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ENDP - Q3 2015 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 3Q15 revenue of $746m and adjusted diluted EPS from continuing operations of $1.02. Expects 2015 revenue from continuing operations to be $3.22-3.27b and reported or GAAP diluted EPS from continuing operations to be minus $3.70 to minus $3.60.

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PRESENTATION

Operator

Good day ladies and gentlemen, and welcome to today's Endo International third-quarter earnings conference call.

(Operator instructions)

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

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

Good morning and thank you for joining us to discuss our third-quarter 2015 financial results. With me on today's call are Rajiv De Silva, President and CEO of Endo; Suky Upadhyay, Chief Financial Officer; Paul Campanelli, President of Par Pharmaceuticals; and Brian Lortie, President of US

Branded Pharmaceuticals. We have prepared a slide presentation to accompany today's webcast, and that presentation is posted online in the investor section at www.Endo.com.

I would like to remind you that 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 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 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 would now like to turn the call over to Rajiv.

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

Thank you Keri, and good morning everyone, and thank you for joining us on 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 third-quarter earnings presentation.

On slide 2, you will see our agenda for today's call. We will start with an overview of Endo's transformation since the beginning of 2013, and how we believe we have differentiated ourselves within the specialty pharmaceutical landscape. We will then review some of our recent accomplishments, and I will follow that with the highlights of our third-quarter 2015 financial results, walking through our US branded, US generics and international businesses.

We will then turn to our full-year 2015 outlook and financial guidance, as well as our projected 2016 financial profile. After our prepared remarks, we look forward to taking your questions.

Moving on to slide 4, shortly after I joined the Company in early 2013, we mapped out a strategic direction that we felt best positioned Endo for transformative growth, and to achieve our goal of improving lives while creating value. We aspired to become a leading global specialty pharmaceutical company, and are focused on areas where we believe we can create value. Our core businesses are US branded pharmaceuticals, US generics, and international pharmaceuticals.

At Endo, we aim to create value through our differentiated operating model, with our nimble decentralized structure and a rational allocation of capital, we believe we are better owners of assets. Ultimately this model is enabling us to achieve sustainable growth through organic expansion, strategic M&A, and a derisked R&D pipeline.

On slide 5, you will see the core tenets of the Endo operating model, and what we believe differentiates us from other companies in our industry. Is important to note that while we continue to see M&A as an important component of building and growing our business is in the future, we have already diversified and expanded our product portfolio and R&D pipeline to support double-digit organic growth. Finally, we are a streamlined, diversified and compliant organization that operates within the rigorous controls of our industry.

Moving to slide 6, you will see the key components of Endo's strategic transformation. First, we have optimized and refocused the Endo business for sustainable growth. Our efforts have enabled us to successfully right size our cost base and upgrade our management talent. We have divested the non-core assets of Healthtronics and AMS men's health to sharpen the strategic focus on pharmaceuticals in our base business.

We completed bolt-on acquisitions like Boca, Dava, and Sumavel DosePro, that added near-term critical mass at key points in our corporate evolution. Finally, we expanded the R&D pipeline with the addition of AVEED, creating a new branded growth opportunity.

Now living beyond our base business, we have created new long-term growth platforms for Endo. The Auxilium transaction which closed earlier this year was an important step in rebuilding our US branded business, and brought XIAFLEX, TESTOPEL and other innovative products into our portfolio. That transaction also helped revitalize our R&D pipeline with additional multiple XIAFLEX programs across a range of potential therapeutic and aesthetic indications.

We established our international platform to further diversify our revenue base. The acquisitions of Somar in Mexico, Litha in South Africa, and a portfolio of products from Aspen strategically augment that Litha business, establish emerging market beachheads for us. These international businesses also facilitate further international expansion in these regions.

Finally, BELBUCA, which was just approved by the FDA formally positions Endo for growth again in the pain market. We are tapping the full breadth and depth of Endo's expertise in this area, as we prepare for commercial launch early next year. In short, we are positioned for successful execution of this opportunity.

We have also taken transformational steps towards leadership in the global specialty pharmaceutical arena. The transformational acquisitions we have successfully pursued, namely Paladin and more recently Par, have enabled us to improve our corporate structure and firmly position the Company for long-term organic growth.

Additionally, we have transformed our pipeline. As I mentioned a few moments ago, XIAFLEX brings a range of new programs to our R&D efforts, from indications with serially underserved patient populations and few treatment options to broader aesthetic indications with significant market potential.

Further, the addition of Par brings an industry-leading specialty pipeline of more than 200 projects to our US generics business. Approximately two-thirds of Par's R&D programs are in alternative dosages and approximately are Paragraph IV first-to-file or first-to-market opportunities. This pipeline has been consistently producing higher barrier to entry products with fewer competitors and higher gross margins, and we expect it to continue to do so, driving double-digit growth for Endo over the near and mid term.

Next, on slide 7 you will see how the Endo transformation has resulted in a strategic shift in our revenues in recent years. Through a mix of portfolio diversification, product lifecycle management, organic growth acceleration and accretive M&A, the Endo of 2015 is a vastly different Company than the Endo of 2012.

For example, in 2012, 72% of Endo's revenues were comprised of non-core businesses such as AMS and Healthtronics, and now legacy branded products like Lidoderm. In 2015, legacy branded products are projected to be only approximately 17% of our overall revenues, and Healthtronics and most of AMS have been divested. In fact today, no Endo product makes up more than 6% of overall revenues. We have truly diversified.

We are also building out portions of our business that we believe will create value well into the future. Our US branded portfolio has expanded. We have in enhanced our generics business and have added an international business.

Moving to slide 8, you will see how this diversification and Company growth has impacted our earnings per share, essentially turning the Company's EPS around from the impact of the decline of legacy products and non-core businesses.

Moving to slide 9 and heading into 2016, we believe our recent milestones make Endo fundamentally stronger than ever, for several reasons. We are positioned for growth, which means that we are projecting into a double-digit organic growth rate over our planning horizon and are increasing our operating margins. We are also progressing our tax strategy.

We have a powerful platform for future M&A. Thus far we have an enhanced corporate profile, scope, size, and manufacturing capabilities. Also, with robust underlying cash flow and adjusted EBITDA in 2016, we anticipate rapidly delevering back to a 3 to 4 times net debt to EBITDA ratio by mid-2016.

And, we have built an expanded diversified portfolio. As I mentioned just a few minutes ago, we have strategically grown our product portfolio and R&D pipeline across all three of our business segments.

So, moving to slide 11, we continue to make good progress in addressing the near-term strategic priorities that we believe will support our objective of becoming a leading global specialty pharmaceutical company. First, we are further enhancing our operational focus in order to help drive organic growth.

In our US branded business we've secured FDA approval for BELBUCA, continued to drive growth for XIAFLEX and supported OPANA ER, working to defend our IP estate and toward a potential label expansion. In US generics we closed acquisition of Par, achieving critical mass for this business. Within international, we closed the Aspen portfolio acquisition for Litha growth, which is now refocused on pharmaceuticals.

Second, we continue to sharpen our R&D focus on near-term opportunities. On the late-stage development front for XIAFLEX, we have made good progress on our additional studies for the treatment of cellulite and adhesive capsulitis. We expect to hold confirmatory meetings with the FDA by the end of this year, and will initiate these two studies shortly thereafter.

Also, I'm pleased to share an exciting update regarding the earlier-stage XIAFLEX pipeline. We have opted into two new potential indications recently, lateral hip fat and plantar fibromatosis. I will talk more of these in detail in a few minutes.

Third, we're focused on deploying capital to accretive value-creating opportunities such as Par and Aspen portfolio acquisitions that I have already mentioned.

Fourth, we remain focused on delivering strong and sustainable financial performance. We have a solid third quarter and are maintaining our guidance for full-year 2015 revenues and adjusted diluted earnings per share from continuing operations. We are also affirming our 2016 guidance for adjusted diluted earnings per share.

Moving on to slide 13, you will see that we are reporting $746 million in revenues for the third quarter, up 14% versus the prior year, and $1.02 in adjusted diluted earnings per share from continuing operations. Suky will provide more details about our third quarter results in just a few minutes.

Next, I would like to discuss the revitalization of our US branded pharmaceuticals business in more detail. On slide 15, you will see our total growth year to date is 25%, and that, while muted by third-quarter under performance versus expectations in some areas of the portfolio such as STENDRA, we continue to see underlying sales growth for the nine months ended September 30, 2015 compared to the same period in 2014. This underlying growth rate includes Auxilium results on a pro forma basis, and includes only same-store sales for other 2014 acquisitions.

