being said, we had indicated in the third quarter that we were a little bit lower than that, so that was probably a little bit of stocking impact going into the fourth quarter. But nothing out of the ordinary, as you pointed out, especially the back end of the fourth quarter tends to be a heavy period because there are many patients who like to schedule their surgeries during that holiday period, so that is also a contributor.

I think as we enter 2016, we are excited about everything, all the changes we put in place, both internal as well as some of the new programs that we have put in place, like the disease awareness program that I referred to on Peyronie's disease. So many of those are just now kicking off. So realistically, for them to have a real impact, I think you're looking at probably the third quarter before we can really report back on successes of these programs, but early indicators of all of them have been very positive.

Jason Gerberry - *Leerink Partners - Analyst*

Great, thank you.

Operator

Our next question comes from the line of Rohit Vanjani with Oppenheimer.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Good morning. Thanks for taking the questions. I just had a couple. So I think on the last earnings call, you said that you expect five to seven new generic product launches in Q4. I was wondering if you got those product launches and maybe what were some of the biggest ones?

Secondly on XIAFLEX, can you outline the number of shipped vials in each indication, Peyronie's and Dupuytren's? And then going back to the mesh claims, I think you said there were 8,000 mesh claims that hadn't been accrued for. What is the potential value of those 8,000 claims?

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure. So let me start on the mesh while we get some of the data for your first question. So on mesh, while we identified this possible portfolio of 8,000 cases, the reason that we are not moving forward with any settlements for that portfolio is, A, the facts are very unclear across this portfolio.

Most of these cases, we don't even have medical records. As I pointed out, there is evidence of fraud, at least in some subset, that we are investigating vigorously. So as a result, we are not in a position to assign a value to it other than to say that we do expect, at this point in time based on the advice that we are receiving from outside counsel, the value of these cases are lower than the ones that we have just settled now. And Q4 launches, Paul do you have any of the data on that?

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

So Q4, the products that we were probably most proud of coming out of Q4 was again the dutasteride/tamsulosin product. That's a from Jalyn from GSK. Also, a product called pramipexole is another product we executed on for fourth quarter. We did indicate that we do have some delays on the Rivastigmine Patch that was a product we were hoping to get out in Q4, so that product will be delayed into 2016.

Rajiv De Silva - *Endo International PLC - President & CEO*

And then on your question on the shipped vials in the fourth quarter, so in Peyronie's we had just a tad under 8,000 and in DC we had about 8,400 shipped vials.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Great. Thanks for taking the question.

Operator

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

Elliot Wilbur - *Raymond James - Analyst*

Thanks, good morning.

First question, for Rajiv, with the launch of BELBUCA and the doubling of the pain sales force, and also the re-optimization around product promotion last quarter, could you maybe just provide us with an update on current sales force size, configuration, and whose doing what in terms of detail allocation, just relatively? And then the follow-up to that, with some of these efforts now you have a collection of small niche-branded assets that you really aren't receiving any direct promotional attention, including a couple of products picked up from Par.

Just wondering what your thinking is around this portfolio of products? STENDRA, TESTIM, FORTESTA, NATESTO and what not. Whether or not these would in fact be candidates for divestiture? And then just a follow-up for Suky, it doesn't really sound like there's been any change to your long term tax rate expectations. Maybe you could walk us through a couple things that are impacting 2016 approval rate versus the expected long-term tax accrual rate?

Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Let me get to your first question and then Suky can talk about tax.

So in terms of field force size, we are not disclosing the size of our field force for competitive reasons, but what I would say is that, so we have essentially three field forces of varying sizes, actually four of varying sizes, in our branded business. The largest of which is our pain field force, which is sized to be competitive with other pain players. And in that field force, we detail BELBUCA, Opana ER and VOLTAREN Gel. So those are the three products that are detailed, and then on occasion, we do some reminder calls on SUMAVEL.

In our specialty business, there are two field forces. One is focused on urology and that field force carries in the first position XIAFLEX for Peyronie's disease and also carries our long-acting testosterone replacement therapies which are AVEED and TESTOPEL. We have a second specialty field force which is a smaller one that is focused on XIAFLEX for Dupuytren's contracture and SUPPRELIN LA, which is our product for central precocious puberty. We also have a smaller field force which we inherited from Par, which I'm going to say we're all very impressed with their early performance.

They are focused on selling NASCOBAL which is a product that came over from the Par transaction. But we are also using that field force as a mechanism to provide some initial launch support, additional launch support of BELBUCA, and over time we'll take on the promotion of some of these smaller brands. So net-net, at this point we're very pleased with the promotional mix we have in our field force. Even our older and more established products are continuing to be important to us, so we are not looking to sell or divest any of them. Tax?

Suky Upadhyay - *Endo International PLC - CFO*

Good morning, Elliot.

