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ENDP - Q2 2015 Endo International plc Earnings Conference Call

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OVERVIEW:

ENDP reported 2Q15 revenue of $735m and adjusted diluted EPS from continuing operations of $1.08. Expects 2015 revenues to be $2.9-3.0b and reported GAAP diluted EPS from continuing operations to be $1.42-1.62.

CORPORATE PARTICIPANTS

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Gary Nachman *Goldman Sachs - Analyst*

David Amsellem *Piper Jaffray - Analyst*

Randall Stanicky *RBC Capital Markets - Analyst*

Chris Schott *JPMorgan - Analyst*

Jason Gerberry *Leerink Partners - Analyst*

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International PLC Q2 2015 earnings conference call. At this time, all participants are in a listen-only mode. (Operator Instructions). As a reminder, this conference is being recorded. I would like to introduce your host for today's conference, Ms. Keri Mattox, Senior Vice President of Investor Relations and Corporate Affairs. Ma'am, you may begin.

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

Thank you. Good morning and thank you for joining us to discuss our second-quarter 2015 financial results. With me on today's call are Rajiv De Silva, President and CEO of Endo, and Suky Upadhyay, Chief Financial Officer.

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 security 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 reason 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. Good morning everyone and thank you for joining us today, this morning. I hope that you have all had a chance to review the Company's earnings press release that we issued earlier today. Let me now turn to our second-quarter earnings presentation.

On slide two you will see our agenda for today's call. We will start with the review of our recent accomplishments including the strategic actions we have been taking to create value and further sharpen our focus on our core pharmaceutical businesses. I will follow that with the highlights of our second-quarter 2015 financial results. We will then turn to our full-year 2015 outlook and financial guidance. After our prepared remarks, we look forward to taking your questions.

Moving on to slide three, 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. Our US Generics business delivered strong underlying growth in the first half of 2015. Generic Valcyte continues to be a highlight among new products and contributed to double-digit volume growth from the base business.

Within International, we announced multiple strategic transactions designed to increase focus on the core pharmaceutical business lines within the Litha Group. Additionally, we completed the integration of Auxilium into our US Branded Pharmaceuticals business during the second quarter.

Second, we continue to sharpen our R&D focus on near-term opportunities. We continue to progress towards the action date on October 23, 2015 for our BELBUCA NDA. Our dialogue with the FDA on this application has been encouraging.

Also on the late stage still open front for XIAFLEX, we continue to expect to initiate additional studies for the treatment of cellulite and adhesive capsulitis by the end of 2015.

Third, we are focused on deploying capital to accretive value-creating opportunities. The acquisition of Par announced in May will create a leading specialty pharmaceutical company with a top five generics business as measured by US sales with a differentiated portfolio and pipeline.

Last week we announced the completion of our sale of the AMS Men's and Prostate Health Businesses to Boston Scientific for a purchase price of approximately $1.6 billion. The net proceeds from that divestiture will help us acquire Par and sharpen our focus on core pharmaceutical businesses.

Along those lines, I would like to thank [Kamil Fahad], his leadership team and all the employees of AMS for the dedication and tireless commitment that they have shown in supporting the business throughout this process.

We are also continuing our discussions around the strategic alternatives for the AMS Women's Health Business.

Fourth, we remain focused on delivering strong and sustainable financial performance. We had a solid second quarter and are maintaining our underlying guidance for full-year 2015 revenues and adjusted diluted earnings per share from continuing operations. The relative strength of revenues from our US Generic Pharmaceuticals business in the second quarter was again a highlight of the value of our increasingly diversified business.

Moving on to slide four, our major announcement this quarter was the acquisition of Par. We believe that the combination will have significant strategic and financial value. Qualitest continues to be an extremely attractive and effective growth driver for Endo. The addition of Par will enable

us to achieve critical mass in our generics business unit expanding our scale and capacity and building upon steady double-digit organic growth at Qualitest by adding a strong portfolio of specialty high barrier to entry products with attractive gross margins.

For Endo, the addition of Par will help us achieve our goal of delivering double-digit revenue growth for the overall business over the longer term. We expect to deliver significant accretion to adjusted diluted earnings per share with a midteens percentage in 2016 and around 20% in 2017. Anticipated financial synergies from the Par transaction of $175 million will help deliver that accretion and returns well in excess of our cost of capital.

Moving to slide five, we now expect the acquisition to close by the reporting of our third-quarter 2015 results subject to regulatory and other customary closing conditions. We expect to divest less than 10 products and projects with no material impact to value in order to secure clearance under HSR. After securing clearance, we expect to close in an expedient manner as all of the deal financing is in place.

Moving on to slide seven, you will see that we are reporting $735 million in revenues for the second quarter, up 24% versus the prior year and $1.08 in adjusted diluted earnings per share from continuing operations. Suky will provide more details about our second-quarter results in just a few minutes.

While acquisitions contributed to the growth of our revenues, organic growth was also an important factor. On the next few slides I will focus on the organic growth drivers in each of our core businesses that we believe demonstrate the underlying strength of our Company.

