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EDITED TRANSCRIPT

ENDP - Q1 2016 Endo International PLC Earnings Call

EVENT DATE/TIME: MAY 05, 2016 / 8:30PM GMT

OVERVIEW:

Co. reported 1Q16 results.



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PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the Q1 2016 Endo International plc earnings conference call.

(Operator Instructions)

As a reminder, this conference call is being recorded. I would now like to turn the call conference over to your host, Keri Mattox, Senior Vice President of Investor Relations and Corporate Affairs. You may begin your conference.



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

Good afternoon and thank you for joining us to discuss our first-quarter 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 is posted online in the Investor Section at Endo.com.

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

In addition, during the course of this call, we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used by other companies. Investors are encouraged to review Endo's current report on Form 8-K furnished with the SEC 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 Health Solutions - 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 first-quarter 2016 earnings presentation.

On the next two slides, you will see a brief agenda and an outline of key themes for today's call. To begin, I will provide a snapshot of our first quarter financial results, which, despite some headwinds, were largely in line with our expectations. However, these headwinds have created substantial challenges to overcome in the remainder of the year. We are providing revised full-year 2016 guidance today to reflect these challenges. We will spend some additional time discussing the state of our business, key drivers for this rebasing, and our action plans moving forward.

Specifically, there are three factors to call out that we'll discuss in more detail on today's call: deeper-than-expected erosion in the legacy Qualitest business, delays in FDA actions related to our 505(b)(2) products, and an earlier than expected generic entrant for Voltaren Gel. Importantly, we will also talk about why we believe that our core growth drivers will continue to provide opportunities to execute against our strategic plan and allow us to return to organic growth, improve margins, and delever in the medium term.

Before we begin, I would like to take this opportunity to welcome our two new Board members on behalf of our Board and the Company. We are delighted that Doug and Todd have accepted our invitation to join. We look forward to their contributions.

Moving to slide 6, you will see the Q1 snapshot of reported segment revenues. In our branded business, we saw solid continued growth for Xiaflex, which performed well despite the expected historical trend of Q1 seasonality. This growth was offset in part by a decline in Voltaren Gel due to that product's loss of exclusivity in March and continued pressure on the pain market.

In our generic's segment, the base business erosion continued into the first quarter and was significantly deeper than we expected at approximately 30%. This was driven by continued pricing and competitive pressures on our commoditized and pain products. The erosion was partially offset by strong performance from our sterile injectables portfolio, including Vasostrict and the overall performance of the legacy Par portfolio. We will return to these themes when we discuss full-year guidance.

The international business performed as expected with a modest decline in reported revenues. However, our emerging markets businesses continued to show both constant exchange rate revenue growth and underlying growth, as well as margin expansion.

On slide 7, you will see our first quarter segment revenues, as well as reported and underlying growth.

Next on slide 8, we provided our first quarter financial results.



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Moving on to slide 10, let's talk about the state of our business and the context in which we are viewing the remainder of 2016. To best understand where Endo is now, it's important to also understand where we've been and what we've built.

When I joined the Company in 2013, we charted a new strategic course and outlined some very clear goals, as seen here in the left column. Over the next three years, we set out to achieve these goals and position Endo for growth. That strategy is still core to Endo and to how we run our business; however, what has become clear is that the 2016 specialty pharmaceutical landscape and market forces require an evolution of that strategy.

So let's talk about our path forward. Our goal has not changed; we continue to aspire to build a leading global specialty pharmaceutical Company. What has changed rapidly is the landscape and market environment within which we are operating, particularly in generics.

What does this mean going forward? It means we are reshaping the path forward for Endo. We are rebasing expectations for the business, and are evolving our current strategy to meet challenges and capitalize on opportunities. Ultimately, we are positioning the Company for long term organic and diversified growth, margin improvement, and delevering.

So let me now turn the call over to Paul to discuss key factors and drivers related to generics. Paul?

