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ENDP - Q2 2016 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 2Q16 GAAP EPS of $1.75. Expects 3Q16 revenues to be $830-870m and adjusted EPS to be $0.77-0.82.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q2 2016 Endo International PLC. earnings conference call.

(Operator Instructions)

As a reminder, this conference is being recorded. I would now like to introduce your host for today's conference, Ms. Keri Mattox, Senior Vice President of Investor Relations and Corporate Affairs. You may begin.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thank you. Good afternoon and thank you for joining us to discuss our second-quarter of 2016 financial results. With me on today's call are Rajiv De Silva, President and CEO of Endo; Suky Upadhyay, Chief Financial Officer; and Paul Campanelli, President of Par Pharmaceutical. We have prepared a slide presentation to accompany today's webcast, and that presentation, as well as other materials, including a frequently asked questions document, are posted online in the investor section at Endo.com.

I would like to remind 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 we are furnishing 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 Pharmaceuticals Inc. - President & CEO*

Thank you, Keri. Good afternoon, everyone and thank you for joining us for today's call. I hope that you have all had a chance to review the Company's earnings press release that we issued earlier today. Let me now turn to our second-quarter 2016 earnings presentation. To start, here is a brief agenda for today's call.

Moving to slide 3, the second quarter was a busy and productive one for us at Endo. I am pleased that we delivered solid revenue and adjusted earnings per share results in the second quarter, with revenue performance across all business units, broadly in line or ahead of Company expectations.

We also made substantial progress on our continued focus on operational execution, and enhancing flexibility for our business. We have made an important addition to the management team, made good progress on key growth drivers, and progressed our ongoing legal entity reorganization, which provides us with operational flexibility and benefits. Suky will talk about this reorganization in more detail, later in the call.

Again the backdrop of this progress, we are taking steps to increase investments in our future organic growth drivers. Branded and generic R&D, as well as BELBUCA and XIAFLEX promotional efforts. Importantly, we are pleased to affirm our full-year 2016 revenue and adjusted EPS guidance, despite these additional investments.

On slide 4, you will see a snapshot of our solid segment results for the second quarter. Moving to slide 5, let me discuss in further detail how we remain focused on operational execution, and achieving our key milestones. We announced the appointment of Joe Ciaffoni as our new President of the US branded business.

We are delighted that Joe has joined Endo, bringing his proven expertise in launching and growing branded products, and look forward to his contributions when he assumes his new post later this month. We continue to drive growth in our generic sterile injectables products, and our generics base business is performing right in line with the expectations we communicated to you in May of this year.

We secured a patent for our largest product, Vasostrict, and continue to launch differentiated generics products and filed new ANDAs with the FDA. In our international business we filed our BELBUCA submission, and secured rights to XIAFLEX in Canada. And we have also advanced our branded R&D pipeline and have recently opted into another new potential indication for XIAFLEX, human lipoma.

So on slide 6, let's discuss our branded business. Our branded performance in the second quarter was broadly in line with our expectations, which underlie our segment revenue and margin guidance, provided in May. We drove continued XIAFLEX demand vial growth, particularly in Peyronie's disease.

We are advancing our BELBUCA launch efforts, increasing the total prescriptions to date and growing the number of repeat prescriptions. In the quarter, we also saw better-than-expected results driven by contracting for the branded Voltaren Gel, and performance across some of other products such as LIDODERM, Nascobal, and Supprelin LA.

Moving to slide 7, let's take a closer look at XIAFLEX performance. We are making good progress with this key growth asset, and that is translating into continued growth. In Peyronie's disease, a market that we think has considerable growth and expansion potential, we delivered nearly 20% demand growth in the second quarter, versus the same period last year. We continue to expand our physician injector base, and our disease awareness campaign, Ask About the Curve, has shown early signs of successfully engaging PD patients.

In Dupuytren's contracture, a more mature market, and one where XIAFLEX launched more than five years ago, we still drove 5% demand growth in the quarter of the second quarter last year. Revenues for the quarter were impacted by greater than expected destocking. For the full-year 2016, we now expect low double-digit pro forma revenue growth for XIAFLEX.

On slide 8, let's move next to international pharmaceuticals. We continued to drive performance in line with expectations that underlie our revenue and margin guidance, provided in May for Paladin, Litha, and Somar. At Paladin, we filed our BELBUCA submission, and acquired the Canadian rights to XIAFLEX last quarter both products are potential long-term growth drivers for the business. And the additions will provide longer-term growth as we manage the expected loss of exclusivity on select products in the Canadian market this year.

In our Litha and Somar businesses, our underlying revenue growth is outpacing market growth rates, largely driven by volume, and we continued to improve our operating margins. Now, to talk about our US generics performance, let me turn the call over to Paul. Paul?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Thank you, Rajiv, and thank you all for joining us on the call. Turning to slide 9, we remain focused on the continued integration of Par and Qualitest, advancing our pipeline and restructuring our manufacturing footprint for improved margins, all while delivering performance in line with our expectations.

Our sterile injectables business continues to grow, led by Vasoscript. Importantly, we also secured a patent for that product that does not expire until 2035, and which we believe further strengthens our market position. In our new launches and alternative business segment, we've launched 11 products since the beginning of the year, and continue to file new ANDs with the FDA, while replenishing our R&D pipeline.

As we expected, and in line with trends consistent across the broader generic industry, our base business declined by approximately 5% sequentially from first quarter 2016, driven by consortium pricing pressures and competitive generic entrants. Finally, our adjusted gross margin for the generics business remained in line with expectations. I would like to note that second-quarter revenues benefited modestly from some favorable time in between Q2 and Q3, driven by customers advancing some of their orders ahead of the Fourth of July holiday.

Moving on to slide 10, I'd like to provide you with an update on the action plan that we outlined last quarter, to drive long-term growth across our generics portfolio. While I won't go into the detail on each of these items, I do think it's important to note that we are in progress, on track, have already completed all the core components of our action plan. For example, we continued to make progress on key growth drivers like our 505(b)(2) and sterile injectable programs, as well as launching a steady stream of new, differentiated products this year. We're also reprioritizing and accelerating our R&D pipeline. We've already rationalized numerous lower value projects as part of our restructuring, and are on track to file to approximately 25 to 30 new ANDA submissions in 2016.

We made progress on our accelerated restructuring plan for the generics manufacturing network, and continue to project approximately $60 million in annual net run rate savings to be fully realized by fourth quarter 2017. We've largely completed the transition of the legacy Qualitest business onto the Par platform, including commercial insight, forecasting, wholesaler data management, and other capabilities.

And finally, we are executing on our operational plan. We have delivered a second quarter that is in line with the expectations that underline our guidance for revenue and adjusted margins previously communicated in May.

So let me talk briefly about our product launches to date, and those anticipated for the remainder of this year. On slide 11, you'll see a familiar chart. We have updated it to show all the products we have successfully launched so far in 2016.

You can also see those projects that we expect to launch into the marketplace in the second half of the year. Importantly, we're on track for our November and December 2016 launches of generic Seroquel XR and genetic Zetia. With that, let me turn the call over to Suky to discuss the financial performance of the Company in the quarter, and our projected outlook. Suky?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Thank you, Paul, and good afternoon, everyone. Let's start on slide 13, where we've outlined finance updates around the recent SEC guidelines, and our adjusted effective tax rate policy moving forward. As you are aware, the SEC issued non-GAAP compliance and disclosure interpretations, or C&DI, guidance in May.

Endo has adopted these guidelines, and as a result, is no longer extruding the non-cash deferred tax expense associated with acquired attributes in our adjusted effective tax rate. This policy has no impact on Endo's historic or forward-looking GAAP tax or cash tax profile. Also, the initiation of a legal entity reorganization in the first quarter has limited the impact of this change on our adjusted effective tax rate for the year, and moving forward.