For comparison purposes, we exclude the sales of Lidoderm and royalties received from Actavis for its generic lidocaine patch from this calculation. One of our expected key long-term growth drivers, XIAFLEX, continues to perform in line with our expectations. I will provide a more in-depth review of XIAFLEX shortly.

We continue our comprehensive efforts to perfect the OPANA ER franchise, including the promotion and development of the product, as well as the vigorous assertion of its intellectual property. The positive ruling in the Paragraph IV patent infringement trial held earlier this year in the Southern District of New York strengthens our IP portfolio, and should remove one of the generic competitors from the market. We also have ongoing litigation being initiated in late 2014 in the District of Delaware, with respect to newly-issued patents covering the products.

In parallel, and following our discussions with the FDA earlier this year, we expect to submit a supplement request for labeling that would potentially add abuse deterrent formulation claims. We expect to file that request in late 2015 or early 2016.

We believe our branded pricing strategies are rational and appropriate, and that volume continues to be the primary driver of our growth in our US branded business. While there is a range of [back] price increases across our portfolio annually, we estimate that our effective annual price increases are approximately 5% for this business after discounts and rebates.

Moving on, as you all know, there have been many questions about the industry's use of specialty pharmacies recently. Let me reiterate that we utilize specialty pharmacies for our complex specialty and physician-administered products, and that specialty pharmacies account for only approximately 3% of total Endo revenues. Additionally, and importantly, Endo does not have any ownership interest in consolidated financial results, or have any affiliations with any special departments.

The specialty pharmacies we utilize are independent, or are part of other independent companies. We recognize revenues when Endo ships to a specialty pharmacy and it takes title of the product, just as we would with any other distributor. With that, let's move on to talk about some of the development initiatives in US branded and the US branded segment that we feel position us strongly for future growth.

Moving to slide 16, we are extremely pleased about the recent FDA approval of BELBUCA, the first and only buprenorphine buccal patch for chronic pain. With more than 100 million adults in the US suffering from chronic pain and more than 130 million opiate prescriptions each year, this is a sizable $13 billion market. We believe that BELBUCA provides a new and differentiated schedule III product for these patients, one that combines proven efficacy and established safety profile of buprenorphine with a novel delivery system that adds convenience and flexibility.

With seven approved dosage strengths, BELBUCA gives physicians the ability to individualize titration and treatment. We are planning for an early 2016 launch of BELBUCA, and will expand our pain field force and infrastructure to support our commercial efforts. We are currently building our product inventory to support that commercial launch.

Moving to slide 17, during the recent approval of BELBUCA and our launch plans, we are undertaking a portfolio optimization across our branded business. Resources will be reallocated to support key growth drivers like XIAFLEX, BELBUCA and others highlighted here in the green box, and as a result, we expect to de-prioritize select products shown here in grey.

On slide 18, let me provide more detail. First, we will increase our support of our primary growth driver products. As I just mentioned, for BELBUCA, we will more than double the pain field force this year, in preparation for an early 2016 launch. For XIAFLEX, we are rolling out a patient engagement campaign to build awareness and we are continuing our efforts to increase our active injector base.

For TRT, we are focusing our efforts on our portfolio of differentiated long-lasting products, AVEED and TESTOPEL. We see these products as a growth opportunity within the TRT market, and for Endo. And we are also continuing our active support for other growth drivers such as SUPPRELIN LA and Voltaren Gel.

We do expect that other products in our portfolio will be deprioritized. First, STENDRA. While our relaunch has stabilized STENDRA in a crowded and noisy ED market, it has not yielded the inflection point, nor accelerated the growth that we were looking towards.

Second, the oral TRT market continues to decline at a rate of nearly 10% over the last 12 months, and topical gel products like Testim and Fortesta have gone generic and become commoditized. Early in its launch, even the novel delivery of NATESTO has yet to gain significant traction within the legacy gel space. The accounting impact of the under performance of these de-prioritized products and the strategic reprioritization is an impairment charge taken in Q3, and Suky will talk more about this in detail in a few minutes.

Moving to slide 19, let's talk about how one of our key growth drivers, XIAFLEX performed in the third quarter. While there was some seasonality in Q3, XIAFLEX performed in line with our internal expectations. Growth and demand drivers remain strong with approximately 13,900 vials of XIAFLEX shipped during the third quarter of 2015.

That is an increase of 21%, compared to the same period last year. Most of their growth is attributable to the launch in Peyronie's disease which accounted for approximately 7,500 demand vials, an increase of 33% over the third quarter of 2014.

We now have more than 2,300 physicians certified and 11,600 PD patients have been treated with XIAFLEX to date. A key metric that we believe illustrates the strong utilization trends of XIAFLEX, is average vials per patient, which is currently at about 4.5 vials.

Demand growth in Dupuytren's contracture was attractive during the quarter as well, and increased 14% over the third quarter of 2014 to approximately 6,400 demand vials in third-quarter 2015. This continued growth is especially encouraging, given that XIAFLEX for DC was launched five years ago.

We have also highlighted our average number of XIAFLEX vials for DC patients, which is currently at about 1.2 vials. The supports early indications of solid induction for MULTICORD use following that label expansion late last year. Finally, to support and grow XIAFLEX demand in Q4 and beyond, we are working to expand the current active injector base, and are launching a targeted DTC campaign aimed at building broader patient awareness of the disease and the available treatment options.

On slide 20, you can see the strong year to date growth in both Peyronie's disease and Dupuytren's contracture. We are pleased by XIAFLEX performance this year, and are encouraged as we move into the fourth quarter and beyond. Next, we remain committed to growing our US branded business organically, and expanding R&D pipeline is key to those efforts.

On slide 21, you will see a broad overview of our R&D projects including several new XIAFLEX programs in both disease or injury related conditions as well as aesthetic indications. We are advancing a Phase 2 program in Dupuytren's Nodules to potentially further expand our treatment capabilities in that indication, and along with our partner BioSpecifics, we are moving forward with several exciting additional early-stage opportunities. In fact, we have just formally opted into two new indications, lateral hip fat and plantar fibromatosis, which is a benign but painful nodule that grows in the bottom of the foot and can require surgery for removal.

Now, let's talk about the transformation of our generics business. Moving to slide 23, US generics continued to deliver impressive results in the third quarter, with sales of $368 million. That contributes to year-to-date total growth of 32% versus the prior year.

Our year-to-date 2015 results primarily benefited from organic growth, including new product launches and a number of value creating acquisitions. While growth from the strategic initiatives was attractive, more impressive is the robust 24% year to date underlying growth rate in our US generics business. Underlying growth, which excludes Par was driven by volume, and essentially now that we have closed acquisition of Par, we are confident that we can deliver double-digit revenue growth for this business for the full year.

Our view on the pricing environment within generics remains consistent. We believe that commodity products face pressure, while specialty products present some strategic pricing opportunities, depending on market conditions. Given the focus of our US generics business and our ongoing portfolio and pipeline optimization process, which will continue to prioritize differentiated products, we believe this business can continue to outperform the broader market.

Organic growth drivers are important for each of our businesses, and in generics, we expect to launch five to seven new generic products in Q4, and remain on track to file 25 ANDAs in 2015. Moving on to slide 24, it is important to note that our US generics business continues to be an extremely attractive and effective growth driver for Endo, with the acquisition of Par, completed in the third quarter. We believe that we have created significant value and have achieved critical mass in our US generics business unit.

Moving to slide 25, the addition of Par's generics pipeline to Endo provides compelling opportunities in both the near and long term. In 2016 and 2017, we expect approximately 50 total launches with $16 billion of current market value, according to IMS Sales Data. Of those launches, we expect 8 to be first to file opportunities, with $8 billion of branded market value.

In 2018 and 2019, we expect approximately 70 total launches with $13 billion of market value, of which we expect 12 to be first to file opportunities with $4 billion of branded market value. That represents a collective potential of approximately 120 launches, with more than $29 billion of current market value, and is an industry leading set of near-term growth drivers. And we have opportunities to increase the contributions on the pipeline, particularly in the 2018 and 2019 timeframe.

Par's total pipeline includes launches through 2019 as well as products currently assumed to launch after 2019. The pipeline includes 47 products that make could potentially be first to file or first to market, and represents a total opportunity of $42 billion in market value.