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Thank you, Rajiv, and thanks to all of you for joining us today. Let's start with a snapshot of our Q1 2016 generic's revenue on slide 13. Here we present a bridge between our pro forma generic sales for Q1 2015, and Q1 2016 underlying and actual sales. The variances between the sales totals resulted from a greater-than-anticipated erosion in base business of approximately 30%, driven particularly by the legacy Qualitest portfolio. While we expected base erosion to be higher in the first quarter than the full year, the actual erosion was much deeper across our pain portfolio and other commoditized products than originally anticipated.

By contrast, the legacy Par portfolio is performing on track with internal expectations. Our sterile injectables product portfolio continued its strong performance with 86% growth over Q1 2015. Our new launches and alternative dosage product portfolio performance was stable and largely unchanged year over year. So let's discuss the factors that impacted these Q1 results and that we believe will shape our full year generic's performance.

Moving to slide 14, there are rapidly changing market conditions that have affected both the broader generic's sector and Par. First, we have seen a steep and rapid price erosion caused by pair consolidation that has been more even profound than anticipated. Its effect has exceeded what might have been expected from an ordinary downturn in the industry's traditional pricing cycle. The impact has been particularly acute in the more commodity like product categories, such as our pains and control substances portfolio and our immediate release solid oral dosage forms.

Second, coupled with this consolidation and new payer environment, competitors are taking aggressive pricing actions to gain market share. Examples include both the 300 and 325 milligrams strength of hydrocodone APAP, butalbital, morphine sulfate, and oxycodone.

Third, there's been a rapid erosion of the pain segment driven by three things: one, continued market contraction; two, increased competitive capacity and pressure; and three, while still too early to judge the full impact, we believe the recently issued CDC guidelines will continue to put pressure on a already soft pain market. As you may know, approximately 40% of the legacy Qualitest portfolio was comprised of pain products. So this sector-specific weakness has had a disproportionate effect on our generic's business.

Fourth, there's been a recent and marked acceleration of FDA approval for generic products. While we'll ultimately expect this to also benefit the Par portfolio and our own pending submissions over time, the approvals and launches seen in late Q1 and in April of this year have resulted in greater competitive pressure for our products.

Fifth and finally, delays in expected FDA actions related to our 505(b)(2) products means that we have yet to see the anticipated removal of unapproved competitive products from the market. Correspondingly, we have yet to achieve the market exclusivity that we expected for these



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products. It's important to note that we still expect these FDA actions but now on a delayed timeline. The removal of relevant unapproved products may not occur before first half of 2017 versus our original expectation of early 2016.

Now that we've talked about what has happened in the generic's market, let's also take a few minutes to review when some of these events surfaced, thereby impacting our generic business. In 2016, it's important to note that the US-generic landscape has continued to shift with significant events and updates as recently as late March and April. In fact, it was not until late March that we confirmed the delays on regulatory actions related to our 505(b)(2) products that I just mentioned.

Then in April alone, we have seen at least five competitive product approvals and additional market entrants. Finally, we've also just completed our consortium bid cycle, with a more negative output and an increased pricing pressure than we anticipated.

Moving to slide 16, I do want to take a few moments to discuss our ongoing integration of the Qualitest and Par businesses. Last fall in Q1 of this year, we were conducting an integration of two complex generic businesses. What became very clear to those of us who have been in the generic industry for some time is that the legacy Par operating model is better positioned to address the challenges of today's evolving market. As a result, we set out to shift the legacy Qualitest portfolio strategy from a high volume approach to the high value operating model long practiced by legacy Par.

As part of the integration activities, we're also transitioning the legacy Qualitest systems and processes to the Par business platform. The legacy Par systems offer more real-time and product-level data, allowing for faster analysis and reaction within a challenging and changing market. While many of these improvements were already planned at Qualitest, the integration of our business will accelerate the benefits.

Next on slide 17, let's talk about what we are doing to address these challenges and best position our generic business moving forward, our action plans. First, we are continuing to maximize our key growth drivers, such as our sterile injectables portfolio led by Vasostrict, and approximately 30 new products we expect to launch this year.