Moving to slide eight, core products in US Branded Pharmaceuticals delivered underlying sales growth of 8% through June 30, 2015 as compared with the first half of 2014. The underlying growth rate that we would like to focus on in 2015 for US Branded Pharmaceuticals includes Auxilium results on a pro forma basis and includes only same-store sales for other 2014 acquisitions. And for comparison purposes, we exclude sales of LIDORERM and royalties received from Actavis for its generic lidocaine patch.

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 are also investing to relaunch STENDRA and so following a deeper drive into XIAFLEX performance, I will focus on progress for that initiative as well.

We continue our comprehensive efforts to protect the OPANA ER franchise including the promotion and development of the product as well as the vigorous assertion of its intellectual property. Following our meeting in June with FDA, we now expect to submit a supplemental request for labeling that would potentially add abuse deterrent formulation claims. We expect to file that request by early 2016.

In addition, we expect a decision soon in the Paragraph IV patent infringement trial have earlier this year in Federal District Court in the southern district of New York. The outcome of this lawsuit however will not impact the ongoing litigation we initiated in late 2014 in the district of Delaware against these generic competitors with respect to newly issued patents covering the product.

One final note on OPANA ER. In a recent IPR proceeding, the validity of one of the patents was upheld by the US patent office in July 2015. Although the court in the Paragraph IV litigation is not bound by this IPR ruling, we view the IPR outcome as an incremental positive given that upheld patent is one of the patents we asserted in this litigation.

We have a diverse portfolio of products in US Branded Pharmaceuticals and we are focused on building momentum for an even broader set of growth drivers.

Moving on to slide nine, XIAFLEX had a solid second quarter and remains on track with internal expectations. On a pro forma basis, US sales of the product grew 52% compared with second quarter 2014 in Peyronie's Disease and Dupuytren's Contracture. XIAFLEX sales and demand in April and May were slow as we implemented commercial changes and reimbursement process updates as part of the integration of Auxilium.

However as expected, we have a strong rebound in June after the implementation of these changes. For the remainder of the year outside of an expected summer seasonality impact, we expect XIAFLEX to continue its strong growth track.

Growth in demand vials remained strong with approximately 13,000 vials of XIAFLEX shipped during second quarter 2015. There is an increase of 67% compared to the same period prior year. Most of that growth is attributable to the launch in Peyronie's Disease which accounted for approximately 6900 demand vials. Demand growth in Dupuytren's Contracture was attractive as well and increased at a double-digit growth rate with approximately 6200 demand vials in second quarter 2015.

Building on a successful launch date in Peyronie's Disease, there was continued traction with new patients and certified physicians. Through the end of June, there were approximately 2100 certified physicians and 9800 cumulative patients enrolled in our reimbursement program. And in May, the American Urological Association issued guidelines recommending the use of XIAFLEX in appropriate patients.

In Dupuytren's Contracture, we believe that the MULTICORD indication will continue to support growth in 2015 and beyond. And in May, we received a label update from the FDA that added an indication for the retreatment of recurrent contractures. Overall we are pleased with XIAFLEX performance to date and after gaining experience with the product, we are focused on optimizing the reimbursement processes and salesforce execution as key levers to maintaining and expanding its growth profile.

Moving to slide 10, we are investing to relaunch STENDRA and believe that the actions taken in the second quarter have stabilized prescription trends. Our efforts are focused on building brand awareness and driving trial use as we believe those are key to growth in this category.

To that point in the second quarter, we launched a targeted DTC campaign to build patient and physician awareness. Digital and print campaigns raised the profile of STENDRA in June and July. In addition, our new contract sales organization is fully deployed and we are focused on pulling through recent managed-care wins that are expected to improve patient access and level the playing field in certain geographies for STENDRA.

We continue to believe STENDRA has a commercially attractive differentiated label including a unique 15-minute onset claim. In order to be successful however, we need to increase awareness and access in a highly competitive market.

Moving to slide 11, our US Generics business continued to deliver impressive results in the second quarter with sales of $338 million that contributes to year-to-date growth of 44% versus the prior year. Our year-to-date 2015 results primarily benefit from organic growth and a number of value creating acquisitions as well as Lidoderm AG which was a strong source of growth as well.

While growth from these strategic initiatives is attractive, more impressive is they robust 24% year-to-date underlying growth rate in our US generics business. Underlying growth was a product of both volume and price and we are confident that we can deliver double-digit revenue growth for this business for the full year. Following the strong first quarter in US Generics, we increased prices on select products during the second quarter. We expect these actions to support improved performance into 2016.

Our view on the pricing environment within generics remains consistent. We believe that commodity products face pressure while specialty products present sound strategic pricing opportunities depending on market conditions. Given the focus of our (inaudible) business in specialty products including controlled substances we believe it can continue to outperform the broader market and the acquisition of Par will further increase the focus of our generics portfolio on specialty products.

Organic growth drivers are important for each of our businesses and in US Generics, we remain on track to meet our objective to file six ANDAs in 2015.