On slide 26, you will see the anticipated product launch information for 2015 to 2019 that we have previously shared with you. We believe this cascade of first to file and differentiated product launches support our growth projections moving forward. Next, let's talk briefly about building our international platform. Moving to slide 28, while 2015 remains a transition year, our international pharmaceutical business is performing well, and meeting our expectations.

The base Paladin business delivered a solid performance, supported by the recent launches of Iclusig and Monurol. Somar, our Mexican business, is delivering results in line with expectations, and we continue to sharpen our focus on core pharmaceuticals for the Litha group in South Africa. We have completed the acquisition of a diverse product portfolio from Aspen, and our previously announced divestiture of Litha's device, vaccine, and additional non-core product lines is expected to close by early 2016, subject to regulatory approvals.

Finally, our international strategic portfolio optimization continues. This process should help us complete the transition for these businesses and deliver the underlying double-digit organic growth that we aspire to in these attractive emerging markets.

So with that, let me turn the call over to Suky to provide some more details of our financial performance for the quarter. Suky?

Suky Upadhyay - *Endo International PLC - CFO*

Thanks, Rajiv, and good morning to those joining us for today's presentation. We are pleased with the solid performance that Endo delivered in the third quarter of 2015. Starting with slide 30, I will walk you through some of the financial details for the third quarter.

Revenues increased 14% versus the third quarter of 2014, and year-to-date revenues have increased 28%, versus the same period in 2014. For our US branded business, the acquisition of Auxilium was the primary growth -- driver of growth. Our US generics business continued to deliver strong base business growth.

For international, a stronger dollar was a key contributing factor to the year-over-year quarterly performance. On an underlying basis, organic year-to-date revenue growth was approximately 4%. For clarity, underlying growth for Endo includes Auxilium results on a pro forma basis, and only includes 2014 acquisitions on a same-store sales basis and we exclude all sales and royalties related to Lidoderm for comparison purposes.

For full-year 2015, we expect our underlying growth rate will approximate our longer-term aspirations for sustainable high single-digit to low double-digit organic growth. And the reason closing of Par accelerates our growth profile.

Moving to slide 31, we continue to expand our adjusted gross margin with 63.5% in the quarter, in line with our overall full-year guidance. And our adjusted operating expenses were approximately 21% of revenues, also in line with our expectations. We have been very efficient in capturing synergies from the Auxilium transaction, and are well positioned to captured synergies from the Par acquisition.

In addition to our positive operating performance, we have an improving adjusted effective tax rate. We posted a third-quarter 2015 adjusted effective tax rate of approximately 1%, and year-to-date that rate is approximately 8.5%. As expected and guided on our recent earnings call, the quarterly tax progression will be lumpy due to technical accounting rules, the acquisition of Par, and the continued implementation of actions to optimize our overall value chain.

The positive operating performance and adjusted tax rate led to third-quarter adjusted income growth at a rate that was significantly faster than our revenue growth. Third-quarter adjusted EPS from continuing operations of $1.02 was lower than our revenue growth rate. Remember that this was impacted by our adjusted diluted earnings share count of 211 million for the quarter, which reflects the additional shares issued as part of our Par financing and acquisition.

Moving to slide 32, I will not review the year-to-date slides in depth. We believe that they are strong results that reflect the value created by our long-term strategy. Before we talk about guidance for this year and full-year 2016, I do want to take a moment to discuss the impairment charges we took in the quarter.

As Rajiv mentioned earlier, we are accounting for pre-tax non-cash impairment charges of approximately $240 million related to intangible assets and approximately $680 million related to associated goodwill. These impairments represent 3% of Endo's total intangibles at the third quarter and approximately 9% of total goodwill prior to these respective charges.

The intangible-related charges are primarily driven by the recent under performance across STENDRA and certain TRT products, in tandem with the expectation of lower future cash flows as we realign our investment priorities toward higher-growth assets such as XIAFLEX and BELBUCA. In addition, our continued prioritization of higher-value products and development projects has led to the reduction of value, primarily across our legacy Qualitest business.

The intangible asset charges related to branded products has triggered to test goodwill across urology, endocrinology, and oncology reporting units within the US branded segment, ultimately leading to a provisional impairment of associated goodwill in the quarter. I should note that our normal testing cycle for goodwill generally occurs in the fourth quarter; however the charges related to STENDRA and TRT products compelled us to accelerate our evaluation of goodwill within certain parts of the US branded segment. So while we have taken a provisional charge in the third quarter, that charge may get adjusted up or down as we complete our enterprise goodwill testing in the fourth quarter of 2015.

The pre-tax non-cash intangible asset and goodwill accounting charges in the third quarter are partially offset by a related $80 million reduction in future contingent considerations. While we're disappointed with the performance of STENDRA and across certain parts of the TRT portfolio, we continue to be very excited about the long-term growth opportunities related to XIAFLEX and BELBUCA, as well as our highly diversified and specialized generics portfolio and international platforms. Most importantly, we continue to remain confident in our near-term guidance and our long-term aspirations.

So moving to slide 34, we are reaffirming our full-year 2015 financial guidance from continuing operations, which we updated around the close of the Par acquisition in September. We expect full-year 2015 revenues between $3.22 billion and $3.27 billion, an adjusted gross margin of approximately 64%, an effective tax rate of 9% to 10%, adjusted diluted earnings per share from continuing operations to be in the range of $4.50 to $4.60, and reported or GAAP diluted earnings per share from continuing operations for the year to be within a range of minus $3.70 to minus $3.60. Remember, we have affirmed this guidance and maintained the upper end of our previous EPS range, with six months of dilution from the Par pre-close financing activities, and only three months of Par revenue for the full-year 2015.

Overall, I am pleased with our year-to-date performance, which continues to be characterized by solid underlying revenue growth, margin expansion, and robust underlying cash flow generation. And I am excited about the opportunities that we have to continue with the transformation of Endo into a leading global specialty pharmaceutical company.

Now, let me turn it back over to Rajiv to close out. Rajiv?

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

Thank you, Suky. Moving to slide 35, as Suky said, we are strongly positioned for growth in 2016, and today, we reiterate the 2016 financial guidance of an estimated adjusted diluted earnings per share from continuing operations in the range of $5.85 to $6.15. We remain confident in our ability to deliver double-digit revenue growth, strong and rapid synergy capture, continued progression and execution of our tax strategy, and robust cash flows from rapid delevering then enables continued execution of our M&A strategy.

To summarize on slide 36, I want to reiterate that we feel fundamentally that Endo is more diversified and stronger financially and strategically than ever before. We are positioned for growth, we have created a powerful platform for future M&A, and we have built an expanded and diversified product portfolio and R&D pipeline. All of this it against the very compelling backdrop of double-digit organic growth projected over our planning horizon.

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

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

Thank you, Rajiv. We would like now 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

(Operator instructions)

Louise Chen, Guggenheim Securities.

Louise Chen - *Guggenheim Securities - Analyst*

Hi, thanks for taking my questions. The first question I had here is what is driving your effective increase in 2015 guidance post the close of the Par deal? And the second question here is your double-digit growth of mid-to long-term aspiration -- how much of that is from price versus volume? And then the last thing here is, how do you differentiate yourself from all of this noise in the healthcare industry on pricing, especially pharmacy -- what's the tagline here? Thanks.

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

Sure. Let me answer your question on the contribution of price and volume to our double-digit growth, and then some comments about what's going on in the industry, and then I will have Suky talk about our 2015 guidance that we reaffirmed today.

So what's key about our business is that our business is not dependent on price as a driver for long-term growth. Historically, if you look at our branded business, that's primarily being driven by volume, and as we look forward into our branded business, it is going to be driven predominantly by new product launches and growth of products like XIAFLEX; right? So I think it is fundamentally a volume growth story in our branded business and similarly for our generic business, while historically the Qualitest business did enjoy a certain amount of price in its growth, and Qualitest itself has grown in the mid teens organically in the last five years and two-thirds of that growth came from volume and mix.

Moving forward, we expect the contribution of price to be much more muted, because if you look at the Par acquisition, what Par brings to us, it's all about pipeline. And as we look into 2016, onward for our generics business, our growth is private dominantly going to be volume-based and the international markets price value is never level, so it's all volume. So if you step back from it, I think if you look at double-digit growth trajectory over the next few years, it is going to be predominantly about volume.