Next, our platform for long term organic growth is our R&D pipeline. We are continuing to advance these more than 250 projects post reprioritization and anticipate filing 20 to 30 new submissions in 2016 alone. We also accelerating the implementation of an optimization and restructuring of our product portfolio and manufacturing facility network. I'll talk more about this restructuring shortly.

Additionally, we are accelerating the move of legacy Qualitest business onto the Par platform. This is already substantially complete, as our commercial insight and forecasting capabilities have been fully transitioned.

Finally, critical to our action plan is our ability to execute. This is not the first turbulent market environment that the Par team has successfully navigated. Our team is seasoned, capable, and proven.

Moving to slide 18, now permit me to provide some additional detail on the restructuring I mentioned earlier. Most importantly, this restructuring is an acceleration of our ongoing integration and broader optimization efforts designed to prioritize and grow high value durable assets. It is entirely consistent with all our integration activities to date.

The restructuring will affect our manufacturing sites in Charlotte and in Huntsville, and will result in more than 60 product discontinuations. In addition, we are pruning less value driven R&D projects so that we can prioritize our investments on differentiated and high-value products.

We expect that the restructuring will be completed by the third quarter of 2017, and will result in a total of approximately \$60 million in annualized net run-rate savings by Q4 of 2017. We expect to see about \$10 million of that gross margin improvement this year.

As a result, shortly, we will begin the process of informing employees about these changes. As part of that effort, approximately 740 employees will be impacted under a phased transition. For Endo, the Par management team, and for me personally, this is both an extremely and disappointing to our Company.



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We value our people, and for those who will be affected, we thank you all for what you've contributed to Endo. We will be providing resources to help manage through this difficult transition. And while change is never easy, it is necessary to better position our generic's division to successfully compete in the US-generic's market.

So on slide 19, let's talk about our full year revenue outlook for the generic's segment. We have previously expected a mid teens underlying growth rate for the business. Given the erosion now forecasted across the sector, and particularly for our base business in the delay and regulatory action related to our 505(b)(2) products, offset by the strong growth projected for our sterile injectables and new launches and alternative dosage portfolios, we now expect underlying growth for our generic's business to be in the low single digit percentage range.

We do expect that erosion of our base business to moderate back to rates typical for the generic industry beyond 2016. The erosion in 2016 is expected to be more acute than historical trends, due to our relative pricing and share levels in the pain markets prior to the observed and expected erosion.

Moving to slide 20, you will see a look at our Q1 2016 reported generic net sales annualized versus our full-year 2016 guidance midpoint. You can see the projected decline due to non-base business competitive entries and base erosion, which we expect to be approximately five years per quarter through the end of the year. Our new product launches are a significant driver of growth, as illustrated by the green block, and bring you to our projected generic net sales midpoint for the year.

Now let's look at our 2016 launches on slide 21. We are on track to launch nearly 30 new products this year; four of these are first-to-file products including our generic's Seroquel and generic Zetia products that will launch in the fourth quarter of 2016. Another 2 launch products are alternative dosages, and another 9 are sterile injectables. Importantly, and as an illustration of our value-focused strategy and platform, nearly one-third of our projected launches are products that will be exclusive or face only one generic competitor.

Finally, let's close this generic's discussion with a quick review of our robust R&D pipeline on slide 22. As I mentioned earlier, we have more than 250 projects in our reprioritized R&D pipeline. We anticipate launching more than 100 of them between 2016 and 2019, representing a total current market value of nearly \$30 billion.

Our pipeline is robust, diversified, and populated by a higher barrier to entry in higher margin generic products. We believe that positions us strongly for future growth. I am confident in our platform and I believe that our pipeline is truly differentiated. I know that our team has the experience and the ability to address these challenges and to deliver future generic's growth and margin expansion.