Moving to slide 14, we've provided more detail about the legal entity reorganization that I just mentioned. As part of the continued integration of our Qualitest and Par businesses, we initiated a legal entity reorganization that moved the generics business to a new US holding company structure, that is separate from the legacy branded business structure.

The reorganization provides the operating flexibility and benefits, while also reducing the potential impact related to future limits on the use of tax attributes, by utilizing most of our attributes to offset an inter-Company gain. As a result of this reorganization, the tax basis of US generics business assets have been stepped up to their fair value, which will provide ongoing cash tax benefits, and flexibility in moving assets with limited tax leakage.

The utilization of acquired attributes that I mentioned earlier would have had an unfavorable impact of approximately $160 million on our full-year adjusted tax expense under Endo's non-GAAP policy, prior to the adoption of the SEC's C&DI. The elimination of this acquired attribute benefit was offset by an improved mix of jurisdictional adjusted pretax income, resulting primarily from the reorganization. This re-org also gave rise to a discrete net GAAP tax benefit of approximately $450 million in the second quarter, from outside basis differences. This benefit has been excluded from our adjusted effective tax rate, in accordance with our policy.

As I talked about earlier, as a result of the SEC's C&DI, Endo is no longer excluding the non-cash deferred tax expense associated with acquired attributes in our adjusted affected tax rate. However, since we utilized almost all of our tax attributes through the legal entity reorganization, the implementation of the updated C&DI guidance is not expected to have a material impact on our 2016 and forward-looking adjusted tax rate.

Endo continues to project an adjusted effective tax rate of 0% to 2% as guided in our first quarter of 2016 earnings announcement. We expect to have a GAAP tax benefit, and a negative cash tax rate for 2016. Importantly, for our outlook for 2017 and future years, we expect our adjusted effective tax rate to be in the high single digits to low double digits, and our average cash tax rate to be below 5% over the next five years.

Next, on slide 15, you will see a snapshot of the second-quarter GAAP and non-GAAP financial results. Rajiv covered Company and segment revenues earlier, so I will not review that here. On a GAAP basis, we delivered earnings per share of $1.75 in the quarter versus a loss of $0.49 in the second quarter of 2015. 2016 second-quarter GAAP results were driven by an operating loss of $48 million, offset by the tax benefit that I discussed earlier. The tax benefit also offset the impact of a higher share count in 2016.

Our GAAP operating loss was largely impacted by a decrease in op gross margins due to a higher mix of generic revenue in the second quarter compared to 2015, and due to incremental amortization expense associated with the stepped-up value of intangible assets from cost. On an adjusted basis, overall Q2 results are slightly better than previously guided.

To summarize the points Rajiv and Paul made, revenue was better than expected due to sterile injectables, stronger-than-expected performance from a number of branded products, and a modest timing benefit related to the quarter-end buying patterns. Adjusted net income and EPS are better than guided as a result of higher revenues discussed earlier.

On slide 16, while the second quarter was ahead of our guided expectations, we are maintaining our guidance ranges, as some of the upside in the second quarter was driven by favorable timing. As Rajiv mentioned, we are also going to invest at a higher level than originally planned in our key growth drivers in the second half of the year, through a reallocation of operating expenses and a modest step up in spending.

Regarding the cadence of revenues and adjusted earnings in the second half of the year, we continue to project the fourth quarter to be disproportionately larger than the rest of the year's quarters, due to the launches of generic Seroquel and Zetia. For third quarter 2016, we expect revenues in the range of $830 million to $870 million, and adjusted earnings per share of $0.77 to $0.82.

This implies a sequential step-down in third-quarter 2016. The anticipated decline is driven by the product order timing benefits in second quarter that we expect to reverse in third quarter; lower US branded sales related to generic competition for Voltaren Gel; continued slowing in the testosterone market; continued declines in legacy pain products, and an increased investment in R&D; as well as XIAFLEX and BELBUCA promotional efforts.

Moving to cash and liquidity on slide 17. On a year-to-date basis, GAAP cash flow from operations totaled approximately $555 million. We have also highlighted some of the material moving parts that have impacted our reported or GAAP cash flows for the year.

On slide 18, we are reiterating our review on cash available to pay down debt in 2016. We continue to project debt pay down of approximately $250 million in 2016, and to exit the year at a mid to high 4 times net debt to pro forma adjusted EBITDA leverage ratio. As noted in our press release, we ended the quarter with approximately $670 million in unrestricted cash, and approximately $390 million in restricted cash, and a net debt to leverage ratio of approximately 4.6 times.

To summarize, we are encouraged by our second-quarter financial results, and pleased to affirm our full-year outlook, while increasing investment in key growth drivers. Now to close up the call, let me turn it back over to Rajiv. Rajiv?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Thank you, Suky. Moving to slide 20, in summary, there are a number of key growth drivers that position our US branded business for long-term growth. We believe strongly in the significant in-market growth opportunities for both XIAFLEX and BELBUCA.

We are continuing to optimize our team and our business to achieve their growth potential, while also managing our diversified portfolio of other products. We are also accelerating our R&D pipeline to advance those programs, and the timelines for their potential market entry. We continue to execute on these growth drivers in the second quarter, and expect to achieve additional key milestones through the end of this year and beyond.

On slide 21, let's recap the key achievements in our US generics business. We are focused on driving growth through our differentiated higher barrier to entry products, like sterile injectables, and our robust pipeline of more than 250 programs post restructuring. We have a diversified reset

base business, and a robust, highly compliant manufacturing network. In 2016 and beyond, our success will be driven by Paul and his proven team, as they continue to execute on these opportunities.

Let's briefly summarize our call today on slide 22. In Q2, we delivered solid top and adjusted bottom-line results, beating our Q2 adjusted results guidance. We made substantial progress on our continued focus on operational execution, and enhancing flexibility for our business. And we are affirming our full-year 2016 revenue and adjusted EPS guidance, while increasing our investment in branded and generics R&D, and BELBUCA and XIAFLEX promotions.

Endo is executing on our strategic priorities, and we continue to believe that this is a time of significant opportunity for the Company, our employees, the patients we serve, and our shareholders. 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 Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thank you, Rajiv.

(Operator Instructions)

Operator, may we have the first question please?

QUESTIONS AND ANSWERS

Operator

Louise Chen, Guggenheim.

Louise Chen - *Guggenheim Securities LLC - Analyst*

So I had a few here. First question I had was on XIAFLEX, if you could give us more color on how you get to the double-digit growth for the year? And also what was going on with the customer destocking this quarter? Second thing is, I wonder if you have any update on the divesting of the non-core assets to pay down debt? And then last thing is, are you seeing any stabilization in your Qualitest business? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Sure. Louise, let me address the first two questions, and then have Paul addressed the third one. So in XIAFLEX, as we have commented in the past, the growth profile does tend to be a little bit lumpy, and have some seasonal fluctuations to it. So as you might recall, we had very robust growth in the first quarter. We have seen a little bit of a slowdown in Dupuytren's contracture in the second quarter. But as we look out over the remainder of the year, we do feel confident in the double-digit growth rate that we have talked about.

Now in terms of the revenue profile, as you know, customer stocking is largely out of our control, though typically XIAFLEX stocking in the special distributors and the specialty pharmacy in general is around 14 days, about two weeks. But from time to time, we do see some unusual changes to it, which is what happened in the second quarter. Our stocking is around one week. So approximately half of what it typically is.

Now we have seen this behavior in the past, and typically over the course of the year, it tends to normalize. But by and large, it is out of our control. So what we look to is demand vial growth, and that's why we would look at the 19% growth in Peyronie's, we do feel very good about the indication, given that from a longer-term perspective for our unmarketed indications, the biggest opportunity is in Peyronie's.