And in terms of your comments about what's going on in the industry around us, certainly, this has been a very choppy time for the specialty pharmaceuticals sector. But I would say, in terms of the specific issues that have been debated in the marketplace, for example the issue of pricing and the relative role pricing plays, I will explain to you why we really don't feel too worried about that, because we have not been dependent on pricing moving forward. We have commented previously and today about the role of intermediaries like specialty pharmacies and how we use them, where we believe we are very appropriate in our use of these intermediaries and they are really are no different than other distributors that we use. So as we step back from this, certainly our industry is going through a downturn, and this is not the first time this is happened to our industry.

But as an important thing for us, is that we have all the tools that we need to ride through this downturn. We just completed a transformational acquisition, we have a great pipeline of projects coming through in XIAFLEX, we just got BELBUCA approved. So for us this is really about operating

our business and executing. We have very attractive business going into 2016 and beyond, and my belief is that the fundamentals of our industry continue to be extremely strong, and eventually the market will come back and the companies that have underlying organic growth potential are the ones that are going to be successful, and we count ourselves among those companies.

So with that, Suky, you want to touch on the 2015 guidance?

Suky Upadhyay - *Endo International PLC - CFO*

Yes so Louise, to your question on what are the drivers on the top end of our guidance post closing of Par, and I would say it's really coming across all elements of our P&L, which for me represent a good quality approach to how we are achieving our guidance for this year. So first, from a revenue perspective, we have had headwinds on the legacy Endo business this year. If you think about foreign currency rates with the introduction of an additional generic Lidoderm entrant with fairly steep price increases, as well as the under performance of STENDRA, which we have been quite transparent about, the overall Endo legacy business continues to operate within the revenue range that we put out at the beginning of the year.

And then if you think about Par, since we signed the deal to where we are today, that asset is actually performing on the top line a little bit better than where we originally expected. So overall revenues are coming in, right in line with how we thought about them.

Then from a P&L perspective, the reason why we are able to offset a half-year of dilution from Par with only a quarter of the year of operating results from Par is really because gross margin is performing better than we expected. It's primarily driven by the generics business, but if you actually look at branded as well as the international segments, they are actually showing some modest improvement, year over year as well, on a year-to-date basis. Operating expenses are better than where we thought, and that's primarily driven by a faster uptake of the Auxilium synergies, and that's also in the backdrop of stepped up investment against STENDRA, and now stepped up investment against BELBUCA within 2015.

And last, we are very pleased with our overall tax rate. There's a number of drivers against that. One is obviously the Auxilium as well as the Par transaction, but our underlying fundamental planning strategies around supply chain are also yielding some very nice and better than expected benefits. So really, again, you are seeing that benefit across our entire P&L.

Louise Chen - *Guggenheim Securities - Analyst*

All right, thanks.

Operator

David Amsellem, Piper Jaffray.

David Amsellem - *Piper Jaffray - Analyst*

Just a few questions. I guess on the assets you wrote down, particularly the testosterone product, maybe give us your thinking on where you miscalculated, when you did the Auxilium transaction, and where you went wrong or what you thought you got wrong about those assets. That's number one. And then I guess the same question could be asked of STENDRA.

And then secondly, on BELBUCA, maybe this is early but if you can, talk about how we should think about price and what other comparators that we should look at there, that would be helpful. Thank you.

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

Sure. David, let me touch on the testosterone market and STENDRA and then I will have Brian talk about BELBUCA and how we see pricing there.

So on the testosterone products, in the Auxilium transaction, there were two assets that came to us in the testosterone space. One is TESTOPEL and the other is TESTIM. So more than this downdraft has been in TESTIM and I think there, really the difference between where we were when we signed the Auxilium transaction and today is that there is much more significant generic competition for TESTIM, and the market continues to decline at a double-digit growth rate, which has affected not only TESTIM but also FORTESTA as well as NATESTO.

So when we step back from this, one of the things that we take great pride in our business model is being rational actors. So we certainly believe in the transactions we do and the assets we support, but upon reflection, if there's anything that is not working as we think it will, we will divert resources and things that are more likely to create value, which is exactly what we're doing here. So the good news though, about the testosterone market for us, is that the two assets that we always thought were longer-term assets which were AVEED and TESTOPEL are collectively in the long acting segment, which for us is growing, and we expect it to keep growing, and that's where we expect to put our investment going forward.

The STENDRA story is very simple, right? We were very clear that we believe that based on what we found out after we closed the transaction, that this was a fully launched product by Auxilium with a lot of miscalculation and missteps along the way. We put a lot of efforts against it to recover it, including additional field efforts, some targeted DTC spend, et cetera. And while we are seeing some encouraging results from those investments, really when you put that against the opportunity that we have with BELBUCA it really pales in comparison, which is why we have taken the opportunity to reallocate resources.

So just to finish off the discussion on Auxilium, I would remind you that for us Auxilium really is about the XIAFLEX platform, and that continues to perform extremely well, and end market indications the pipeline is richer than we thought at the very beginning, so there's actually a lot of positives about Auxilium that we are very encouraged by. And as Suky said, we have over delivered both in terms of size as well as timing on our synergies, which has also been a big driver of success in 2015. So we are actually overall very pleased with the Auxilium transaction and we believe that the ultimate reader for success on us, should be taken with respect to the longer-term expectations for that business.

So Brian, maybe you can comment on BELBUCA pricing, and how we are thinking about it?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Sure, happy to. Thanks, Rajiv, and thanks, David, for the question. We're obviously very excited about BELBUCA. We think we've got a very nice label and a first pass approval was a big success for our R&D team. We like the profile of this product, we think it's going to have a very important place in the armamentarium of pain products on the market, and being a product with a nice safety and efficacy profile accompanied by the Schedule III designation, we think that it is going to, as I say, fit in very, very well.

I am not going to guide too specifically on price, but I think if you looked at the other long-acting opioids that are in the market treating chronic pain, you can get an idea of the range that we will be playing in. Philosophically, our goal here is to provide access for as many patients as possible, and also to provide access cleanly and smoothly on managed-care formularies, and our conversations are underway behind that. But just, as we've said, we plan on stepping up in a major way to resourcing behind BELBUCA because we think it really provides us with a very compelling growth profile going forward, and frankly, we are excited to get it on the market as soon as we can in 2016.

David Amsellem - *Piper Jaffray - Analyst*

Thank you.

Operator

Marc Goodman, UBS

Marc Goodman - *UBS - Analyst*

Good morning first on XIAFLEX, I want to make sure I understand, you said that for frozen shoulder and cellulite, you have not met with the FDA yet, but you are planning to launch the studies literally in the next month? So I'm just curious, did I hear that right, or you have met with them?

Second, in the generics business, can you tell us how much the Lidoderm AG represented, and what the gross margin was? And you started to talk about TESTOPEL a little bit, but is there any way you can give us a sense of the revenues there, and maybe what the revenues were when you bought it, just to give us a sense of what happened for that product? Thanks.

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

Sure. Let me answer the XIAFLEX question, and TESTOPEL and then I will hand it over to Suky for the Lido AG.

On XIAFLEX, on both frozen shoulder and on cellulite, there has been ongoing dialogue with the FDA. However, prior to actually initiating the next Phase 2B study, our expectation is that we would want to have a complementary meeting with the FDA to ensure that we are fully aligned in endpoints as well patient populations. So those meetings are being set up and for cellulite has been set up.

We're in the process of doing that for adhesive capsulitis/frozen shoulder as well. And we are hopeful that those will be bought by the end of the year, which will then allow us to immediately enter into the trial. So that is where we are on the timeline.

In terms of TESTOPEL, if you recall, there was some changes in TESTOPEL reimbursement that happened, just in the backdrop of our acquisition, and actually happened before our acquisition of Auxilium, so there has been some rebasing of that product going into 2015. But we've seen a very nice stabilization of it, and we expect it, to along with AVEED, to contribute to a growing, long-acting franchise heading into 2016 onwards.

Suky, do you want to talk about the Lidoderm AG question briefly?

Suky Upadhyay - *Endo International PLC - CFO*

Sure, so Lido AG even in the backdrop of the most recent entrant on that product is still about a third of the market. It's done about $20 million to $25 million within the quarter and gross margin of the profile of that product, subsequent to the new entrant is somewhere around or maybe slightly below the division or segment gross margin average in the mid-50%s.

Marc Goodman - *UBS - Analyst*

So gross margin for the whole generic business is mid-50s this quarter?

Suky Upadhyay - *Endo International PLC - CFO*

That's right.