So around the tax rate, in 2016, the movement from 2015 is primarily driven by the addition of the Par income, which is all US revenue sourced, so that's why you see a step up from between 2015 and 2016. Having said that, the low double-digit, high single-digit estimate that we have for 2016 is well below our initial expectations that we set for 2016 when we closed Par, where we said that we thought that the tax rate might be closer to the mid-teens. So we actually are seeing some progress versus our original expectations.

As you think about 2017 moving on, we characterize that as low-teens type of tax rate, and the reason why that migrates up a little bit is, you continue to drip off deal attributes that were created over the last couple of years. But otherwise, the underlying fundamentals of the tax rate are still very attractive. And as I said for 2017 and beyond, there's still a number of opportunities and strategies that we can deploy to bring that down over time.

Operator

Our next question comes from the line of David Risinger with Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. So I have two questions.

First, with respect to the Qualitest outlook, just so that we understand how to model it, should we be thinking about a 20% decline in 2016 similar to, or in the ballpark of, what was of what the number was in the fourth quarter of 2015?

And then turning to Slide 13 in the deck, Suky, I was hoping that you could just take us through the walk through from the $1.5 billion in the pretax cash call and then the $575 million in the post-tax cash call. I know that you mentioned a $700 million tax refund, but obviously there's another number in there to bring that figure down to $575 million. Thank you.

Suky Upadhyay - *Endo International PLC - CFO*

Yes.

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure, David, let me address your first question, which is, first of all, keep in mind that as Suky pointed out, there was some non-recurring impacts in the fourth quarter that impacted Qualitest, which should not see any roll forward impact. And secondly, I think back to the comment that Suky made, we are not providing guidance for Qualitest distinct from Par, simply because at this point Paul has a combined portfolio, he is negotiating customer contracts across a combined portfolio.

He will make some portfolio optimization decision as he goes into the year in terms of what products he prioritizes with customers, and that means that Par products, it means [Qualitest] products. So as a result we don't expect to provide any guidance for the legacy Qualitest portfolio going forward, other than what we already commented on, which is that for the combined business we expect to see mid to high teens underlying growth for 2016.

Suky Upadhyay - *Endo International PLC - CFO*

And good morning, David, relative to your question on the mesh post-tax liability, for 2013, how do we get from $1.5 billion down to $575 million. The first thing I would do is break it down into what the pretax cash calls are in 2016 and 2017. In 2016, we expect that to be somewhere around $850 million to $900 million and then you back out the tax refund of approximately $700 million from that.

That's one component. And then in 2017, we expect the pretax cash call to be somewhere between $600 million to $650 million. If you apply a US tax shield against that of approximately 35%, you get down to your post tax cash call of somewhere around $400 million. When you put those two pieces together that should get you into the $575 million range.

David Risinger - *Morgan Stanley - Analyst*

Thank you.

Suky Upadhyay - *Endo International PLC - CFO*

You're welcome.

Operator

And our next question comes from the line of David Buck with Northland Capital Markets.

David Buck - *Northland Capital Markets - Analyst*

Yes, thanks.

For Rajiv, can you talk a little bit about the branded pricing experience that you had in the fourth-quarter and for full-year 2015? What was the realized branded pricing and what's the expectation embedded in the guidance for pricing for brands in 2016?

And then for Suky, a just quick one. Can you talk a little bit about the gap between EBITDA of about $2 billion plus for this year and what we should be thinking about for GAAP cash flow from operations, including the mesh liability [bins]. Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Thanks, David. So on the branded pricing, our experience in 2015 and 2016 actually are not dramatically different. It is well within what we -- how we always characterize our branded pricing strategy, which is that we take appropriate prices, price increases, they typically range from the low single-digit -- actually zero in certain cases to potentially after 20%, 25%. The high end of that range is typically for our mature products that already have multiple generics on the market.

Our portfolio is generally contracted, which means that our price increases are capped so even if we are taking price increases are higher than that mid single-digits the realized price increases for us in our branded business is somewhere in the lower to mid single-digits, so that was our experience in 2015.

Our price increases that we took on our Branded portfolio are already public for 2016, and they're in the same range that I just described. And we would expect a similar type of lower to mid single-digit impact on our Branded business this year, as well. That's all incorporated into our guidance.

Suky Upadhyay - *Endo International PLC - CFO*

And regarding, David, good morning your question around cash flow for next year. The way to think about it is, first of all, we would expect underlying cash flow from operations as we depicted for 2015 to have a very high correlation to adjusted net income. But to give you some of the moving parts for next year to help model, if you started with the mid point of our revenue range and assumed mid 40%s EBITDA margin, you get roughly into the $2 billion plus EBITDA range.

From there your movements on cash, you've got interest expense, which we talked about, you've got cash taxes in the mid single-digits on the underlying business, you've got a mesh post-tax cash call of about $150 million to $250 million as we've talked about. Working capital on a day sales basis is relatively steady throughout the year, however because of the fourth-quarter launches of Seroquel and Zetia, we do expect there to be a call on cash in the fourth quarter of somewhere between $200 million to $300 million that will normalize in the first quarter of 2017 as that launch pulls through. We have CapEx of ability $150 million and contingent consideration of about $150 million. So if you put all those pieces together that should get you close to where we see cash flow for the year.