In terms of divestments of non-core assets, I just wanted to be clear that from a Company perspective, we don't feel compelled to divest any assets. We are confident in our business, and the natural delevering nature of the business, given the substantial cash flows, particularly as you look beyond the known mesh payments in 2016 and 2017. That being said, I think we've also been clear that as a Company and as a Board we are always -- we are shareholder friendly, and in the event that there are any opportunities that come our way that are value creating, we will certainly evaluate them as an as-needed basis.

Paul, maybe you can comment on the Qualitest base business?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Sure. So Louise, I would say that we're really not separating out the Qualitest and the Par businesses too much any longer, but at a high level, when you look at the Qualitest business for the most part, it's really known as a base business play. When you look at our base business play, we define that as the pain control substances, as well as the oral extended release and immediate release products. That also includes some of the Par portfolio.

When you look at that on a quarter-over-quarter basis, we communicated this at our last earnings call, that we were anticipating about 5% erosion quarter over quarter. And that's exactly where we landed. So it's in line with our expectations and how we communicated, so generally our base business is falling in line, and we're not seeing the heavy erosion that we realized in Q1.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we have the next question, please?

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

I have a few. First, for Rajiv, can you comment on whether the Company is considering any business combinations right now? I know you're open and shareholder friendly in general, but maybe you could comment specifically whether there's anything being considered at this point.

And Paul, can you confirm that there been no P4 certifications on Vasostrict since you got that patent issued? Can you quantify the stocking benefit for your business? And can you comment on whether you have an ephedrine filing in, or a program in the works? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Thank you, Gregg. As you know the Company doesn't comment on any ongoing business deals, though I would continue to stress that our priority for this year is operational execution, and hopefully what you've seen from us is a quarter of delivery around that. And again, as I have said in the past, our Board is always open to shareholder friendly strategic opportunities, and we will remain open to such opportunities that they come our way. But really our focus now is on the operations of the business. So let me just turn to Paul, and there were three parts of the question, Paul, for Vaso, stocking, and ephedrine.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

I'll be brief. I think in case of Vasostrict, to answer, we have not been noticed of any Paragraph IV filing. In terms of stocking, I think we're at normal course right now. We believe that we are -- basically our run rate is, we have converted all the unapproved product to approved products, so we're

really normalized in that regard. And then Gregg, I think your last question was on ephedrine, and I think what we can say right now is the case that any product that we are essentially not our policy to discuss any product that we don't already disclose into our corporate presentations at this point in time, Gregg.

Gregg Gilbert - *Deutsche Bank - Analyst*

Sorry on the stocking, I meant for you to quantify the wholesaler buying pattern benefit in the quarter, for the overall portfolio, sorry.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Gregg, this is Suky. That's always an inexact science, when you're trying to measure exactly when an order comes in from one period to the next, especially around a holiday weekend. But where we are now, we would estimate that around $15 million to $20 million in revenue.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator can we have the next question, please?

Operator

Annabel Samimy, Stifel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

I was just curious to know, last quarter, you talked about some I guess paring down of the commoditized portion of the base business. And so I was just wondering from that perspective on top of your balance sheet, how can we think about the way that's shaping up for 2017, in terms of reaching your delevering goals of being under 4 times in 2017? And can you still satisfy that with some of the mesh payments that you're still seeing? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Let me just have Paul address the portfolio rationalization question you had, and then Suky will talk about the delevering profile and expectation.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Sure. So regarding, really what we refer to as the restructuring the operations, there is about 70 or so products that we have discontinued or are in progress of discontinuing. So we're right on track, and that goes back to the $60 million annual net run rate that we anticipate for fourth-quarter 2017.

We've made some difficult decisions that we've talked about regarding the Charlotte and the Huntsville facilities, with respect to in terms of employees and the synergies. Those decisions have had essentially three waves to them. We've executed on wave number one, and we are on track to meet the expectations that we've communicated. So, so far we are executing on the plan.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Does that have any revenue and EBITDA impact right now?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Nothing above what we have already talked about on our first-quarter call, with part of the restructuring Annabel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay sorry. And that if you could just talk about the leverage? Sorry.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Sure. As I said, we're about 4.6 now, we expect to exit the year somewhere between mid to high 4s. A key component of that going into 2017 is we remain committed to delevering below 4 times over the midterm, is how we characterized it back on the first-quarter call. So we're not putting specific timing around that.

And then I think the offshoot to your question was something around mesh, and what I would say there is, as of the second quarter, we had just below $1.6 billion accrued on the balance sheet, with just below $400 million in restricted cash. So that's essentially money that's already out the door for funding of mesh, which leaves an incremental or remaining $1.2 billion on a pretax basis. We would expect that $1.2 billion to be serviced as another $300 million to $400 million in the second half of this year. And then somewhere around $600 million to $700 million on a pretax basis in 2017.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay, thank you.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we have the next question please?

Operator

Stephan Stewart, Goldman Sachs.

Stephan Stewart - *Goldman Sachs - Analyst*

Just a follow-up on the generic business. Wondering how much of the performance this quarter was volume versus price, if you exclude the base business and the benefit from the wholesaler buying patterns?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Suky, do you want to?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Sure, so I'd say, first of all, overall on a total generics portfolio basis, we're seeing more pricing pressure than pricing opportunity, and overall, our growth for this year on a pro forma and underlying basis, which we set in the low single digits will be primarily volume driven.

Stephan Stewart - *Goldman Sachs - Analyst*

Great, and just one quick follow-up. On the CDC prescribing guidelines, I know you did include something in the full-year guidance last quarter. Has there been any meaningful change to how you were thinking about it then?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

The trends continue, Stephan so there's continued pressure in terms of prescription volumes, in the opioid space, if you look at the branded space alone, new prescriptions on the brand in the branded world are down double-digit since the announcement of the CDC guidelines. But that is all incorporated, it was incorporated into our forward-looking guidance in May, and we don't have a different view in terms of the full year. We will of course take stock when we think about 2017 later on this year, or early in 2017.

Stephan Stewart - *Goldman Sachs - Analyst*

Great. Thanks for the questions.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we move onto the next question, please?

Operator

Gary Nachman, BMO Capital Markets.

Gary Nachman - *BMO Capital Markets - Analyst*

Rajiv, you mention improved contracting for some of the branded products in slides 6. Could you explain just a little bit more, how did this help you in 2Q, and is that sustainable? And also specifically, what are you planning to do to accelerate BELBUCA going forward? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Sure. Gary, in terms of the improved contracting, I think you may be referring to the statement that we made about Voltaren Gel, if I'm not mistaken. But certainly, in terms of our defense of the branded product, we've had better than expected success with contracting that we've done with commercial plans, and that's largely speaking, what's helped us in the first half of the year and as you know we have authorized the launch of our Voltaren Gel AG and that is taking place as we speak. I know over the course of the year.

And as you know, we have authorized the launch of Voltaren Gel AG, through Par, that is taking place as we speak. I know over the course of the year, we do expect the Impax generic to take more share of the oral molecule. And then Gary, your second question, I guess if we can repeat that.

Gary Nachman - *BMO Capital Markets - Analyst*

Yes, BELBUCA, you said you are increasing promotions behind it, so I'm just curious what your plans are.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

So in BELBUCA the feedback continues to be similar to what we talked about in the first quarter, which is positive feedback from physicians, positive feedback in the patient experience. The two areas which are leading to slower uptake of the product, beyond just overall environment for opioids, one is the process of getting the physician community comfortable with the tapering and titrating requirements, in terms of switching patients between different opioids and onto BELBUCA.