Moving to slide 12, while 2015 remains a transition year in our International Pharmaceuticals business, it is performing well and meeting our expectations. The Base Paladin business delivered a solid performance and Paladin's business [still open] efforts are progressing at a similar pace to historical levels.

In June, Paladin signed a commercial distribution agreement with ARIAD Pharmaceuticals to buy Iclusig in Canada. Iclusig, which is an innovative therapy for specific populations of leukemia patients, is approved by Health Canada and Paladin is preparing for launch by late third-quarter 2015.

Somar, our Mexican business, is now fully integrated into Indo and is delivering results in line with expectations. As part of the transition year for International, we announced multiple strategic transactions that sharpened the Litha Group focus on core pharmaceutical businesses.

In May, we announced the acquisition of a diverse product portfolio from Aspen including 60 unmarket pharmaceutical products and 70 pipeline programs. We continue to expect that deal to close in third quarter.

Last week we announced Litha's divestiture of its device, vaccine and additional non-core product lines. We expect the divestiture to close by the end of 2015 subject to regulatory approvals.

Finally, we expanded our International leadership team through the appointment of general managers for our Litha and Somar businesses. The addition of permanent in-market leadership 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.

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 and good morning to those joining us for today's presentation. We are pleased with the performance that Endo delivered in the second quarter of 2015.

Starting with slide 14, I will walk you through some of the financial details for the second quarter. I will not cover revenues in detail as Rajiv has already addressed that early in the presentation.

Revenues increased 24% versus the second quarter of 2014 and year-to-date revenues have increased 36% versus the same period in 2014. On an underlying basis, organic year-to-date revenue growth was approximately 13%. In addition to solid organic growth, the second quarter benefited from favorable order and shipment timing especially around the Fourth of July holiday.

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 the full-year 2015, we believe that our underlying growth rate will approximate our longer-term aspiration for sustained high single-digit to low double-digit organic growth and the closing of Par should accelerate that projected growth profile.

As Rajiv discussed earlier, our year-to-date results were driven by high single-digit underlying growth in our US Branded Pharmaceutical business and strong double-digit underlying growth in our US Generics business. While the International business was unfavorably impacted by a stronger dollar, the underlying performance of the business was in line with our expectations.

Moving to slide 15, adjusted gross margin increased in the quarter when compared to the second quarter of 2014 primarily as a result of improved margins within our US Generics business that offset unfavorable trends in segment mix. Our adjusted operating expenses were approximately 22.5% of revenues, in line with our expectations. We were very efficient in capturing synergies from the Auxilium transaction and our positioned to invest to support growth drivers. Those investments include launch preparation for BELBUCA and new R&D programs for XIAFLEX.

In addition to our positive operating performance, we have an improving adjusted effective tax rate. We posted a second-quarter 2015 adjusted effective tax rate of approximately 7% and year-to-date, that rate is approximately 12%. As expected and guided on the first quarter call, the quarterly tax rate progression will be lumpy due to technical accounting for various initiatives and one-time items. The second quarter rate includes

benefits from the implementation of actions to improve the efficiency of our global supply chain that improve our mix of earnings ultimately reducing our full-year adjusted effective tax rate.

Positive operating performance and positive adjusted tax rate performance led to second-quarter adjusted income growth at a rate that was significantly faster than our revenue growth.

Second-quarter adjusted EPS from continuing operations of $1.08 was slightly lower than our revenue growth rate. However, it is worth noting that second-quarter 2015 adjusted diluted shares includes the weighted average of approximately 28 million shares included in June 2015 as part of the financing to fund the pending acquisition of Par Pharmaceuticals. If we exclude the effect of the additional shares, adjusted EPS would have been $1.12, up 26% versus the second quarter of 2014.

One final note regarding the second quarter. As referenced in our earnings press release, we have a number of balance sheet items that I will cover briefly.

First, we recently issued approximately $1.6 billion of 6% high-yield notes, called approximately $500 million of 7% high-yield notes, and retired the remaining principal on our 1.75% convertible notes along with the associated hedged transaction.

Second during the second quarter, we increased our accrual for product liability related to the mesh litigation by $269 million. As might be expected in these situations, we have recently become aware of additional or potential claims that we continue to evaluate with respect to their ability and as we continue to refine our settlement and litigation strategy.

Importantly, we continue to believe that the current product liability accrual includes all known claims for which liability is probable and estimable.

Moving to slide 16, I will not review the year-to-date slides in depth. We believe that they are strong results that reflect the value created through the execution of our strategy. For additional details on our second quarter 2015 financial results, please review today's earnings press release.

Moving to slide 18, I will share some thoughts regarding how we are addressing the acquisition of Par within our financial guidance.

First, we expect to update full-year 2015 financial guidance following the close of Par acquisition to include both operating and financing effects and we expect the transaction to close prior to reporting third-quarter 2015 subject to regulatory approval and other customary closing conditions. The revised guidance that we have issued today effectively affirms our prior expectations for full-year 2015 operating performance prior to the dilutive impact associated with the pre-close financing related to the acquisition of Par.