With that, let me turn the call back over to Rajiv for a discussion on our branded business. Rajiv?

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Paul. Let me now take a few minutes to discuss our US-branded business. Before I start, I would like to acknowledge the contributions of Brian Lortie, President, US Branded Pharmaceuticals, who will be leaving us to pursue other opportunities. Brian has been a critical part of the efforts to reposition our Company over the last three years. We will miss him at Endo and wish him well in his future endeavors.

Moving to slide 24, let's talk about factors affecting our US-branded business. First, there has been a recent generic entrant for our Voltaren Gel product. This generic came into the market earlier than we expected, and it has affected our 2016 outlook for VGel.

Second, we have seen increasing pressure on our brand pain segment. This includes additional competitive entries, as well as a continually increasing number of public policy and regulatory actions, such as the recent CDC guidelines around opioid prescribing end use. Additionally, there are reimbursement restrictions now in place for Lidoderm, further limiting the use of that brand of product.

Against this backdrop, we do continue to see significant growth potential in our differentiated product BELBUCA. However, it has progressed at a slower pace than we initially expected, due to pain market pressures. That said, we continue to believe in the future of this product, as a schedule III alternative in the opioid category.



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On slide 25, you will see the opportunity for BELBUCA, the first and only Buprenorphine buccal film for chronic pain management, which we launched in late February this year. There are about 90 million total prescriptions written for the treatment of chronic pain below 160 milligrams morphine sulfate equivalents, or MSEs.

BELBUCA is well-positioned to [source] patients, both from short-acting opioids as well as other long-acting opioids. Given the size of both these segments, even with the relatively small share of the available prescription base, BELBUCA could become a very meaningful product in this category.

It is also important to note that even in these early days, BELBUCA is not only capturing switches from LAOs, but also from SAOs and new therapy starts. Further, we have seen an increasing number of repeat prescriptions week over week. Its differentiated profile is resonating well with physicians and patients across the spectrum, and our early feedback on access, ease-of-use, efficacy and side-effect profile have all been positive.

Along these lines, let's look at slide 26 to talk more about early progress on the BELBUCA launch. There are three areas that we have focused on in terms of early launch traction and feedback. While I won't talk through each bullet here, we did want to provide a comprehensive look at where we are making progress and where we see opportunities to further accelerate BELBUCA launch traction.

Next, on slide 27, let's talk about Xiaflex. Xiaflex continues its double digit demand growth profile, and we are making good progress in growing that business. We see a significant opportunity to expand both our share of the current treatment market, as well as the size of the overall markets for both Dupytren's contracture and Pyronie's disease.

Across both of the DC and PD indications, we have new initiatives focused on driving growth. We are working to broaden our active injector base and have improved targeting to reach the most appropriate physicians.

Our DTC and print ad campaign efforts are also showing signs of real traction. For example, visitors to the Ask about the Curve website spend about 10 times longer on the site than an average website visit. And about 1 in 10 visitors click through to find the Pyronie's disease specialist in their area.

We have also worked to improve convenience of physicians through our reimbursement support initiatives and our product savings program. Overall, these efforts position Xiaflex for strong, continued growth. We expect mid- to high-teens percentage growth in 2016.

Moving to slide 28, let's talk about the other driver for Xiaflex growth over the long term: our robust R&D pipeline. We see significant opportunity and substantial value for Xiaflex across both therapeutic and aesthetic indications, and have talked about how the product could be \$1 billion franchise for Endo by the mid 2020s. That opportunity is driven by the more than 12 potential indications currently in the R&D pipeline and the multiple additional programs and even earlier stages of development.

As part of our evolved corporate strategy and initiatives to return to organic growth, we are accelerating our R&D programs for Xiaflex and plan to move five programs into the clinic even earlier than previously expected in 2016. It is a time of significant opportunity for these growth drivers in our branded business. We have taken steps to best seize those opportunities and accelerate their growth, while also managing the legacy products within our portfolio.