And secondly, it's around the payer environment and how they see the schedule 3 product. So on the latter, we made good progress. At this point we have contracted roughly around 85% of commercial lives, and about 70% of that without any restrictions beyond the label. We expect to continue to improve that over the course of the year, but of course at this point in a launch of a product like this, we don't yet have common reimbursement.

But what we see as being the real opportunity is the pharmacoeconomic and public health argument for why a schedule 3 product like BELBUCA is preferable to other opioids, such as the schedule 2 products, in terms of where is introduced in the treatment algorithm. And a lot of the investment that we are now making is around improving our fact base in terms of making those market access arguments. And clearly, we still continue to have a large investment from a field force standpoint, and that continues.

We also are increasing our investment around physician education, particularly around the treatment and titrating on the product. But really, the upside benefit and the longer-term growth of the product is really predicated on us being able to really anchor buprenorphine as an effective and safe alternative in the opioid space, both from a payer standpoint, as well as from a physician standpoint.

Gary Nachman - *BMO Capital Markets - Analyst*

Okay. Thanks a lot.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, I think we can move onto the next call, please.

Operator

Liav Abraham, Citi.

Liav Abraham - *Citigroup - Analyst*

First question is a broader question on the generics environment. Paul, I'd be curious if you anticipate any change in the environment, given that the Teva and Allergan Generics deal closed last week. And then secondly a question on XIAFLEX. I'd be interested in your thoughts on how you see the growth trajectory evolving post-2016, if possible. And perhaps you can touch on any updates on reimbursement and physician training, and how you feel about ongoing double-digit vial growth post-2016? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Paul, do you want to talk about the generics environment first?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Sure, Liav, it is Paul here. I don't anticipate any major changes for Par Endo, with respect to the Teva deal closing. I think we've stated before, in terms of competition, and how we feel about the consortiums, that at the end of the day, we've got ourselves four large consortiums that are representing about 90%, and we're going to have to still compete with Teva head-on, as we would in any case. And typically, you want to just be very careful about trying to go after too much share.

You just got to take the balanced approach. So I envision that we're strong competitors, Teva is a strong competitor. Even with the portfolio getting larger, we need to execute on our plan of bringing new products into the marketplace, and I don't think the fact that they've got the Actavis portfolio is a negative impact to Endo Par, if that's in fact is your question that you're trying to allude to.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Going to your XIAFLEX question, we continue to believe that there's a real long-term opportunity with XIAFLEX as a oral platform for the Company, given the fact that is a biologic, given the multitude of potential indications that we have, as well as potential in the unmarketed indications. That being said, we are not making any particular predictions around 2017 and beyond, but I would say that we are very optimistic when we look at the current results, that we are seeing in Peyronie's disease, which we think is a great opportunity of the two unmarketed indications.

And there are three areas in which we have made promotion investments, and we expect to step up for the remainder of the year, as well as going into 2017, and they will be the following: one is an area which you already talked about, which is that we continue to need to make the lives of patients when we prescribe a product easier, and it's mostly around reimbursement support, and we have substantially increased the level of internal resourcing around that, as well as targeted third parties to support that.

The second is a longer-term opportunity around disease awareness building, and we've been on to do piloting and early investments, particularly in Peyronie's, through our online campaign, Ask About the Curve. And it's of course it's too early to fully realize the benefit from it, or fully conclude what the benefits will look like, but the early signs of web click throughs and patient interest in going on to our site, to a physician selector, for example, is substantial uptick in that.

Now clearly for a product like this, the cycle from the time you get a patient interested in the product or interested in going to a physician, to the time that he would have an injection could be six to nine months, right? Which is why we always pointed to the back half of this year, 2017, before we really begin to see the benefits from it.

And the third thing I would say is, and this is probably more so true for Dupuytren's contraction than Peyronie's, is the need to make a compelling argument around the pharmacoeconomic benefits of an intervention like XIAFLEX versus surgery. And that's more for an opportunity for us in Dupuytren's contracture, where the hand surgeons and others who treat the condition often see the surgical option as the first option. And we of course, have had very good success with the product with these physicians, but getting to the next level is going to require making an even stronger argument around why is this in the best interest of patients.

Liav Abraham - *Citigroup - Analyst*

Thanks.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we have the next question please?

Operator

David Amsellem, Piper Jaffray.

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

So on Vasostrict, now with the patent in place, this is a question for Paul, maybe talk about how you're thinking about the longer term durability of the product. I think you'd said that competition could be a couple of years away. Is that still your latest thinking, or does the patent give you some more wiggle room?

And then secondly on the generics pipeline, and it may be premature to ask this, but beyond the bigger launches for later this year, maybe talk about some potentially significant launches, that you think could happen in 2017? Thanks.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Yes sure. So regarding Vasostrict, I would tell you it's still a little bit early. We do, in fact, feel better. Obviously we've got the Orange Book patent listed in June, I think it was June 28. The way we look at this product right now simply is from two different, two different views.

There was always a possibility that there could be a file that was an issue with the FDA pre-Orange Book patent listing, and that's something where maybe we feel a little bit better about -- and typically what would happen is if an application was in at the FDA for several months prior to the Orange Book listing, what you would expect is for a generic competitor to file a Paragraph IV very quickly, and then we would have been noticed. That didn't happen. From that standpoint, we feel a little bit better.

If an application went on file a month or two pre-June 28, or shortly thereafter, that's where we're not going to have that visibility. But if we were to get a Paragraph IV, say today, it would take about 60 to 90 days for an application to be accepted for filing. So we would probably look to be in a 30-month stay taking somewhere late fourth-quarter. That's the way I would start looking at it. So from that standpoint, we had originally said that we felt good through 2017, we probably will be in a position to say that we feel a little bit good through 2018. But we'll have better visibility around fourth quarter.

In terms of the generic pipeline, from a standpoint of where we feel real good about, I think we'd like to focus a little bit on the 505(b)(2) side. I think that's an area of strength of the Company. So while we haven't disclosed specifics, we do have a series of 505(b)(2)s that are starting to come through fruition, and frankly maybe we can talk a little bit more in terms of products that we feel a little bit better about.

We had previously talked about two 505(b)(2)s that we did not shed a lot of light on. We feel a little bit better about them now. They are two forms of potassium. One is a liquid, and one is a powder form.

We had started to receive positive feedback from the FDA in terms of removing unapproved sources. That's going to come to an end, whereby these unapproved sources will have the remainder of 2016 or so to have product into the market. These types of products will show benefit to Par and Endo in 2017. So that's an area that we like to focus in on.

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

Thank you.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we move to the next question, please?

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

I may have missed it, but could you just remind us what the BELBUCA sales were in the first and second quarter of this year, and how much you think you can ramp over the next couple quarters? Second, you mentioned that generics was reassessed to fair value. I haven't had a chance to look at the numbers there. Could you just talk about that, how it was valued, and what it was determined to be worth?

And then third, in terms of Vasostrict, we saw that you took a recent price increase at the end of July, of 20%. Just wanted to get a sense for how much upward potential you have for pricing. It seems like you have a lot of flexibility to raise price, but then again there may be push-back, I don't really know, and maybe you could also comment on how much of that will be able to flow-through, should be just assume that 20% largely flows through to pretax income? Or not? Thank you.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Let me answer the BELBUCA question and touch on Vaso, and I will, then on the pricing philosophy, I will have Suky and Paul build on the answer. So for BELBUCA in the first couple of quarters, we have been clear that we are using a pull through method to recognize revenue, so it has been minimal revenue recognition in the first half of the year, so single digit. And we've also been clear that, given our launch ramp expectation, that we expect the contributions in 2016 in total to be relatively modest. So we would look to 2017 really as the first year of revenue contributions in BELBUCA, and then we would be clear about what those expectations are at the appropriate time.