As highlighted during my review of results, second-quarter 2015 adjusted EPS excluding the pre-close issuance of approximately 28 million shares in June would have been $1.12 versus $1.08. Due to timing of the share issue, the second quarter effect was relatively modest. The full effect of those additional shares and certain portions of the debt financing will have a larger impact in the second half if not offset by the operating results that we expect to include from Par after closing.

One final note on this topic. If the acquisition of Par does not close before the end of the third quarter 2015, free close financing activities are expected to reduce adjusted earnings per share by approximately $0.23 in the third quarter.

Moving to slide 19, we had a strong first half with overall results in line with expectations and certain parts of our business performing better than expected. Looking ahead, we expect to update guidance following the closing of Par and that would create the opportunity to factor in any continued underlying operational strength in the base business.

For now, we expect full-year 2015 revenues between $2.9 billion and $3 billion. We have maintained our range for estimated adjusted diluted earnings per share from continuing operations of $4.40 to $4.60 and we project reported GAAP diluted earnings per share from continuing operations for the year to be within our range of $1.42 to $1.62.

To reiterate, our updated 2015 guidance excludes the dilutive effects associated with the pre-close financing activities related to the acquisition of Par.

Before closing, I would like to provide some comments regarding the earnings cadence for the remainder of 2015.

We had a strong first half in a number of areas and we believe that we can use that strength to set up and improved performance heading into 2016. As previously discussed, second half 2015 remains on track for approximately 51% to 52% of our full-year revenues with fourth-quarter expected to be seasonally stronger than the third quarter for both revenues and adjusted EPS and representative of historical trends in the second half of the year.

We were able to rapidly execute on certain tax items in the second quarter. As a result, we expect our full-year adjusted effective tax rate to be 13% to 14%. We may continue to have lumpiness throughout the remainder of the year due to the mechanics of intra-period accounting as well as the timing of realization of certain discrete tax items in the second half of the year.

Overall I am pleased with our first-half performance which continues to be characterized by solid underlying revenue growth, margin expansion and robust underlying cash flow generation and I'm 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 to Rajiv to close out.

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

Thank you, Suky. Before we start the question-and-answer period, I would like to close with a few brief thoughts.

Moving to slide 20, first, we are investing to support current and future organic growth. As we have detailed in today's presentation, we have attractive underlying growth within Endo and we have a disciplined approach to supporting the current commercial portfolios and pipeline opportunities for each of our businesses.

Second, we continue to increase organizational focus on our core Pharmaceutical businesses. The divestiture of the AMS Men's Health and Prostate Health businesses along with acquisition of the Aspen portfolio and the divestiture of non-core businesses by the Litha Group, move us in the right direction strategically and free up resources to be focused in areas where we can create greater value.

Third, we are focused on deploying capital to accretive value-creating acquisitions. We are nearly done with planning for the integration of Par and look forward to creating a leading specialty pharmaceutical company with an expected double-digit revenue growth profile and a top five US generics business.

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

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

Thank you, Rajiv. That concludes our prepared remarks and 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

Gary Nachman, Goldman Sachs.

Gary Nachman - *Goldman Sachs - Analyst*

Good morning. On XIAFLEX regarding your plans to further accelerate that franchise, what are you doing exactly to optimize reimbursement? Some more detail there. On the additional indication cellulite and frozen shoulder, what will those Phase 2b studies look like in terms of size and scope?

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

Sure. So on the XIAFLEX reimbursement front, the optimization has come in a couple of different directions, Gary. One is that we have put more resources behind it versus what was in place certainly in the first quarter and before. And then secondly, we obviously continue to encourage the trend towards buy and build for the product as well so obviously that requires for physicians who are not used to the buy and build concept support in terms of getting them comfortable with it. So it is basically mostly a resourcing and level of intensity of how we have approached it.

In terms of the trials for adhesive capsulitis and cellulitis, planning is progressing well. We have not yet finally concluded on the sizing. We do expect to conclude all of those and initiate the trials towards the back end of this year. But obviously one of the things that we will be looking for is whether we size these trials in a way that they could be pivotal trials for registration as well. But we have not yet concluded that. Part of it is that we are still trying to make sure that we streamline and finalize the proper patient population for the adhesive capsultis population and then obviously on cellulite, it is continuing the dialogue with the FDA on exactly the endpoint that we think is optimal for both registration as well as commercial viability.

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

Okay, just one quick follow-up on the pipeline. For BELBUCA, are you still confident in a timely approval and potential for Schedule 3 status and what are you doing at this point just to plan for that launch in terms of reimbursement? Thanks.

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

So on BELBUCA, it is steady as she goes. Our discussion with the FDA have been encouraging, constructive and with that being said, the agency can act in a lot of different ways so we don't want to be presumptive in terms of what the outcome is. But so far we are very optimistic about our progress. And there is no new information from the DEA that would lead us to believe that the scheduling would be any different than Schedule 3.

And in terms of our launch preparation, it is going to take forming multiple different venues obviously. We have a pain field force which will be the core launch platform. As we get closer to an actual approval and labeling discussions, we will be in a better situation in terms of our final approach to pricing and reimbursement. So it is too early to comment on it at this point, Gary.