Marc Goodman - *UBS - Analyst*

Thanks.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just with some of the recent stock market and fixed income moves, any changes in priorities for capital deployment? I guess where does share repo fit versus debt paydown? Are you seeing any signs from sellers that price might be resetting given market dynamics?

And then my second question, which is building on some of the earlier comments are there any learnings from the Auxilium transaction that we should think about, as you look at future deals in terms of either things you would or wouldn't do, or the way you managed acquired products? I'm trying to understand that a little bit better. Thanks very much.

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

Thanks, Chris. In terms of capital allocation, and I think we have always been very clear in terms of where we are in our profit cycle, of rebuilding the company and repositioning it. For us, really capital allocation was in the following order, which was towards new acquisitions, and also obviously funding organic growth. Debt paydown next, because we do believe in maintaining a very attractive balance sheet, and then share repurchases which came at the end of those priorities.

I think as we sit here now, clearly from the standpoint of where we see our own shares trading, we believe we are substantially undervalued. That being said, we don't want to lose sight of the fact that our fundamental mission here is growing the Company and creating long-term value. And we do continue to see some very attractive assets out there, and as you pointed out, prices have come down substantially.

And with the part-run section disclosed, we will be rapidly delevering going into 2016 and with maybe that base in excess of $2 billion. So we will very soon be in a position with substantial resources to pursue acquisitions, so that will be our priority.

We certainly take the obligation that we have to pay down debt very seriously. That's the commitment that we made to the rating agencies as well as the shareholders, so we intend to do that going into 2016, as well. And of course from time to time, our Board will take a look at share repurchases as a strategic alternative to capital allocations. But I would say we do continue to see some very attractive opportunities, to continue to build the Company, which is quite encouraging.

In terms of your question on Auxilium, as I explained in my previous answer, the core expectation that we had in the Auxilium transaction, which was acquiring a very long-term platform, has proven to be exactly the case, right? And certainly in terms of what we have found with the XIAFLEX platform both in terms of on-market indications and the pipeline, continue to be at or above our expectations. Certainly in the pipeline as well.

However, I think there are always learning opportunities, every time we do a transaction, so when I step back from Auxilium, I would say there were two learnings that we had. One is, I think we have always said that for us to play in predominantly primary care type products is going to be difficult, and we proved that to ourselves again with STENDRA. And in particular relaunching a primary care product in a very crowded competitive environment, where there's a lot of money being spent, and it's not something our business model is intended for, so that certainly informs how we might think about opportunities like STENDRA in the future.

And the other thing that I think that we've also been very clear, in terms of some of the commentary that we've made in the last couple of quarters, is that we did not -- we had to move to make some corrections, particularly around the reimbursement support that we had for XIAFLEX in terms of continuing the product's growth, which we probably were not fast enough, right? So those of the two learnings that we have, but overall, I would say that the other types of things that you worry about in integrations, which is synergy capture, keeping our compliance mindset in a transition, all of those things have gone extremely well. So net-net, if I step back from the Auxilium integration, I am actually quite pleased with it.

David Amsellem - *Piper Jaffray - Analyst*

Thank you.

Operator

Annabel Samimy, Stifel Nicolaus.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Thanks for taking my question, I guess it's similar along the lines of the prior question. But right now -- you've got some of the best performing assets and brands that are some of the oldest ones, or potentially going away. We are excited to have BELBUCA and continued opportunity for XIAFLEX, but with these assets, you do you feel that you are in the right areas of growth right now, and can you get to the double digit growth with these assets?

And what can we expect with regard to M&A in this revalued marketplace? I know you are interested in that but are you refocusing on some of the areas that you're moving into? And on the generic side, what has allowed you to take advantage of certain pricing opportunities where other competitors in the same areas have not been able to? Thanks.

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

Thanks, Annabel. So in terms of your question on the branded business and double-digit organic growth, I think what we've been clear about is that for the Company as a whole, we expect to be in double digits in our planning horizon. Our branded business is likely to be in the high single digits, where we stand now, and that's obviously before the impact of the XIAFLEX pipeline, which happens at the very end of our planning horizon.

So if you look at our branded business and think about XIAFLEX, think about BELBUCA, that is a big component of how we expect growth to be supported in the next little while, but let's not forget, we have products like SUPPRELIN LA, AVEED, which are doing quite well. TESTOPEL, we are confident will swing back into growth, so we actually have a nice stable of products that we expect to contribute to growth.

And Voltaren Gel is a real wild card, it's a product that has grown very nicely under our watch. Our promotional agreement comes to an end in mid-2016 but we continue to have a dialogue with GSK and Novartis, it's a joint venture, around potentially extending that. And we've been clear that would be something that we would be very interested in doing. We've disclosed that in prior earnings calls, and we continue to have this dialogue, and we're hopeful that they will be resolved in the near term.

In terms of your question on M&A, and I suspect your question was mostly focused in the branded arena, one of the things that we have said consistently is that we need to build further critical mass in our branded business, so right now, what we have are essentially two legs, which is the pain business, which now has a flagship product built in the front-end, OPANA ER behind, and then hopefully Voltaren Gel on an ongoing basis. And then we have the specialty products business, which is led by XIAFLEX, with TESTOPEL and AVEED in the portfolio as well.

But for us to really aspire to leadership in branded, I do think we need another platform. Our views on what those platforms are frankly have not changed very much. I think for us, it's all about the right opportunistic entry, where we think we can create value, and that's certainly what we're going to be looking for as we head into 2016 and 2017.

And finally, on your question on generics, this is mostly a Qualitest question, so I will take it, and maybe I'll ask Paul to comment on his view of generics going forward. For us, the Qualitest portfolio had three legs, right? There's pain, there's controlled substances, there's liquids, and then our portfolio of very small products, of which we have up to 800 products, right? And a lot of the smaller products that a lot of the big competitors don't make any more are often competing with small players.

The controlled substance space has been one where there's been events that allow for price increases, like the oxycodones or the hydrocodones, and the small products are an area where oftentimes the supply-demand dynamics are such that there are opportunities for pricing, because many of these don't last very long, and they are temporary, but net-net they contribute to Qualitest growth. However, we are also being clear that it was

not our expectation that opportunity continue forever. Right? There will be diminishing opportunity, which is why prior to the acquisition of Par we signaled for Qualitest to be high single digit growth versus the double digit growth.

So hopefully that answers your question. Maybe Paul, you can comment a bit on your views on pricing and generics going forward?

Paul Campanelli - *Endo International PLC - President of Par Pharmaceuticals*

Yes. I think clearly when you look at, on a go-forward basis, Rajiv talked a little bit about the narcotics, I view that is technically challenging products. I would look at it the same way on a go-forward basis, to be very select. So from that standpoint, you're not going to see me-too products seeing price increases.

I think where we see it going, is it's going to be driven on volume, and that's really where the Par portfolio comes in, in terms of new R&D products that we are looking to launch, and it's really about operational execution and getting the pipeline approved as quickly as possible. I think it's going to be a little bit more challenging across the board on price increases, as you can see the consortium's getting a little bit bigger. But we have to execute on the pipeline. I think that's really the story here.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay. Thank you.

Operator

Liav Abraham, Citigroup

Liav Abraham - *Citigroup - Analyst*

A couple of questions. Firstly, Paul, can you comment on how Par performed in the quarter? I'm aware that the results weren't consolidated, but it would be helpful to get a sense of the performance of the business and also any meaningful calculus on the Par side that we should look out for, over the next 6 to 12 months?

And then secondly on pricing, Rajiv, in the unlikely event that politicians are able to collapse Medicare rebates to Medicaid rebates, can you frame the potential top line impact to your branded business? Thank you.

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

Sure. So I will just, before I hand it to Paul, I just want to remind you that we only consolidated four days of results of Par we are not going to comment on the financials of Par in the third quarter; however Paul can certainly comment on the qualitative aspects of how the business did in the third quarter and the highlights. As well as his views going forward, but again, we are not going to provide any specific revenue or profit numbers specifically for Par for the remainder of 2015, either. Paul?

Paul Campanelli - *Endo International PLC - President of Par Pharmaceuticals*

I will just be really general. I think to Rajiv 's point, I am really proud of where Par has landed over the last several quarters, and really the way we look on a go-forward basis, to really at the end of the day, we have performed as predicted, right? So I think that's probably the best way of putting it at this time. Without giving any specific numbers, the team continues to execute. We delivered on what we had promised to the Endo team.