Operator

Our next question comes from the line of Andrew Finkelstein with Susquehanna Financial Group.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Good morning. Thanks for taking the question. If we could go back, you mentioned that the Par contribution was $359 million.

Can you clarify whether that was the contribution of Par to the Generics segment, or whether that included the brand contribution as well? And in particular, if I look at the Brand sales of $379 million for the quarter, are there any moving parts there to consider? Is STENDRA still in there or is

that in discontinued operations? I see quarter-on-quarter, Q3 to Q4 from the products you give us, that explains about half of the quarter-to-quarter increase. So what other contributors were there on the Branded side? Thanks very much.

Rajiv De Silva - *Endo International PLC - President & CEO*

So on the Par number, which is very finely set, but I believe that number is a Generics only number and excludes the Brands. And then your second question, Andrew with respect to--

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Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

With respect to the brand segment overall, $379 million for the quarter, about $305 million in Q3, so up about $75 million. The products you'd break out, if I did my math, explain about $38 million of the increase. So some of the smaller products seem to have stepped up Q3 to Q4 and some of that is a full quarter of the Par brands. But were there any other factors, you know, products that were -- had a bounce in Q4 in brands?

Thanks.

Rajiv De Silva - *Endo International PLC - President & CEO*

Sure.

So as you say, Andrew, some of the smaller brands. So we had success for example, with AVEED in the fourth quarter was a contributor; STENDRA, although we announced that decision on it in the third quarter, actually had a decent fourth quarter. SUMAVEL was a contributor. So it's a series of the smaller brands, and again it goes to show the value of our more diversified, established and other products part of our Branded business. And many of them do contribute and when you add them altogether it is a material contribution.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

STENDRA was out for 2016?

Rajiv De Silva - *Endo International PLC - President & CEO*

Yes. STENDRA is out for 2016.

Suky Upadhyay - *Endo International PLC - CFO*

One thing, Andrew, I would add for 2015 fourth quarter in LIDODERM we do see a benefit, one-time benefit of some returns reserves adjustments that won't repeat in first quarter of 2016.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much.

Keri Mattox - *Endo International PLC - SVP of IR & Corporate Affairs*

Operator, I think we have time for one more question.

Operator

Douglas Tsao with Barclays.

Douglas Tsao - *Barclays - Analyst*

Hi, good morning. Thanks for taking the questions. Just a couple.

Paul, maybe on the delay for eXcelon, what's your visibility in terms of the timing of the launch there? And then just for Rajiv and Suky, in terms of the visibility on the mesh liability you sort of cited the lower quality of some of the outstanding cases. Just curious in terms of the historical precedent in terms of some of those perhaps moving up into a higher quality claim as things like medical records perhaps become available to you? Thank you very much.

Paul Campanelli - *Endo International PLC - President, Par Pharmaceutical*

I would say on the eXcelon patch, Doug, we're probably looking at late to second half of 2016.

Rajiv De Silva - *Endo International PLC - President & CEO*

With respect to mesh, Doug, I think consistent with the answer I gave to a previous version of this question, we are taking a different approach to what remains here. So we've taken, based on the advice of outside advisors, as well as looking through the portfolio of plaintiffs' attorneys, in terms of those who are more likely to have credible claims and effectively focus on the high value.

As we said, as we look out over the remainder, while there is less information there is also other pieces of information we have, such as the potential fraudulent claims that leads us to believe that it is of lower value. And this is consistent with the advice we've gotten from our outside advisors, as well. And we also believe that it is to our benefit and to our advantage to be more aggressive with this remaining portfolio and clearing, potentially taking some to trial if we need to.

So our current belief, based on the factors we have, we do believe they are lower value cases. We will deal with them over time and there is no anticipation of any other settlements in the near term.

Douglas Tsao - *Barclays - Analyst*

Okay, great. Thank you.

Operator

I'm showing no further questions at this time. I would now like to turn the call back over to Mr. Rajiv De Silva.

Rajiv De Silva - *Endo International PLC - President & CEO*

Well, thank you very much, everyone, for joining us for today's call. Just to summarize where we are with respect to 2015 earnings as well as the outlook for 2016, we are very pleased with the solid performance that we had in 2015. We believe it's the fundamentals of the business are very strong; strong underlying growth that will sustain us through 2016 into the medium-term that we've talked about in the past.

We are positioned for growth in 2016. We have some strong growth drivers like XIAFLEX, BELBUCA and a generics portfolio that we continue to -- a laser-like focus on. We are progressing the XIAFLEX pipeline, creating some real momentum around new indications, potential new indications like cellulite.

Clearly, our focus this year is on execution, and on generating strong underlying free cash flow, which will allow us to continue to de-lever despite the incremental accrual that we talked about with respect to the mesh liability. With that I thank you for your time and look forward to joining all of you on our next quarterly call. Thank you.

Operator

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