With that let me turn the call over to Suky to discuss our full-year 2016 financial guidance. Suky?

Suky Upadhyay - Endo Health Solutions - CFO

Thank you, Rajiv, and good afternoon, everyone. In an effort to provide you with more clarity, we are providing additional details on how the factors and market conditions that Paul and Rajiv discussed will impact Endo through the rest of 2016.

On slide 30, we have provided an outline of the key components of change to our rebased revenue guidance that lead to an 11% reduction. As you can see, the largest driver of the change is the greater-than-expected erosion in our generic's base business. As a reminder, we define base generics as extended release, immediate release, and pain and control substance products.



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As with the branded business, our rest-of year projections are based on business and commercial assessment and recent trend analysis at a product-by-product level that also takes into account the outcomes of recent bid cycles and competitive actions.

Approximately 55% of the decline is related to price erosion and 45% relates to volume declines. This is an important variable, as price declines fall to margin at 100%. I should also note we expect to realize the value of delayed 505(b)(2) actions later in 2017.

Next on slide 31, let's look at the drivers for the changes in our projected gross margin for 2016. Our previous guidance was 63% to 65% for the full year. Given the impacts of key events and market factors, we now expect full-year gross margin to be in the range of 59% to 60%.

Using the midpoint of the previous and revised guidance range, we expect gross margins to decline about 17% versus prior expectations. We are projecting a disproportionately higher erosion on gross margin versus revenue due to a number of factors that you will see detailed here in the blue callout box. Importantly, we do expect to realize gross margin for our 505(b)(2) products in 2017, and we expect to offset the 2016 under absorption through rationalization efforts into 2017.

Moving to slide 32, we have provided a bridge from our previous EPS expectations for the full year to our revised guidance. The reduction in EPS reflect the revenue and gross margin drivers that I've just discussed. We've taken actions to help offset the declines we are projecting.

In 2016, we are reducing OpEx across SG&A, while remaining focused on prioritized investments against growth drivers and accelerating our branded R&D programs. And we project improvement in our tax rate. Lastly, we are taking actions to improve our gross margin profile through the plant rationalization that Paul covered earlier.

On slide 33, you will see our 2016 financial outlook by business segment, including expected, reported and underlying growth rates and gross margins across the portfolio. The branded business growth rate reflects the loss of exclusivity of VGel. The generic's outlook reflects the declines in the base business and the delayed regulatory actions that were discussed earlier. And international is broadly in line with previous expectations.

Next on slide 34, we have outlined our full revised 2016 financial guidance. From a cadence perspective, we continue to see revenues and EPS weighted to the second half of the year, driven by the launches from the Par portfolio and continued growth from Xiaflex and BELBUCA.

We now expect approximately 46% of revenues and 39% of full-year EPS in the first half of 2016. This implies a sequential step down in Q2 due to a number of drivers, including the full-quarter impact of recently launched generic competitors that we talked about earlier on the call. In addition, we expect a ramp-up in spending in the second quarter primarily related to our acceleration of R&D programs and commercial efforts in US branded.

We have talked through the moving parts around revenues and gross margin. We expect interest expense to continue to be about \$455 million. Our tax rate will be lower due to continued progress around planning strategies, and due to a lower mix of US-sourced income while maintaining static debt benefits and acquired attributes. Depending on the nature and timing of potential discrete items, the cadence of tax rate through the year can be lumpy. Consistent with prior commentary, we do expect a step up in our tax rate in outer years. We now project that rate to be in the high single digits.

Next on slide 35, while first-quarter cash flow from operations was negative, it was impacted by a number of items that we consider to be non-core. After considering these items, underlying cash flow from operations continues to be well correlated to adjusted net income.

I will also note that our working capital metrics are in line with our expectations. Consistent with prior quarter, we have provided more details around working capital in the appendix of this presentation.