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

Paul, do you want to comment on what the drivers are going to be in the next 6 to 12 months?

Paul Campanelli - *Endo International PLC - President of Par Pharmaceuticals*

So at the end of the day we keep on talking about this operational execution, and we still have a portfolio of products that we have to work with the FDA, and we are excited about the portfolio. We certainly, in the slides that we've shown, we have a series of products that we are excited about, notably the quetiapine and ezetimibe products that we are planning on executing and delivering as we get into 2016. And overall, we have our goals and objectives on the number of applications that we need to file, and we have a very strong focus on filing products, launching products.

Again as we file, we need to get them out of the FDA, and we have to drive our sales. So ultimately, we have our plan to continue to file in the area of 20 to 30 applications on an annualized basis, and our goal is to launch those, as we forecasted. So far, very excited about the prospects of execution.

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

Perfect. Suky, do you want to cover the Medicare Medicaid rebate question?

Suky Upadhyay - *Endo International PLC - CFO*

Sure I think the first thing to understand is it is important, it is a very diversified portfolio even within our branded business, where no one product accounts for more than 6% of revenues. If you have to think about Medicare moving to Medicaid-like rebates or discounts, the way we've trained that in, is that a Company level, the impact would be in the low single digits.

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

As a percent of revenue.

Suky Upadhyay - *Endo International PLC - CFO*

As a percentage of revenue. Yes.

Liav Abraham - *Citigroup - Analyst*

Thanks very much. That's very helpful.

Operator

Andrew Finkelstein, Susquehanna Financial.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

I was hoping you could help us -- I know you don't want to give the Par figure specifically for the quarter, but within generics, we had talked earlier in the year about some of the quarter-to-quarter dynamics within the Qualitest business. If you give an idea of some of the moving pieces there?

I think in the second quarter you had talked about a $16 million stocking benefit, but also the impact of the price increase penalties and then moving into third quarter, I think the expectation was -- you would get the benefit of the increases that we are taking in the second quarter.

So if you could talk at all about how much the net realized price was relative to your expectations, and what the benefit is going forward, and any of the key products from the Qualitest business, or that bowel side or the potassium product in the controlled substances portfolio. Any idea of what -- any big changes on particular products?

And then finally on the Par business, I think the working capital profile looked, at least as of the last quarter, a lot different for Par versus your business. So just any comments there about how that changes as their customer terms are folded into your contracts? Thanks.

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

Sure and let me start on this, and then I will have Suky answer. So we're not, for example on things like constant contracts, we're not going to comment on it. That's something that Paul is right in the midst of. He's handling that himself personally because it's such an important topic and we will see the outcome of that going into next year.

But on your questions on the impact of price, et cetera, just to make sure that we set the facts straight, when we took our price increases on the backend of Q2, we were clear that the level of the pipeline accruals and price penalties that we were paying would mean that the real net benefit of those price increases would likely happen in the very back end of the year, and more importantly, for 2016, right? So in Q3 there is no benefit from this price increase, in fact the price penalties actually continued to drag down Q3 results. As a result, our Q3 growth in Qualitest is all volume, and really there's no price in it.

We continue to be very pleased with the performance of cycle urea, the potential for that product, and the HydraPak, and we have signaled that we expect some competition for the low-dose HydraPak and Valgan sometime in the fourth quarter, and we continue to expect that. But certainly in terms of how they performed in Q3, we were very pleased and we are also somewhat, we can tell, off to a reasonable start to the cough-cold season. The ultimate result of cough-cold season will only be known in Q1, but the shipping for the cough-cold season began in Q3 and it was a reasonable outcome for that business, as well.

Suky, do you want to talk about the working capital?

Suky Upadhyay - *Endo International PLC - CFO*

Sure. Just to reiterate on the generics piece, sequentially even excluding Par, the Qualitest business did grow from Q2 into Q3, and that's even with the backdrop of a steeper price decline in Lido AG than we originally anticipated, so the business fundamentally is still performing quite well.

Regarding working capital, I think the first thing to understand is there's a little bit of noise whenever you acquire a business like this so late in the quarter and how that impacts working capital. So first, as a part of opening balance sheet of the acquisition of Par, you are going to put the full inventory balance and the full AR and AP balances, but you've only got potentially four days of operating results as part of your denominator, so that's going to skew your working capital pretty significantly.

But the way I would think about Par is that on a DSO basis, they are probably slightly better than the overall Company average for Endo which we currently see as somewhere around in the low 50s. From a DPO standpoint, Endo is probably a little better, and where I see that is the average of somewhere in the mid-30s and then on an inventory basis, both companies are relatively at the same level, which is at about 60 days.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much.

Operator

Gary Nachman, Goldman Sachs.

Gary Nachman - *Goldman Sachs - Analyst*

Rajiv, when do you think we will start to see even more of an inflection with XIAFLEX? How exactly have you adjusted formulary support for it, and if you are removing some of your focus from urology, could that potentially hurt uptake with Peyronie's?

And then on BELBUCA, how much of that uptake will be driven by primary care, since you said that's not a great place for you to compete? And did you actually get confirmation it's Schedule III?

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

Sure. On XIAFLEX, I'm going to actually hand it over to Brian to talk about some of the some of the things that we're doing vis-a-vis Peyronie's and DC for the next year, but what I would say is that in terms of a inflection point, DC is expected -- I would continue to think about DC as a steady grower. Certainly at some point the MULTICORD indication will begin to kick in, we hope, in more substantial fashion, but I'm not sure that's going to create inflection other than to continue to stay on the growth trajectory.

Peyronie's, also I believe it's going to continue to grow, and certainly at a higher growth rate than DC. As to whether there is a single inflection point or a sustained inflection over time is yet to be seen, because I think our biggest area that we need to create further momentum for that is patient education and getting more patients into the funnel. We already have a pretty nice set of injector base, and the additional dynamic there we need to see is to really increase the number of truly active injectors.

So maybe Brian, you can talk a little bit about these actions that we're planning on doing.

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Sure. Happy to do that, and thanks for the question, Gary. Before I do though, let me just reinforce the difference between our specialty urology capabilities and our retail urology capabilities. So our specialty team, which is really anchored, as you know, by XIAFLEX, has a dedicated team in specialty urology. XIAFLEX, AVEED, TESTOPEL, and there will be absolutely no change to that business, we think we've got that business on the right foot now with everything from demand creation to reimbursement support, and we're very excited about what they can deliver going into 2016.

So I just wanted to underscore that, and in fact as we do reprioritize away from STENDRA, we have a customer continuity plan in place that we will execute very carefully to make sure that there is no disruption there. So just wanted to make sure we were clear on that.

As Rajiv said, on XIAFLEX, we are actually very happy. You've got year-on-year growth of about 20% plus, and underpinning that, even after five years of launch is about 14% on Dupuytren's. And we think as we've learned more about XIAFLEX, going into 2016, there are some untapped opportunities for growth in how we think about the channels and creating and supporting demand beyond, let's say, the core launch group of injectors, and we will step into that in a big way.

One of those ways is with patient engagement, and as we spoke too, we already have started the early stages of a patient engagement direct to patient campaign, intended to make sure we are flowing patients into our prescribers, while at the same time, we are working to grow the prescriber base, so we like the prospects very, very much. We like what we see in terms of vials per patient in both Dupuytren's as well as Peyronie's, and frankly we are just excited by, and will continue to step into XIAFLEX going forward.

You also asked about BELBUCA relative to targets, so let's be clear there. Any primary care docs that we, and frankly this is consistent, I think with most players in the market, any primary care doc that we target really are acting more like pain specialists than typical broad primary care specialists. So we will allocate our selling against that, so we don't think about this as a big primary care play necessarily. And in doing so, we will target what we think the profile of the product will lead to some great uptake.

And then your C3 question, we see this is a C3 product, and that's based on the fact that it's buprenorphrine which has been well established and already scheduled, so uniquely we get to take advantage of that, and we will bring the product to market accordingly.

Gary Nachman - *Goldman Sachs - Analyst*

Okay. Did you get confirmation it's C3 yet, or you're waiting to hear from the DA on that?

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

So Gary, the way this works is that the scheduling is for the class, because this is a well-established molecule that's been around. And unless the DA takes specific action against the entire class, we don't expect action specifically on BELBUCA at this point.

Gary Nachman - *Goldman Sachs - Analyst*

Okay. Thank you.