Gary Nachman - *Goldman Sachs - Analyst*

Okay, thanks a lot.

Operator

David Amsellem, Piper Jaffray.

David Amsellem - *Piper Jaffray - Analyst*

Thanks. So just wanted to get some additional color on the generics pipeline, maybe talk about how many ANDAs you have pending now. And also the maturity of the pipeline, obviously maybe you can't comment on the Par piece since it is not closed yet, but maybe just on Qualitest, how many CLRs you have gotten the average age of filings and just your level of expectations in terms of the pace of approvals? Thanks.

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

Sure. So I can certainly comment on the Qualitest pipeline and as we have talked in the context of the Par transaction, we have a pipeline of roughly about 90 programs. Of those, a substantial majority have filed ANDAs and pretty much if you take that 90 programs and you take the assumption of the say 60 to 70 file NDAs, you would expect those to be approved and launched within the next three to four years. So that will give you a rough sense of the pace of launches coming out of the Qualitest pipeline.

That being said as you know, there's a lot of back and forth on some of these files and complete response letters so you can't quite the exact sequence and the pace. But we have a large number that we believe prior to the acquisition of Par would have contributed to a high single-digit growth as we talked about in the past.

Now with Par although we can't comment on it since we are not yet closed the transaction, we have done a fair bit of integration planning already and we continue to be extremely pleased with the progress that Paul and the team are making with their own pipeline and their own launches. So just this second quarter, Par launched four generic products as well as one branded product and that has continued into the third quarter with some important approvals with (inaudible) acid and (inaudible) orphan injection as well.

So net net as we look forward, the predictions that we have made about the combined Par and Qualitest pipeline contributing to double-digit growth for the generics business and Endo overall is very much on track.

David Amsellem - *Piper Jaffray - Analyst*

If I may sneak in just a quick follow-up in terms of the FDA backlog, any color on the extent to which you see that easing anytime soon or is that easing?

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

It is very spotty I would say and I think that is certainly the experience that we have had and also what we have seen from Par as well. We don't yet see a consistent trend toward a speed up. Obviously if things speed up, we would only be toward one [page] than less, but we are not counting on increasing speed in terms of how we thought about our longer-term view on growth and guidance.

Operator

Randall Stanicky, RBC Capital Markets.

Randall Stanicky - *RBC Capital Markets - Analyst*

After the Par deal was announced, you had talked about accretion in 2016 and 2017 of 15% and 20% and that seemed to imply around a $6 EPS number in 2016 and just over a $7 EPS number in 2017. Can you just update us as to whether those still hold? Has anything changed in terms of how you are looking about the combined Endo and Par asset?

And then the quick follow-up would be is generic Voltaren Gel one of the products that you are planning to divest from the Par side?

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

So let me answer the part of a question that I can answer and the one piece that I am not going to answer are potential divestitures related to Par. I think we have already made the comment about how many we think there will be but due to ongoing dialogue with FTC I don't want to comment on specific projects.

But what I would say is that we remain very confident in the aspirational guidance that we put out for 2016 and 2017. As we have done more integration planning with Par, we continue to be very impressed with the business. We are confident about our synergy numbers that we put out there which is roughly $175 million of financial synergies of which is about $100 million are operational. Plus we have now become more confident that there is further upside to that number through supply chain and cost of goods reductions which were not included in that number as well. So net net all of that points us in the direction of being very confident about the midteens accretion for 2016 and roughly 20% accretion in 2017 and the rest of our business is progressing as expected.

Randall Stanicky - *RBC Capital Markets - Analyst*

That is great. Suky, I think you had talked about the COGS opportunity on that combined generics business. Should we be thinking about this as a 300 basis point opportunity over the next couple of years? Is there a way to quantify that?

Suky Upadhyay - *Endo International PLC - CFO*

Yes, I mean it is too early to tell right now. There is a sizable opportunity here when you think about the cost of goods profile of the combined business thing well over $1 billion with about half of that across API and the other half across conversion costs. So as Rajiv said, we are more confident in our ability to generate synergies from there but we are not ready to put a number out just yet.

Randall Stanicky - *RBC Capital Markets - Analyst*

Got it. Great, thanks, guys.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Thanks very much for the questions. First, just on the generic pricing environment, can you just elaborate a little bit more there particularly on the controlled substances side? I know one of your competitor said some cautious comments last week and just interested how you are seeing the pricing environment play out in that part of the market?

And then my second question was on the expected leverage post the Par deal and how quickly you will delever? I guess as part of that comment, can you just talk a little bit about the business development priorities as you think about for Endo at this point? And is it fair to assume that those are more on the branded side of the business at this point? Thanks so much?

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

Sure, Chris. Let me talk about the pricing and the BD priorities and Suky will talk about the leverage question that you had. The pricing environment for us is performing in line and consistent with what we have seen in the past and how we expect it to evolve. We have been pretty clear that our portfolio given its focus on controlled substances also as well as focus on older products where we have less competition that on average we are likely to have more pricing opportunities than not because we are now focused on our commodity type business in qualities and that has proven to be the case this year as it did last year.