In terms of pricing, and I'll let Paul answer the specific question on Vasostrict, but I will point out the following, which is from an oral perspective, the Endo business benefits from volume, not price. And in particular, our generics business has predominantly more price pressure than upward price potential, and any prices, any price increase that we might be able to take on the two generics part of it is all run by the price erosion that we see on the base business.

Now, products like Vasostrict are a little different in that they are sold on the basis of NDA, although they're sold within Par. Even within those cases, we take a responsible approach to price increases, and just because we have flexibility, does not mean that we would take a price increase. In the case of Vasostrict, Par has been very thoughtful about how the price and the product is an NDA. If it were a life-saving product, it is still in the low hundreds in terms of -- about $125 or so, plus or minus, in terms of what a unit costs.

And a substantial money investment has also gone into our Rochester Michigan facility to support this product, and CapEx in excess of $100 million. And from a forward-looking standpoint our philosophy on price increases will not change, which is that we will be responsible about how we think about it. But Paul, I don't know if you have any specific comment on Vasostrict?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

I think Rajiv captured it very well. At the end of the day, we look at this life-saving drug and when we got the NDA approved, we do have to make commitments to the FDA, and we have to ensure that there's not going to be any drug shortages, and that we're going to be able to continue to supply the market. And to Rajiv's point, we had to make investments in raw materials and components and specific equipments for this particular product.

We had the CapEx that Rajiv is referring to, and in essence, 20% of our overall CapEx goes into the Rochester facility, to keep it compliant. So it's a big commitment specifically on this injectable product that's a life-saving product. And then in terms of like general price increases, and whatnot, I think again, when you look at the total generics business, in essence, we are a volume-driven company, to Rajiv's point. When you want to look

at it as a one-off in a product specific, in the case of this one product, it's true that we have taken some price increases, but they have been responsible. So with that, I'll turn it over to Suky to talk about the pretax question.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Sure. So we would expect that price increase to fall to pretax operating income, as any other price movement, either up or down, would fall to the bottom line, and through margin. And then, David, to your question on the generics fair value, you're correct.

Ultimately the restructuring or reorganization that we implemented ultimately steps up the fair value of many of the assets within our generics business. That is the tax basis of those assets, which provides ongoing and durable cash tax benefit, and also provides flexibility in our ability to move those assets throughout our legal entities, without residual tax leakage. Which is our policy, we don't talk to specific asset values.

But directionally, the way to think about how we value them, is on the future value, based on discounted cash flows of our outlook for each of the products, and that goes into all of our intangible testing, as well as our goodwill testing, et cetera. It's the same analysis that underpins the valuation, and ultimately the step up.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just two here. First, Paul, broadening out on Liav's question earlier, as you move past this reset of your generic base business, do you inherently see a more competitive generic industry than we have seen in the past, when we factor in a higher level of new product approvals from FDA, the behavior you're seeing from some of your larger and smaller competitors, et cetera. Or is this similar competitive dynamics than we have previously experienced in this space? And the second question was on the comment on the potassium products.

Can you maybe give us a sense of the size of those opportunities, as we think out to 2017? How attractive are these? How large of an end market can we think about? And finally are there any other 505(b)(2)s, not necessarily the names, but should we think about additional approvals in 2017 that could help revenue? Thank you.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So on the first part, in terms of the market competitive nature. I mean clearly with the consortiums getting larger, and we're seeing it now with Walmart now being part of the McKesson OneStop. The consolidation does put more pressure back on us, but I think from where we stand, we feel good about how we reset the base business. We talked a lot about that, in terms of, and I hate referring back to Qualitest versus Par, but when you look at our total business, we've made our decisions.

Right now it gets down to operational execution, and the way that we, that we compete is to execute flawlessly on our R&D pipeline. That's where we're focused right now. R&D execution and quality. These are things that are going to set us apart, because clearly consortiums are getting bigger, and that is going to create some more pressure on all the generic manufacturers.

The companies that are going to outperform are going to be the companies that are strong in compliance, strong in service levels, and have a pipeline. Those are three components that we feel that we're very well-positioned on the go-forward basis. Regarding the question on potassium, if I recall, and help me out here, I think we had shown a waterfall bridge about some, maybe the last quarter or so, that we were referring to some unapproved products that were delayed.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

I think what I would say Paul as we had referred to it, and Chris, if you would refer to our Q1 presentation, we had identified it, although we did not identify this is potassium, but now we can, the amount of revenues associated with this product that is pushed out of 2016. I would hasten to add though, that as the removal of the FDA, of the products gets pushed out, the possibility of new generic competition for the product is there at some point, right? So there is a finite life for potassium chloride, we don't quite know what that is. So I would not automatically assume that the same upside that we've moved out of 2016 would be there for 2017, but clearly, a substantial component of that will materialize in 2017.

Chris Schott - *JPMorgan - Analyst*

Thank you. One last question just on the final 505(b)(2)s. Are there other ones we should think about in 2017, or should we think about potassium at this point?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

I think right now, we're just prepared to talk about the two potassium products.

Chris Schott - *JPMorgan - Analyst*

Thank you.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we have the next question please?

Operator

Douglas Tsao, Barclays.

Douglas Tsao - *Barclays Capital - Analyst*

First, maybe Paul, if you could help us understand, in terms of your comment about 505(b)(2)s, in terms of the pipeline. Are you suggesting that the bulk of the growth we see from the generics business will come from the 505(b)(2) program through 2017, and does that last into 2018? And then just also, I was hoping to provide some additional color in terms of comment in the slides, that the generics business is going through some of the same dynamics that they were in 2008, 2009. Could you provide color in terms of what exactly those dynamics were?

And just in terms of the controlled substances generics business, one of your competitors had a better quarter, similar to you in terms of the near-term, but they did suggest that maybe some of the headwinds would persist into 2017. Are you expecting to see that same dynamic play out? Thank you very much.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Okay, so there's a lot there. Let's see if we can tackle it one by one. In terms of how we're looking at 2017, no, we're not going into great detail about 2017. I think that's something we have avoided providing guidance.

But maybe generally high level we are launching somewhere between 25 to 30 ANDAs in 2016. I would say that is probably a normal run rate for just an ANDA standpoint. On top of that, you're going to see the potassium product start to gain some traction. But I would tell you that there's not a blockbuster Zetia I am pointing to right now for 2017, but we have 25 to 30 launches that are going to make up a good part of 2017. They are all important, and that's the way that we're building out ourselves.

So you have to look at the ANDAs, you have to look at the 505(b)(2)s, and then on top of that, we have a very successful and growing injectables business, that is still a big part of our future, and we'll start to see more benefit of that particular segment, and our alternative dosage forms, all coming into play. So new launches are important, but we're also still driving value through some of our launches that we've seen in 2015 and 2016 on the injectable side. So that was the first question and --

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Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

I think I would just add one thing to that, Doug. Obviously I think what you are seeing from us is that the 505(b)(2) strategy is an important one to Paul, and there's obviously multiple ideas that Paul and the team have progressed at any given time, but we're not going to specifically talk about anything beyond the ones that we have, simply from a competitive standpoint. Paul, I think the remaining questions are on the dynamics in the market, and the 2008 timeframe and the controlled substance outlook.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So 2008, some of the challenges that we all had is that we all went through the economic crisis, and we had to make some difficult decisions back in 2008 and 2009. I think Par was hit fairly hard because of the type of portfolio that we had, which was a, for the most part, a commoditized business. And we had to make certain and tough decisions, based upon how we started looking at products on a go-forward basis.