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Yes just a couple follow-ups on XIAFLEX. I don't think this came up yet, but can you talk about the net price -- it looks like the implied net price was down in the third quarter from the second quarter, so can you confirm that and talk about what's going on with that? And can you also talk about how you expect the average vial utilization to grow from the current level, whatever the current level is as the mix of the business continues to shift by indication? Thanks.

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

Again let me have Brian talk about the vial issues, but XIAFLEX is not a product in which there is any substantial price movement. There's a big component, operators just buy and bill, so that really restricts us in any case in terms of the types of price increases that we take, and also, it's not a product that is broadly discounted or rebated, either. There are some very, very controlled areas in which there some volume discounts that are given, but they are not substantial, so there really is no movement on XIAFLEX and pricing very much. Maybe Brian, do you want to talk about the vials?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Sure. Happy to do it. Greg so in Peyronie's, we're sitting at about 4.5 vials per patient. There's the chance for that to migrate upward a little bit, but we don't build that necessarily into our expectations.

It's a different story, however, for Dupuytren's, because as you know, we are still early in the MULTICORD rollout and we are frankly pleased with the fact that it's migrated a bit up from 1 to 1.2, and we do see some potential for that to grow obviously to 2 vials over the next coming months or so.

Gregg Gilbert - *Deutsche Bank - Analyst*

And then maybe for both you, a bigger question on XIAFLEX, not to look backwards too much, but can you talk about changes made in people and programs, and post-acquisition, and are you confident that you have the right sort of resourcing behind it? I ask because investors are very concerned these days about acquisitive companies that sometimes have to reset the bar on products they've acquired, or lower expectations after ownership.

So maybe a bigger picture question on XIAFLEX and how you are resourcing it. I know it's an important long-term but can you talk about some of the specifics? Thanks.

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

Sure, let me start, and Brian can add to it. We've made some changes on the XIAFLEX team after we bought the brand. We have Glen Davis, who runs the franchise for us.

We have a new individual who runs the sales efforts on the urology side, and a very strong individual who runs the sales efforts on Dupuytren's. We also changed over our managed care efforts and reimbursement efforts. I would say at a senior level, I am confident in the team that we have, and maybe Brian, you can talk about at a more specific level, any observations you have?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Yes I think I would just say exactly the same thing, like any integration, you're going to have some turnover. What's important to recognize is that we were successful in bringing over and retaining, especially in the sales and reimbursement arena, some very experienced and talented people who knew the product very, very well and they've continued to stay with us. And again I will reinforce that, especially in reimbursement, where knowing the product, knowing the customers, and understanding the intricacies of access for our patients was so critical. And the vast majority of those people remain, and are engaged in and producing very, very well.

And as Rajiv said, we've made changes at various levels, but we're very happy with the people that we are able to bring on, and frankly coming out of the disruption we've talked about already earlier in the year, we think we are on a very solid footing, and we're very happy with the growth trajectory going forward.

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

And all I would say Gregg, is that you can look at into 2016, actually our resourcing behind this brand, will be higher than it has ever been under Auxilium, both in terms of sales and in terms of other support we're going to put around patient engagement, patient awareness. And more importantly, the R&D spend on this product, which is -- it's going to become much more robust headed into 2016, 2017 and beyond, in a way that Auxilium could not have done, so I would argue that for the core franchise that we acquired in the Auxilium transaction, the resourcing is actually going up.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks a lot.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. Yes sorry my apologies. I have a couple questions.

First of all, with respect to XIAFLEX, it seemed like the year-over-year growth versus what was reported in the September quarter last year was 3%. Could you just walk us through how we should think about volume growth versus -- I don't know, inventory changes, or other swings to connect the dots between some of the growth figures that you've provided in volume and the year-over-year sales growth?

And then second, with respect to BELBUCA, could you just paint a picture for formulary access, specifically how long it will take, and what your targets are formulary access for that launch? Thanks very much.

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

Sure. Suky, do you want to take the XIAFLEX question?

Suky Upadhyay - *Endo International PLC - CFO*

Sure, so in the third quarter this year, I'm not sure what you're referring to, low single digits David, but in the third quarter this year, XIAFLEX grew in the mid teens. As Rajiv talked about, price is not a major driver either up or down for that product, especially given its buy and build profile.

Relative to your questions on inventory, because a large component of both of these indications is in fact buy and bill, you do not have large inventory positions out of the channel or do you see large inventory swings. So inventory was not a major driver for growth in the quarter.

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

If anything, inventories on XIAFLEX were a little lower. It's typically somewhere between a week and two weeks, and we were probably were at the low end of that spectrum. So inventory was not a driver of it either.

David Risinger - *Morgan Stanley - Analyst*

I'm sorry. What was the revenue booked last year for XIAFLEX in the third quarter? Maybe I had it wrong, but I was trying to calculate off of what was booked last year in the third quarter by Auxilium.

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

Suky do --?

Suky Upadhyay - *Endo International PLC - CFO*

I think it was -- as I said, everything I am talking about is pro forma for Q3 versus last year.

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

I'm sorry interrupt, but one thing to keep in mind -- Auxilium is to report ex-US revenues of XIAFLEX together with the US revenues. So to be clear what we're talking about here, are US revenues.

David Risinger - *Morgan Stanley - Analyst*

And do you know what the US revenues for XIAFLEX were in the third quarter of last year?

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

So that's where we are getting the mid-teens growth calculation from.

David Risinger - *Morgan Stanley - Analyst*

Okay. Thank you.

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

Brian -- do you want to cover the BELBUCA?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Sure David, you also had a question, so let me hit that quickly on formulary access. As we commented before, we are finalizing our pricing, and as I said, our goal is to make sure we have access to majority of patients. We're beginning our engagement with payers right now. I'm not going to guide specifically to how we think that will shake out, but again I will point back to the profile of the product, and we think it's differentiated within the space, and therefore we are optimistic that we will be able to get solid formulary access going into 2016, that will enable a sharp uptake once we launch.

David Risinger - *Morgan Stanley - Analyst*

Thank you.

Operator

Jason Gerberry, Leerink Partners

Jason Gerberry - *Leerink Partners - Analyst*

Good morning and thank for taking my questions. Just two for me.

First of on XIAFLEX for cellulite, just curious, the product that is priced right now based on what we saw in Phase 2 isn't priced for the cash pay cosmetic market, so just curious as you think about the Phase 2B, having a commercially viable formulation or dosing format, whether or not you expect to have that in place for the Phase 2B, or if that's something you have to work on subsequent to the Phase 2B? Any thoughts you could provide us in terms of what that dosing format might be look like, be it pre-filled syringe or something else?

And then my second question, just on international pharma can you let us know, what was the year-over-year growth of that business on a constant currency basis, and how do we think about the impact on these divestitures in 2016? Just wondering if we have more rebasing in 2016 before we get to your growth outlook for that segment? Thanks.

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

Sure. Let me quickly cover the cellulite question. Short answer is this is still something that is in discussion with the FDA. I think the most important thing for us is to with the FDA to come to agreement on the clinical endpoint.

The commercial format of the product, the formulation, with its pre-filled syringe, the actual volume of it and therefore the pricing of it is a topic that will continue to evolve. But I think the priority now is to find the clinical endpoint that is acceptable to the FDA.

And then Suky, do you want to cover the international business briefly?

Suky Upadhyay - *Endo International PLC - CFO*

Sure, international year to date has grown 19%, but again that's partly due to the midyear acquisitions. Foreign currency has had a headwind on the business through the nine months of about $20 million in top line. And the way we would see underlying growth is somewhere around negative 10% and that's again primarily driven by the transition we are taking in a number of our businesses. Specifically with Litha, as we talked about at divestiture which has impacted sales in that business unit between now and when we actually close it, across vaccines, as well as our medical device distribution business.

Within Somar we have seen the change of control in a couple of products also impacted that growth rate, and the same is true within Paladin. Going into 2016, those impacts are largely behind us, but we will continue to see a slight or modest step down in 2016, primarily due to the loss of the revenues from the divestiture in Litha, but I will say that while we should see a modest step down in overall revenues, those revenues were a very low margin, specifically because they were in vaccines, as well as device distribution, so our overall EBITDA contribution for the business will actually increase into 2016.

Jason Gerberry - *Leerink Partners - Analyst*

Okay. Thank you.

Operator

Irina Koffler, Mizuho.

Irina Koffler - *Mizuho - Analyst*

Thanks for taking the question. I just wanted to revisit the reorganization for next year with the sales forces. Is there an opportunity there to gain an additional cost efficiencies? That's the first question.