We are prudent and opportunistic when we take price increases and not all controlled substances lend themselves to price increases. It all depends on the competitive set and the supply-demand situation in the market at any given time. However, we have a very broad portfolio so we have at least 700 SKUs that we market and manage and at any given quarter we do have opportunities to take price and this second quarter was no different. We actually had some meaningful price increases that we took which is reflected actually in some (inaudible) adjustments and other price accruals that are reflected in our second-quarter results and have taken down already a little bit.

But all of that being said, if you look at this year, you look at growth of predominantly volume and mix, not price. However the price actions we have taken this year should help us going into 2016 and as we have talked about in the past for Qualitest, we generally look at it as a two-thirds volume and mix and a one-third price type of growth environment which we expect to continue into 2016 given what we have seen in the past. And we have also been very clear that from a future planning standpoint in terms of the aspirations we put out there for the longer-term, we don't count on pricing very much because we do expect that pricing will continue to be spotty in terms of where we can actually take price increases.

In terms of your next couple of questions, on the business deal from priorities, we are very pleased with the Par acquisition and we are very hopeful that we can close that transaction soon and get Paul and the team going on combining the business and really delivering the results that we expect.

But there was a big outlay of capital and we remain committed to growing all three segments of our business and a priority will be our branded segment. So as we look over the course of the next six to 12 months we expect to focus our BD efforts in that direction. Obviously we will continue to be opportunistic with respect to our international portfolio as well.

Suky, maybe you can talk about the leverage question?

Suky Upadhyay - *Endo International PLC - CFO*

Sure. As we talked about, we expect to close the Par transaction some time on or just after the third quarter. As you know, we completed all the relevant financing to secure that deal. The way we see it now is that the closing of the transaction will be at about the mid-4s from a net debt leverage perspective and by the end of 2015, we expect to be in the low 4s.

Moving into 2016, we would expect to consistent with our prior statements, expect to be in our target leverage range of 3 to 4 times net debt leverage some time by the mid-2016 time period.

Chris Schott - *JPMorgan - Analyst*

Thank you so much.

Operator

Jason Gerberry, Leerink Partners.

Jason Gerberry - *Leerink Partners - Analyst*

Good morning. Thanks for taking my question. Just wanted to follow up on XIAFLEX and how that is launching in Peyronie's. In terms of docs that are certified, it looks like you are kind of focused now just on the specialist. Just kind of curious if you look -- growth in terms of certifying more doctors to prescribe it, in terms of the 10,000 patients, can you talk a little bit about adherence, are they getting a full treatment course which I believe is about six vials a patient? And if you can quantify proportion of the business going through buy and build versus specialty pharmacy that would be helpful. Thanks.

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

Sure, Jason, let me answer the first part of your question and see how far I can get on the second one.

So with respect to the physicians, our focus in this integration period in the first part of our ownership of the product has really strengthened our position and the level of confidence that the injecting docs have. So the 2100 or so physicians that we have currently, we are very pleased with the progress we are making. We actually think the real opportunity next is in terms of it will come in two directions.

One is expanding the base but as importantly increasing the referral base and driving more patients into the injecting physicians. So now that we have begun to see good performance after the changes that we made in the reimbursement process, the field force integration, that is an [exert portfolio of our physician] views that we are going to focus on in the second half of this year of going into 2016.

With respect to buy and build and specialty pharmacy, I'm going to have to get back to you on the split of that. But in all cases what we have seen is an increasing trend toward buy and build which is an advantage for us because that is a phenomenon that we think reflects not only a positive trend but also increased confidence that physicians have in the product and their ability to see a volume of patients.

Jason Gerberry - *Leerink Partners - Analyst*

Great, thanks.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Good morning. So you had mentioned that you took the big price increases and that there was a hit that you took to revenues for shelf stocking stuff. Can you help quantify what that number is?

Second on OPANA, you talked about abuse deterrent language potentially getting into the label. Obviously there is a panel coming up for some other products for abuse deterrence next month so has the FDA changed their mind finally? Can you just give us a sense of what is going on behind the scenes in your discussions with them and whether you actually believe that you are going to get a label change? And if so, it is going to differentiate from the generics and so is this going to have an impact to your business? Thanks.

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

Sure. Thanks, Marc. Let me have Suky maybe comment on the (inaudible) adjustment piece and I will comment on the OPANA ER piece.

Suky Upadhyay - *Endo International PLC - CFO*

As we guided back in the first quarter, we anticipated taking these price increases in the generics business and at that time we characterized the sizing as the impact on gross margin of about 800 basis points sequentially from first quarter into the second quarter. And the actual results actually came pretty much in line with that where we saw about a 700 basis point erosion from roughly a 57% gross margin in Q1 for generics going to about 50% gross margin in Q2 for generics. So that primarily was driven by the price increase penalties.

We would expect going back into the back half of the year to get back into the mid to high 50s on a gross margin basis.