And we were also a little bit on the volume side versus the value side, and we made a conscious decision to start to look towards more difficult to make products. Now, that's something that we've executed very, very well on, and that's where we're looking at our total portfolio. Now, immediate release products are always going to be important to Par, and that's going to help build volume incentive for wholesalers, but we're looking for longevity, and that's why you're going to see us move more towards the alternative dosage forms, the injectable forms, and continue at the Paragraph IV side.

That is a key difference from today versus where we were back in 2008. The challenge that we have today is the consortiums. The consortiums have gotten bigger and stronger, and that goes right back to having to execute on the earlier statement that I made, is the companies that are going to survive and do well are the companies that are going to have compliance across the board, something that we've done very, very well. We spent an enormous amount of resources and CapEx into compliance, service levels, and execution on the R&D side. And there was a question on controlled substance.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Controlled substance. The outlook.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So controlled substances, again, an important part of the overall portfolio. But it's not the barrier that it once was, and I think with the consortiums getting larger, they have allowed some new players to come into market and get quoted. We talked about this in the past. Still an important part

of our business, but it is more of a base business play, as I see it, right? So it's important but it's not the growth driver that it had been previously for a number of years. But again, for Par, every product is important. It just doesn't have the barrier that it once had.

Douglas Tsao - *Barclays Capital - Analyst*

And do you expect some of the headwinds to persist into next year?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Specifically in pain?

Douglas Tsao - *Barclays Capital - Analyst*

Yes, controlled substances.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Again, so where we're stunning to see the challenges that we're just seeing on the opioids, from the sheer nature of these types of products being somewhat out of favor right now, you're seeing erosion, that natural erosion across the board, right? Now what you're going to see is an uptick in other pain medications, right? Those are things that we also have to take into consideration.

So I'm not going to say it's an even trade-off, but the scripts have to go someplace. So maybe they're going to be moving away from opioids, but you have to look at our entire portfolio, and we have other products in our portfolio in pain that are outside of opioids. So that's pretty much the way we're looking at today.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

The other thing we would say is we don't expect to see a major reset, as we saw in Q1, against our pain portfolio, as most of that impact was already felt behind us.

Douglas Tsao - *Barclays Capital - Analyst*

Great. Thank you very much.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thanks, Doug. Operator, can we move to the next question, please?

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Paul, just to confirm. On these 505(b)(2)s, you have had the conversations with the FDA, you're comfortable that the FDA is actually comfortable with you, and the whole supply issues, and now the guidance is, we thought these products were going to launch next year, but now we have a lot of certainty, and we will be launching these products next year. So I just want to make sure that's what I'm hearing.

Second, when you talked about the $15 million to $20 million of buying patterns in generics that 2Q pulled out of 3Q, can you just tell us which area it was in? You break out the business and the base, but the injectables are the new launch alternative, so which one was it in? And then third, can just tell us what the gross margin was for generics for the quarter? Thanks.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Regarding the potassium products, I think the safest way to address the question is what the FDA is telling us is that we need to be prepared to produce product. And that is what we're doing. So in essence, our understanding is there's been a communication to the unapproved sources of liquid and powder, that there is a specific timeline that they have to finish up certain amounts of manufacturing, and the ability to sell through at a certain point in time. That's going to come to an end in 2016.

Now, there's going to be a product that will be in the market. What we don't know is exactly the number of units that these unapproved sources will be making of both forms of potassium. That will carry into some period of time. What we're saying now though is, that we have with reasonable confidence, that we are going to get the benefit in 2017. Likely we'll see the benefit in Q1 or Q2.

Marc Goodman - *UBS - Analyst*

And just to be clear, so what is new here is that actual communication from FDA to the generics has already gone out?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

That's our understanding.

Marc Goodman - *UBS - Analyst*

And that just went out, like in the past month? Or this is new news?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

This has gone out over the last several weeks.

Marc Goodman - *UBS - Analyst*

Okay.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Your question on the buying?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

So Marc, it's Suky on the customer stocking and the advancement of the orders, where we characterize about $15 million to $20 million. It's really across the entire portfolio, it's not a specific customer, or a specific product or segment. I kind of allocate it proportionately to our different business units within generics.

So base business is roughly around 50% of the total revenue so I would account for maybe 50% of that $15 million to $20 million in base, and the rest of it across the other portions of our business. I think there was another question on the gross margin, sorry. Gross margin held up, right in line with expectations. So we set guidance for full-year of generics gross margin in the low 50s, and that's where we ended in Q2, and our outlook remains consistent for the full year.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we move on to the next question, please?

Operator

Randall Stanicky, RBC Capital Markets.

Randall Stanicky - *RBC Capital Markets - Analyst*

I just have another generics question, and then a mesh question. But Paul just to approach the same topic from maybe another angle. As you think about the generics base environmentally 2Q versus 1Q, should we think about this as a reset and move forward with things improving, or do you still view this as, I'll call it cyclical uncertainty, that's going to linger as FDA continues to ramp approvals? Or a combination of the both?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So Randall, I don't think anything's really changed in terms of what we have communicated on the sequential erosion, right? So the important thing is that we dealt with the consortium bid cycle, and we all know what that impact was. The important thing is that the portfolio has been reset, resized, and we had 5% erosion sequentially between Q2 to Q1.

And while the major consortium hit is behind us, we still have the right of first refusal, if those are normal course. That's still going to come at us from a base business place, so I think we're going to stay with that 5% sequential base erosion, quarter over quarter, throughout 2016. After that happens, and we still feel good, we communicated as we get to 2017, that base erosion should normalize, and normalize was defined as historical Par base erosion, and that's where we were getting to that, that 10% number, maybe even a point or two higher. But about 10% is where we're looking at on a go-forward basis we enter 2017.

Randall Stanicky - *RBC Capital Markets - Analyst*

But stable beyond?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

I feel that it will be stable, I don't see a large consortium hit that we experienced with the McKesson OneStop, so from that standpoint, yes. It will normalize. Now, I'd like to see what happens with Walmart as it enters into OneStop, that's also something that we need to think about. But at this point in time, taking that into consideration, we still feel that 10% will be the right erosion factor on a go-forward basis.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay, great. And then, Suky just a quick question for you on mesh, for the after-tax mesh liability for the next year. Has this changed from the number you gave us in early March, and then the lingering 8,000 cases, any change in how you are thinking about those?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Sure. I'll talk to the numbers, and maybe Rajiv, you'll talk to where we are on the rest of the cases. So on a pretax basis, consistently around $600 million to $700 million next year, and then there is a tax shield on that, which is ultimately embodied in a low single digit tax rate for 2017. So we do expect to see a cash tax rate for 2017, so we do still expect to see a post-tax mesh cash call, which is significantly lower than $600 million to $700 million, so nothing has changed on the front and then on the remaining 8,000 cases?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Sure, Randall. I think you are referring to that comment that we made earlier this year, when we entered into a settlement around some high-value cases. At that time, we said that there was another purported 8,000 or so cases out there, which largely speaking, did not -- largely speaking, did not have much information about those cases. That has not changed.

And the incidence of new claims coming in has also been -- has trickled down to the low single-digits on a weekly basis. And has been fairly consistent for the last several months. The other thing we pointed out with those 8,000 cases, was that there was potential fraudulent scheme that was running through, some component of that, and our priority was driving that to the ground, and figuring out whether in fact there was fraud perpetrated.

So we have a series of subpoenas that have been issued, we are in litigation more around those subpoenas, but as you pointed out back in the beginning of the year, this process could take months, if not several quarters, to solve, and we continue to vigorously defend ourselves through this process. So in other words, no new news, in terms of mesh.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay, that's great. Thanks.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thanks, Randall. Operator, can we have the next question please?