Moving to slide 36, it is important to note that we continue to project robust cash from operations prior to legal related cash calls. I will note that in early Q2, we received the full tax refund that we pointed to earlier in the year. Ultimately, we expect to use remaining cash to pay down approximately \$250 million to \$300 million in debt in 2016.



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Finally, on slide 37, let me provide you with a snapshot of our liquidity profile. This is important because our cash position and liquidity ratios remain strong and well within our covenants, as defined under our debt agreements. We do not foresee any challenge in remaining well within those limits in 2016 and beyond.

We expect our net debt leverage ratio to remain in the high 4 times in 2016, with some fluctuations based on quarterly cadence. We continue to remain committed to delevering into 3 to 4 times range over time.

In summary, as we rebased our outlook for our business, which is driven by the factors that Rajiv and Paul spoke to earlier, we remain: committed to driving financial discipline, including taking actions to improve gross margins; investing in growth drivers; becoming more efficient around G&A; continuing to improve our underlying tax rate; optimizing our cost of capital; driving improvements in working capital; and improving after-tax cash flows from operations to service our liabilities and for investments in future growth.

With that, let me turn the call back over to Rajiv.

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Suky. Now that we have discussed the market factors, what we are doing to address them, and the anticipated impact on our 2016 financial expectations, let's talk about how Endo is positioned for 2016 and beyond.

On slide 39, you will see the corporate strategy as we laid it out in 2013 and the actions we took to rebuild the business over the past three years. We have successfully changed the structure, the businesses, and the growth profile of Endo. Now, given the evolving market conditions, it is time for us to continue to evolve our corporate strategy and transform the Company for long term, durable growth.

On slide 40, let me talk about how we feel Endo is positioned for growth. Our aspiration to build a leading global specialty pharmaceutical Company that improves lives and creates value has not changed. We are mindful though that we need to set appropriate medium-term goals, reflecting current market conditions. This has meant a rebasing of our financial guidance for 2016 and a reset of our previous expectations for 2017.

However, our goals are clear: return to organic growth at levels above market averages, improve operating margins to be greater than 40%, and delever to between 3 to 4 times. Three core areas of focus will enable these goals: growth in our branded business and the Xiaflex pipeline, growth in our generic's business and pipeline, and the ongoing optimization of our existing business.

Moving to slide 41, there are many key growth drivers that strongly position our US-branded business for long-term growth. We know we have significant end-market growth opportunities in both Xiaflex and BELBUCA. We are continuing to structure our team and our business to achieve that growth potential, while also managing our diversified portfolio of legacy products.

We are also accelerating our derisked innovative R&D pipeline to advance those programs and the timelines for their potential market entry. As we execute this year, we will be achieving key milestones across our US-branded business and we will keep you updated regarding our progress.

On slide 42, let's talk about the durable portfolio and pipeline we have in our US-generic's 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 and, importantly, 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 execute on these opportunities.

Let's summarize on slide 43. We have rebased our business and believe this is the time of significant opportunity for Endo. We have a clear plan to focus on strategic priorities: a return to organic growth, margin improvement, and delevering.

Our key future growth drivers continue to provide promise to deliver against these strategic priorities. And perhaps most important, Endo is a resilient organization and we're all committed to our future. Together, we will execute on our evolved corporate strategy and achieve our goal to deliver products that improve patients' lives while creating value for our shareholders.



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

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

Thank you, Rajiv. We'd 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

Randall Stanicky, RBC Capital Markets.

Randall Stanicky - *RBC Capital Markets - Analyst*

Rajiv or maybe for Paul, can you just talk about how much of this impact in generics is from new competitive entrants versus some of the consortiums coming back and pressing you on price? And then part of that thinking is as the FDA continues to approve more drugs, is there a risk that this continues? Is this just in pain or is it more broadly? Thanks.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Randall, I'll have Paul answer that question.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

I think it's really ultimately, it's a mix. When we look at the consortiums, clearly we're disappointed. We did have some loss of business across the legacy Qualitest business. So from that standpoint, it was hurtful. I would say that it was tempered by some successes on the sterile side from the Par portfolio, so from that standpoint it was a positive effect.