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

And then on your question of OPANA ER, so we did meet with the FDA in June with respect to our complete response as well as o go through the most recent epi data that we have as well. And we left that meeting with more optimism than before. But that being said, I would not say that we have a very clear view to how the FDA would look at this but it was clear from the meeting that we would be in a position to file for a label update as soon as we can get that data together which will likely be the back end of this year or early in 2016.

But as you pointed out, there are lots of moving parts, there is a panel that is coming up and also how our patent hearings would also have bearing on this. But we always have been clear which is that there is a scenario where there is upside left in OPANA either because of the patent hearings going our way and all the FDA relabeling issue going our way. And as you know with the patents if they are upheld, they will at least last through 2023 and the Delaware patents that we are contesting actually last even longer. So we are cautiously optimistic on this one but it will be 2016 before we have any clear view on if there is true upside or not.

Operator

Liav Abraham, Citi.

Liav Abraham - *Citigroup - Analyst*

Good morning. Just following up on a previous question on business development. Rajiv, I would be interested in your thoughts on the valuation in the space given your focus on branded opportunities. Is this is a -- given what we have seen in terms of valuation, is this a limiting factor at all in executing on business development?

Secondly, just on the approval this morning of an additional generic for Lidoderm, can you just confirm that this launch is already contemplated and included in your 2015 guidance? Thanks.

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

Sure. Let me take the second question first because it is a simple one. The short answer is yes. From the very beginning of this year we had communicated our belief that there would be another generic entrant in the Lidoderm space in the second half so we are a month and a half into the second half roughly so this is in line with our expectations.

With respect to the business development question, I continue to be optimistic about the deal flow and the deals that we are looking at. Valuation certainly if you look at public market assets, there are certain assets that you could argue are trading at higher than higher values than they should

be. But keep in mind that in the end, our real value is we bring it back down to our M&A criteria. So we have clear views on what kind of internal rate of return we want to see, cash payback period, accretion to our organic growth rates and our overall margin profile and also time to accretion.

So we have been clear that as we do transactions that are in the branded space and are more likely to be longer duration assets that we may tolerate a longer period to accretion. So we have been clear that if we have assets that take 12 to 18 months to get to accretion that may be okay as long as we have a view to longer duration assets as well as accretion for our double-digit organic growth profile.

And I would also say we are not only looking at pure public market assets but we are also looking at cohorts and individual brands and other concepts like that. So our pipeline is pretty robust both in branded as well as the on the international front. So I'm cautiously optimistic that as we close the Par transaction there will be other things that we can turn our attention to.

Suky, do you want to add to that?

Suky Upadhyay - *Endo International PLC - CFO*

Yes, just to build on Rajiv's comments around Lidoderm, as he pointed out earlier, this was built into our assumptions for full year so it does not impact our guidance ranges around revenue and/or EPS as that was already again built in.

Liav Abraham - *Citigroup - Analyst*

Great, thank you.

Operator

Swati Kumar, Guggenheim.

Swati Kumar - *Guggenheim Securities - Analyst*

Thank you for taking my question. So in terms of STENDRA, you talked about starting the DTC campaign. Can you give us any idea on the color you have seen since you have done that? And also maybe your views on the US Generic business since there has been a lot of consolidation especially in the past year, how do you see that going and how do you see that impacting you as well? Thank you.

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

So on STENDRA, ultimately it is too early to tell because we are not seeing a step function change in the prescriptions yet. But that being said, most of our DTC was rolled out just towards the back end of June and in the month of July so and now we are in the summer period so we are probably looking at September, October before we can have a real view on the traction that we are getting.

But what I would say is that on the bulk of DTC which has been online and print and at least we are focused on the online part of it, there has been a very substantial increase in the number of hits that we are getting on the STENDRA advertising. But that is all a precursor to what we hope is a step up in prescriptions. So far so good but ultimately we need to see a real step up in prescriptions for us to be comfortable that this is a brand that we want to continue to invest in going forward.

On your question on the US Generics business, we have a very clear view that the true future at least for growth oriented companies in the US Generics is around specialty generics, higher barrier to entry products and that is going to continue to be hard on the commodities side. For us what is really encouraging is that this is exactly why we are acquiring Par and have had the pleasure of visiting many of the Par sites with Paul over the course of the last few weeks. And I have even greater encouragement and enthusiasm for the Par portfolio.

The injectables business in Rochester is doing extremely well and that is a business that we have a lot of optimism around as well as the broader pipeline of assets that Paul and the team have put together.

So I would say in general we don't see size as being the differentiator. Once you pass a certain threshold of critical mass, I think it really is the portfolio and the type of products will differentiate companies and I think we are ideally suited within the top five to be a company with one of the leading growth rates which we have already been clear is going to be at least in the low double digits.

Operator

Annabel Samimy, Stifel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Thanks for taking my question. Just wanted to get back to the branded business for a bit. After the Auxilium acquisition, the guidance was for double-digit growth. You are still at 8% growth so are you where you want to be with the branded business with the assets that you have right now to get to that goal? And when we are talking about business development there, is the need just more bolt-on asset acquisitions or are we looking more transformational again? Thanks.