Operator

Andrew Finkelstein, Susquehanna.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

I was hoping to go back to Vasostrict. There was a suit filed by a potential competitor, and I was wondering if there any statements you can make about your contractual relationships with API suppliers for vasopressin. And as we look at the run rates for some of the branded products in the quarter, is there anything else to point out? You talked about the destocking on XIAFLEX, but some products like LIDODERM and OPANA, how do you characterize the sales for those in the quarter, relative to what you might consider a run rate, based on where the scripts are? Thanks.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So on Vasostrict, obviously we're not going to be speculating on any ongoing litigation, and I think what we can do is just really reaffirm some of the facts that we've discussed on some of the other earnings calls. It is true that we do have an exclusive arrangement with a single API source, and it is understood that there are multiple API sources available. And ultimately, we are prepared to vigorously defend our intellectual property and also our position with respect to this particular case. So that's probably as far as we can go at this point in time.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Is that to say that you do not have exclusive arrangements with the others?

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

I think what we said is that we do have a single exclusive arrangement with an API source.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

And Andrew, just on your question about the branded products. We have the benefit of a pretty diverse portfolio of products beyond BELBUCA and XIAFLEX, though obviously we pointed those out as our future growth drivers. And from quarter to quarter, we are able to benefit from the performance in those brands.

So there are brands like LIDODERM, which as a branded product, has now really been reduced to a small component, because the product is, as far as we are concerned, fully genericized with three generic competitors in the market, including an authorized generic. But from a contracting standpoint, we still hold some proportion of the market on our branded product. But feel it is subject to generic pressures.

OPANA, we pointed to OPANA as one of the products that was impacted by the CDC guidelines and the general slowdown in the opioid market, and I think that trend is continuing along the lines that we expected. We also have a series of smaller products that we don't talk much about, that are also doing quite well, there are promoted. Supprelin LA has been a very sticky and very good performer for us, for a long period of time.

Nascobal, which is a product that came over with the Par transaction, and is a branded product that is promoted by our field force, is also doing quite well. So as we look across the portfolio in the branded business, beyond the ones that we actually talk about, we do see points of good performance, which has helped us in Q2, and we expect to help us over the course of the remainder of the year, as well.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks very much.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thanks, Andrew. Operator, can we move onto the next question, please?

Operator

Jason Gerberry, Leerink Partners.

Jason Gerberry - *Leerink Partners - Analyst*

Most have been asked, but maybe Paul, I didn't hear you mention adrenaline as a 505(b)(2) opportunity. There was a big pickup in price in June IMS sales, and just curious if that's there's the potential opportunity there, how you think about the market, where is the market competition mainly in compounding pharmacies? Just curious if you have any thoughts there, that would be great.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Adrenaline is very similar to Vasostrict, with the exception that adrenaline is typically first-line therapy, when you go into an emergency room, with respect to cardiac resuscitation or anaphylactic shock, followed by Vasostrict. So they are basically sold and promoted exactly the same way, just one is first line and one is second line.

With respect to the uptick, right now we took an appropriate price increase, it is an NDA. We follow the same practice in terms of it being an unapproved product. It is now an approved 505(b)(2), so it's now similar in nature to what we've done with Vasostrict. But for the fact that there are unapproved sources of adrenaline on the market today.

Jason Gerberry - *Leerink Partners - Analyst*

Okay. Thanks.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thanks, and operator, can we move onto the next question, please?

Operator

David Buck, Northland Capital Markets.

David Buck - *Northland Capital Markets - Analyst*

One for Paul, and one for Suky. Paul, in your commentary on Vasostrict, you talked about converting the unapproved products, and talk a little bit about the price increase that you recently took. Is it fair to say that you have gotten most of the volume opportunity that you've expecting, and that there will be more even volume, and you're just benefiting from that recent price increase?

And for Suky, can you talk a little bit about what you see is some of the key detractors sequentially, with regard to the third-quarter revenues. Looks like a fairly strong downtick. I know that the wholesale volume is not going to recur, but what other items are you expecting to go the other way, to go negative? Thanks.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

So Dave I think you understand the Vasostrict situation pretty well. We launched the product probably about a year and a half ago, and the way we see it right now is that we do not believe that there's any more unapproved drug in the market, so maybe the last quarter or two, you're seeing standard run rate for Vasostrict, so I think we've met our max on the volume side of Vasostrict. That's where we are now.

As Rajiv indicated, we took a modest price increase. That's the way this product is going to behave on a go-forward basis. So I think we've maxed out on the volume side, and it's just being able to navigate with the market, and if we were to take appropriate price increases on a go-forward basis, but we haven't made any determinations yet.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Yes David, and this is Suky, on your question around the third-quarter sequential reduction. The first thing I would say is, generally as a default, we tend to prefer not to give quarterly guidance, because there are a lot of things that can affect a quarter specifically around timing, that could be material to the quarter. But in a whole year basis, they're not meaningful.

But having said that, given our reset in Q1, and given the launches that we've got in the fourth quarter, we are providing quarterly guidance, at least for this year. For the third quarter, the way to think about the step down is one you talked about already, which is the stocking that we saw on the second quarter. Our assumption is that reverses in the third quarter.

Also what underpins our assumption of the step down is continued erosion in V Gel, as that continues to face competition from a generic standpoint. We would expect LIDODERM to step down modestly. Our testosterone products continue to decline quarter over quarter, particularly because of the market. And then again we also expect to see some modest decline in our pain products.

All of those declines are partially offset by growth in XIAFLEX and BELBUCA as well as Par launches, but net-net, our assumptions lead us to a decline on revenue into the third quarter. From an investment standpoint, that's all coming in the backdrop as we increased our investments against generics R&D as well as branded R&D, and BELBUCA and XIAFLEX, as Rajiv has talked about earlier. So those are the moving parts that lead us to the third quarter. Again, what we're doing is taking a very prudent approach to applying quarterly guidance, given the lumpiness of the year.

David Buck - *Northland Capital Markets - Analyst*

That's helpful. And is there any change in assumptions for branded gross to net, that's negative sequentially?

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

At this point we wouldn't see anything material sequentially. Again, there can always be lumpiness from quarter to quarter, but for the full year, our gross margin profile for the brand remains.

David Buck - *Northland Capital Markets - Analyst*

Okay. Thank you.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thank you. Operator, can we move to the next question, please?

Operator

Donald Ellis, JMP Securities.

Donald Ellis - *JMP Securities - Analyst*

But since you traffic in the opioid market pretty significantly, what can you tell us about your current thoughts about when, how, and if there will be a meaningful transition to the opioid deterrent versions of narcotics?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

As you pointed out, we have had a lot of experience in heritage in the pain market, including in opioids. And we ourselves have done a lot of work around OPANA's reformulation, in effect to make the use of the product more difficult. That being said, I think the public health environment debate around this, if you look around this, while encouraging abuse-deterrent formulations, it's still unclear at what point the entire market will shift to products that are quote-unquote abuse deterrent.

So in terms of the FDA's own determination of what constitutes it, there's a lot of debate. We don't have a crystal ball, and we'd be speculating, but we certainly as we look, forward longer-term perspective one of the things that the long-acting products would transition to more abuse deterrent formulations, but is that going to happen in the short term? That is anyone's guess.

Donald Ellis - *JMP Securities - Analyst*

How do you think that they are going to do with the pushback from the PBMs and reimbursing for likely more expensive abuse-deterrent versions?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Again, look, I'd be speculating but I would also say the following which is, while there is a lot of debate in the public health environment about this, and certainly from the payer environment as well, in the end, chronic pain is one of the most unmet needs, in the country. There are 100 million patients who suffer from chronic pain, and there are certain categories of pain, such as cancer pain, where your are going to need an opioid in order to survive and manage that kind of pain. So I think in the end, from a pure patient need standpoint, we do believe that the opioids and schedule 2 opioids will have a place in the market for that. From a pricing standpoint, and how PBMs view it versus regulated, that I really can't answer.