And then the second question is, going forward, do you see the company doing these smaller deal transactions like NATESTO or Sumavel, or are you going to be focused on larger opportunities, because it seems like those little things are the ones that haven't been working as well. Thanks.

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

So in terms of the changes in the business going into 2016, this is really not out about cost reduction. It's really about optimizing and expanding to support the launch of BELBUCA, so we really are in growth mode in our branded business from that standpoint.

With respect to the smaller transactions, what I would say is that each of these transactions need to be viewed in the context of the circumstances under which they were done, and what the facts are today. So for example, we see at the time where we have a lot of excess capacity in our pain sales force, it's a nice tuck in, and I would say in terms the contribution that's made, it is in line with what we would expect. Are we thrilled about this performance and is it going to be a huge growth driver going forward? Absolutely not, but at the time we did it, it filled a very important need for us.

NATESTO is a novel delivery system and at a point in time when we thought that the gel market would recover quickly. It seemed to be a good opportunity, and it might still be a great product.

However what I would say is that for us to maintain a retail urology field force just to support NATESTO is not viable. It would have been viable only if STENDRA also was performing well, which is why we are taking action on NATESTO, so really it's not a reflection on our view on that product itself. It's really more about the viability of maintaining a field force just for that product.

Irina Koffler - *Mizuho - Analyst*

Thank you.

Operator

Randall Stanicky, RBC Capital Markets.

Randall Stanicky - *RBC Capital Markets - Analyst*

Thank you. I just want to go back to the share repurchase question. I've been looking at the stock now, it's down 7%. You've got $836 million in unrestricted cash on the balance sheet. You have not been shy about issuing equity to do deals in the past.

So why not go back -- buy back stock, send a message to the market right now, and then use equity to finance deals at higher prices should the stock recover? And the related question to that is, given the pullback on the stock and the leverage here, you're roughly 4 times on a trailing basis, what is your ability to finance some larger acquisitions? And maybe specifically, what type of deals should we be thinking about you looking at? Thanks.

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

Thanks, Randall. So I will repeat the answer I gave on the share repurchase, which is that it is within the various levels that we have. We have an active and ongoing discussion with our Board in terms of how we allocate capital, so I'm not necessarily ruling out share repurchase, all I'm stating is that in a market like this, we need to keep our head on straight, and we have a lot of resources at hand and assets that are growing.

And we also need to be mindful that we want to keep paying down on debt. Right? And that there are many targets around us, but it's the smaller ones that are becoming much more within range, and I think that leads to my answer to your question, which is that in the very near term, we are going to continue to be focused on smaller transactions that we can do on an all-cash basis. Obviously at this level, we've been very prudent about how we think about using our equity.

At the same time, we are also open to the concept of doing larger, more transformative transactions where it is not so much the value of the equity, but rather the relative valuation that might actually come into play, right? So it's in that sense -- we continue to see opportunities. We're also going to be patient in terms of how we evaluate opportunities, but you can be certain that we are very active ongoing dialogue with our Board about how we allocate our capital.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Fair enough. Thanks.

Operator

Corey Davis, Canaccord Genuity.

Corey Davis - *Canaccord Genuity - Analyst*

Thanks very much. I just have 32 questions, so it shouldn't take that long. The first one is, on your ANDA pipeline, what is the average time for ANDA approvals, and are you expecting or experiencing the same degree of frustration that other generic companies are? And I have one more quick question.

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

Paul?

Paul Campanelli - *Endo International PLC - President of Par Pharmaceuticals*

Sure. It's a hard question to answer because the majority of our portfolio are Paragraph IV, so we're tied into the 30 month stay, and if you go to an appeal process, you're out 4 to 5 years. I would say when I look at the real answer to the question are we getting our timelines, when we have our earliest entry, I would say yes. So I'm not seeing, generally speaking, a backlog on the Par portfolio.

So with that, the Paragraph IV timeline is what allows us to catch up when we are in a situation. I've got -- I'm not going to say that's across the board on every product, but we have a small percentage of products to get backlog, but the vast majority, we hit our timelines based upon a 30 month stay.

Corey Davis - *Canaccord Genuity - Analyst*

Okay. Thanks. And second question, it still wasn't clear to me -- are you still investing in the testosterone market? And would you find that an oral testosterone would be effective, or is this market just going to keep declining forever, regardless of whether or not you had an oral or the best testosterone ever, it's just not a market where you want to be?

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

So just to be clear Corey, we will continue to invest in the long-acting testosterone space which is TESTOPEL and AVEED. And AVEED is finally kicking in, in terms of its launch trajectory, and TESTOPEL, we believe is going to recover. So we do think that there is a nice runway for the long-acting testosterones.

In terms of oral therapies, it's entirely possible that there would be a change in this marketplace one day, when there's a viable oral therapy. The question is, will there be one and when? Maybe, Brian, you can comment on that?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

I really don't have anything to add. I think it comes down to product differentiation and as Rajiv says, if there's a truly differentiated product that has an acceptable safety and efficacy profile, it has the potential to perform well, but again, you have to look at the gel market, which has been declining significantly over the last couple of years and that's led us to refocus into the area that we think gives the most compelling opportunity for growth, and we will continue to support those products very strongly, both of which are in our specialty business. And as we've said, we will be stepping up our investment overall in that business.

Corey Davis - *Canaccord Genuity - Analyst*

Okay. I was just kidding. I will save my other 30 questions for later. Thanks.

Operator

Austin Nelson, Nomura Securities.

Austin Nelson - *Nomura Securities - Analyst*

Hi guys, this is Austin on for Shibani. Just bigger picture, the comments you made differentiating your use of specialty pharmacies from some of your peers. We were really just wondering, we understand that your products are traditional specialty pharmacy products but we are wondering if in your view you see anything wrong with using them for more primary care, or even specialty type products that aren't necessarily physician-administered? And also if you think that the use of distributors really makes sense long-term too.

And then we had just one other one. On the re-prioritization, is there potential to divest some of the assets that you de-prioritizing? As you pointed out, STENDRA -- part of the issue is that primary care doesn't make sense for Endo, but could it make sense for someone who is in primary care to at least attract some value for Endo shareholders?

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

Yes so on the question on specialty pharmacy, I really can't comment on other companies' use of specialty pharmacy. All I can say is they are a very valuable channel for us, in terms of reaching the physicians that we need to with our physician-administered products in particular, and it's a very important role for patients who rely on those physicians.

I would also say there's a big and growing portion of our business that is buy and bill, which is largely speaking, a service by specialty distributors, who are of course different than specialty pharmacies. And again, we think it's a very important channel for us to be able to serve the needs of the physicians who rely on the buy and bill channel. So from that standpoint we continue to think that they're an appropriate vehicle for our products that they are more complex, have a more complicated supply chain, and are physician administered.

In terms of your question on the reprioritization and how we think about those assets, it's important to know on both STENDRA as well as NATESTO, we are partners, so you can imagine that we are in active discussions and will be in active discussions with those partners, in terms of finding the appropriate promotional setting for the products, and if that means the product needs to be in someone else's hands, we are very open to that, as well.

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

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

Operator

Tim Lugo, William Blair

Raj Persad - *William Blair & Company - Analyst*

This is Raj in for Tim. Thanks for taking the question. Just a quick one on BELBUCA, is there a plan to apply for ADF formulation language on the label? And given the OPANA ER, I assume those were in vitro sites that were done to support the SNDA? Thanks.

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

Brian, do you have perspective on that?

Brian Lortie - *Endo International PLC - President of US Branded Pharmaceuticals*

Sure. So yes, I mean with OPANA ER, the agency, as I think we've spoken about before, did ask us to do some abuse liability trials, which were in vivo and in patients. On BELBUCA in terms of ADF, we currently are not contemplating that, although we will watch -- remember buprenorphine in its own as a molecule is inherently less prone to abuse because of the lack of euphoria, and we see this across the existing products. And that, coupled with the dosage formulation, we think gives it a differentiation based on that, but we don't plant to actively promote on that. We think that the efficacy and safety profile differentiates the product very well.

Raj Persad - *William Blair & Company - Analyst*

Great thank you.

Operator

At this time, there are no further questions. I would like to turn the call back over to Keri Mattox for closing remarks.

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

Thank you, operator, and thank you all for joining us for today's call.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This does conclude the program. You may now all disconnect.