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

Thank you, Annabel. So on the branded side, it is good progress but we are not there yet because what we have signaled is that on a longer-term basis we would expect this portfolio to get us to high single-digit to low double-digit. I think a clear expectation and aspiration is double digits. I think what we would need to see for that to transpire is a timely launch of BELBUCA and we are currently projecting assuming an on time approval that to happen in early 2016, continued progress on XIAFLEX including the new indications. So I would say we are making good progress but we would like to see a step up going into 2016.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay, thanks. The second part was the acquisition, the asset type acquisitions or is it more transformational that you are looking for there?

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

All of the above. Our appetite continues to be very aggressive on the business deal up in front and ultimately there is going to be a question of value creation and our views and any specific opportunity and we have no size limitations nor structural limitations in terms of the types of transactions that we would contemplate.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay, thank you.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. With respect to the growth outlook, could you just talk about some of the existing franchises and what your assumptions are and how we should think about pressures on certain franchises that you are expecting pressures for? So specifically for Voltaren, what should investors expect on that front in the context of you modeling double-digit organic revenue growth on a pro forma basis? Are you factoring in Voltaren winding down? And then if you could comment on any other franchises so we just understand how to model the balance of some of the upsides with some of the downside pressures? Thank you.

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

Sure, David. I assume your question is on the branded portfolio. Is that correct?

David Risinger - *Morgan Stanley - Analyst*

Yes, correct.

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

So let me step through it. I think if you go through the major products I think our expectations on Lidoderm are very clear which is that we expect this to be subject to multi-source generics by the back end of this year and therefore should be at some tail going into 2016. That is not going to be a meaningful contributor to growth.

OPANA ER, I have already discussed which is that in our basic guidance we have assumed a flattish profile for it which is kind of a maintenance of the current status quo. But if we are able to build on the momentum we have generated with the FDA and we are able to get to a positive outcome in 2016 and all be successful in our Paragraph IV litigation, there could be some upside in OPANA.

Voltaren Gel, in our own planning, we have assumed that the product will go away sometime in mid 2016 which is when the current agreement with Novartis expires. But we have also been open that we are continuing our dialogue with Novartis -- sorry, this is now the Novartis GSK joint venture which actually owns this brand, to find a way to potentially continue that promotional agreement beyond mid-2016.

All that being said, a lot of this is dependent on if and when the first generic Voltaren Gel appears and we have looked at our guidance as an assumption that we would have a generic for this product towards the back end of this year. But I have to admit there is no conclusive evidence that there is one. But we do continue to model that in into the back half of this year.

And assume that the product goes away in 2016 so really the growth assets that we are relying on for the go forward branded business are BELBUCA and the XIAFLEX franchise and STENDRA could be a toggle up or toggle down on that which is I think that if we are successful with the relaunch that will be a contributor to growth and if not, it will not be a brand that we continue to support.

There are a whole host of other brands that also contributes to growth. So AVEED is actually showing very nice performance in 2015 really building on the new (inaudible) and the combined field force. Smaller products like Supralin LA are doing very well and growing nicely as well.

So there is a portfolio of these smaller growth assets which will supplement BELBUCA and XIAFLEX so that is generally how you think about the branded portfolio. Does that help?

David Risinger - *Morgan Stanley - Analyst*

Yes, that is very helpful. Thank you.

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

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

Operator

Corey Davis, Canaccord Genuity.

Corey Davis - *Canaccord Genuity - Analyst*

Thank you very much. Just in general, how are you feeling about the overall environment for pain drugs right now? And what do you think of the trajectory for BELBUCA is going to be at launch and is there any change to how big you think this drug could ultimately be?

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

I think there is obviously a lot of discussion around the pain therapeutic area but the reality is that is an area of extremely high unmet need and despite the concerns around opioids I think they have a place in therapy, especially for postsurgical patients and others dealing with severe pain and we do continue to see a future in it.

We continue to be very encouraged by BELBUCA simply because of the progress that we are making with the FDA in our discussions around the product and also our continued belief that this is going to be a Schedule 3 product because we have seen a contraction of the market for example the hydrocortisones as they have been up scheduled from Schedule 2 to Schedule 2, so there are patients that are dropping out of the system and we think for an effective product that is Schedule 3 with hopefully a label that is on par, that there will be a real place in the market. We are have continued not to provide specific guidance on what our peak sales estimates are for BELBUCA but we continue to be very optimistic about it.

Just wanted to additional things as Jason had asked about the buy and build percentages we do have it. So if you take -- if you kind of blend Peyronie's and Dupuytren's is roughly 65% specialty and 35% buy and build and the buy and build percentage is a little higher for Dupuytren's versus PD at this point but as I said, it is an increasing trend and we are hopeful that we can continue to see that balance shift more towards buy and build.

Corey Davis - *Canaccord Genuity - Analyst*

Thanks, Rajiv.

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

I believe that was our last call and question. Thank you everyone for joining us today. Have a great day.

Operator

Ladies and gentlemen, thank you for your participation in today's conference.