Donald Ellis - *JMP Securities - Analyst*

Thank you very much.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Thanks, Donald. Operator, we have time for maybe one or two more questions.

Operator

Elliot Wilbur, Raymond James.

Elliot Wilbur - *Raymond James - Analyst*

Real quickly, maybe just a point of clarification for Paul. Paul, earlier when you talked about 2017 returning to more of a normalized erosion environment for the generics business, mentioned essentially a 10% erosion rate, maybe a couple percentage points more. I just wanted to make sure that applies to the entire generic book of business, or just my assumption would be the injectable piece, of course, would be much more stable, and that rate would apply to the solid dose business. But I wanted to confirm that.

And then for Suky, a question earlier was asked about the ability to realize price increases on Vasostrict, and just trying to get a better sense of how we should be thinking about the Company's ability to realize list price increases, whether or not there's been a change in the relative realization rate, in terms of what's actually dropping to the pretax line.

And the last question, for Rajiv, you talked about several times now about accelerating investments and continuing to invest additional resources on the R&D, and the selling and marketing side to drive some of your future high-growth assets. And obviously the message is been heard loud and clear with respect to 2016, but I guess in thinking about external expectations in 2017 and 2018 and beyond, it seems like the anticipation at this point is that spend levels remain relatively flat. I'm wondering how you're thinking about that, maybe in general terms, at least directionally. Thanks.

Paul Campanelli - *Endo Pharmaceuticals Inc. - President, Par Pharmaceutical*

Elliot, this is Paul. To the first question, I apologize if I wasn't clear. In terms of that 10% range on base erosion, that is as we define, the collective Par and Qualitest business, as we look at how we define base business, and that includes our extended release solid oral doses, our immediate release solid oral dosage, and our pain control substances group.

So it excludes injectables, it excludes the alternative dosage forms, and of course new products. So that's the way we're defining it. And maybe could just help me out on your Vasostrict question, I want to make sure I understand it. I know it went to Suky. Maybe just repeat that for us?

Elliot Wilbur - *Raymond James - Analyst*

The long and short of it is, if the list price goes up 20%, has there been any dramatic change in terms of what the Company can actually realize? The pretax line.

Suky Upadhyay - *Endo Pharmaceuticals Inc. - EVP & CFO*

Sorry, Elliot, and I guess this goes back to the question that David asked, as well. We don't see any major change in the complexion of gross to net on Vasostrict than where we are now.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

And then Elliot, in terms of your question on investment, probably step back for a second here. Over the course of the last three years, we made some major steps, major progress in reshaping the Company, and I think we find ourselves now in a very good position, where we have some great assets across all of our businesses. And as we transition our business to really being a organic growth story, it is a very important imperative for us that we begin to really invest for future sustainable organic growth.

And hence the investment step up that we're talking about in R&D, hence the investment behind assets like XIAFLEX and BELBUCA that we think are going to be real growth drivers over the course of the next five years. At this point, we can't make any comment on investment levels in 2017 or 2018, but I would point to the fact that what we're talking about is investing in long-term growth assets. So long-term growth asset requires long-term investment, and that's our philosophy. And obviously, we will take a more specific view on what that means for 2017 and beyond when we get there.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, can we move to the next question, please?

Operator

Rohit Vanjani, Oppenheimer.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Thanks for taking the questions. One, did you notice any favorable share shift in OPANA, after the District Court ruling in May? Two, I think you took price increases at the beginning of 3Q on a series of products. LIDODERM, Percocet, Supprelin, and then we mentioned Vasostrict. Are your wholesaler contracts structured pretty typically, where they have a 30-day buy-in, so you'll see two thirds of the price increase in 3Q and then the full amount in 4Q?

And then could you actually give the XIAFLEX vials shipped and the breakdown in Peyronie's and Dupuytren's for 1Q and 2Q? And then lastly, the strength in -- so for the guidance, where you maintain the guidance, but you have this added expense in BELBUCA and XIAFLEX. So what's making -- I was a little confused about how you're maintaining. Is it from the strength in the quarter, and the surprise in V Gel and other products that's allowing you to maintain the guidance, or where is that offsetting strength coming from?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

So there were a lot of questions, there. I'll see if I can get at all of them, and I'll ask Suky to help me with that. In terms of OPANA, just to clarify your question, was it, were you talking about the patent cases, the rulings, and our path forward, there? Is that accurate?

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

I was just asking if you saw a share shift because one of the products got pulled, right?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

A share shift. I'm sorry. So yes, we've seen a modest share shift, but as we had always indicated, the majority of the prescriptions we expected to go to the Impax generic, which it did.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

I was just wondering if there was any upside from whatever you thought.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

Look. There are puts and takes in OPANA, right? So there's a little bit of modest uptick in share, and possibly continued uptick because of our increased promotion, because the product is in a P2 position behind BELBUCA, and our pain field force. On the other hand you have the declining opioid market effect, right? So net-net, it is not a product where we expect to see any substantial uptick.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

You had a question on XIAFLEX, so in terms of XIAFLEX vials, I would be happy to go through them, but they are in our FAQs for the first quarter as well as second quarter.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

We could do it off-line.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

It's already in, if you want to take a glance through it. It's identified between the two indications.

In terms of your question about investment, the increased investment in R&D, and the markets. So some of it, as Suky mentioned in his script, is simply a reallocation. And some of it is a modest uptick in investment level, particularly in the third quarter. Which is one of the other contributing factors to how we guided the third quarter.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

I was asking for the offset, so you had, what's new is you have the added expenses in BELBUCA and XIAFLEX, and you're still maintaining your EPS guidance, right? So I was wondering what changed for you that was positive to make you keep that? Was it the strong quarter where you got strong V Gel and other products, or is there something else going on, where you're allowed to maintain your guidance?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

So part of it is the upside coming from the second quarter. Part of it is that we do feel good about how gross margins, how the gross margin profile is trending in the second half, as well.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay and the last one I had was the bit about your price increases, where you took some price increases on LIDODERM and Percocet and Supprelin. Do you have typical wholesale contracts, where they get a 30-day buy-in so you see maybe two-thirds of the price, and then the quarter you take the price, and then the full amount in 4Q?

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

We don't have, we don't have that phenomenon in our wholesale agreement. What I would also say is that much of our branded portfolio is contracted. So list price increases don't automatically translate into gross margin improvements. We have generally pointed to the overall price increase benefit generally is in the mid single digits for our branded portfolio, on a full-year basis.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay. Great. Thanks for taking my question.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

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

Operator

Irina Koffler, Mizuho.

Irina Koffler - *Mizuho Securities USA - Analyst*

It seems like XIAFLEX is doing really well, and it's a very durable asset, and same thing with Supprelin LA, you are doing a great job with those two products. But are you really the best owners of these assets? Do you have the right synergies, and would someone else potentially value these assets more? Thanks.

Rajiv De Silva - *Endo Pharmaceuticals Inc. - President & CEO*

So Irina I can't speak to how someone else would value the assets, but I would say that these assets fall squarely into the type of assets that make sense for a company like us. They require a relatively small sales and marketing footprint. The type of support, in terms of advertising and promotion, that's required around the brand, even with the step up, is well within the means of a company like us. And also when you look at the R&D pipeline, and the investments that are required to develop XIAFLEX, which is already a well-characterized molecule from a safety and effectiveness standpoint, we do think we're the right owner of these assets.

Keri Mattox - *Endo Pharmaceuticals Inc. - SVP of IR & Corporate Affairs*

Operator, I think that wraps up the call. We would like to thank everyone for joining us this afternoon.

Operator

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