When we look at the balance in terms of specifically in the legacy Qualitest portfolio, we had challenges both in pain and really the solid oral dosage immediate release portfolio. And what we were seeing was it was a combination of new competitors coming into the market that were established, as well as just first time players, as well. So it was a combination of some smaller generic competitors entering the market that ultimately pushed the price down. And a lot of these occurrences were coming in the late March and April timeframe.

So in essence, it was several factors in terms of competition, as well as loss of business. And clearly on the FDA side in terms of new competitors coming in and new approvals rather, I think with the GDUFA really starting to hit, we are going to see more players in some of these commodity-based products. But at the same time, we have 150 products at the FDA, so you should also assume that we will also get the positive impact of the quicker approvals. So at the end of the day, we will get our fair share of wins.

Randall Stanicky - *RBC Capital Markets - Analyst*

Paul, on that, on slide 20 you call out, I think it's \$415 million of new launch revenue that you're pointing to on the back half. How much of that is date certain versus assumed or approvals?



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Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Yes. Right. So we've talked a little bit about this, around 75% is the new launches.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Great, thanks.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Thank you.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Thanks, Randall.

Operator

Jason Gerberry, Leerink Partners.

Jason Gerberry - *Leerink Partners - Analyst*

I just wanted to follow up on this 505(b)(2) issue that you're facing. I imagine the Vasostrict was a strong product for you in the quarter, based on the IMS data. But how many products -- it sounds like -- it's not that you didn't get 505(b)(2) products approved, but that the FDA didn't remove certain unauthorized product from the market. So how many products are we talking about? If you can provide a little bit more detail there, that would be great.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Sure. So Jason, we have two 505(b)(2)s. They're both approved, so when we say the delay, we're talking about, to your point, working with the FDA to follow have the unapproved sources come off the market. Now, what we were seeing in the case of Vasostrict, we were successful in a timely fashion. But it's getting harder because the FDA is looking towards drug shortages and really having a high confidence that we're going to be able to supply the entire market.

So in these two particular products that we were talking about, that's where we are faced. We are partnering with the FDA to show that we have the ability and give confidence that we can supply the entire market. We are hoping that was going to happen in early 2016. I think the benefit of having these unapproved sources exit the market will be realized in 2017. It's not that it won't happen, it's just really pushing until next year.

Jason Gerberry - *Leerink Partners - Analyst*

If I could squeeze a follow-up in. Just for Suky, I know you're pushing out the leverage target to mid-3s now beyond late 2016. Can you just talk about some of the 2017 variables on cash generation that will help you delever? I know you have the FTC lawsuit now. You've got mesh. But could you just walk us through some of the puts and takes there?



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Suky Upadhyay - *Endo Health Solutions - CFO*

Yes, sure.

We're not going to give guidance on 2017 at this time. There are a number of moving parts that have to play out throughout 2016 before we're in a position to provide that type of guidance. But going into 2017, we would expect to continue to delever. We do see ourselves pushing that target from 3 to 4 times from 2016 into 2017 or beyond.

There are a number of moving parts that will help with that. Without giving specific guidance, some of the things I've pointed to earlier is late in this year we will build about \$200 million of working capital as part of the Seroquel and Zetia launch; that will be recovered in the first half of 2017 as we actually collect the cash on that revenue booked in 2016.

As we move into next year, we expect mesh gross payments to moderate down slightly. This year we would see those mesh payments as being somewhere \$800 million to \$900 million. Next year we would predict that would be somewhere around \$600 million, so we should see a step down in gross mesh payments into next year.

And then the other big drivers are on capital expenditures, we do see a step up this year as part of the integration of Par and Qualitest. It's primarily around the implementation of ERP systems; that should moderate down into 2017. And then we could see a slight step up in the contingent consideration line that I've outlined here for 2016, primarily due to the 505(b)(2) products that Paul has spoken to, as well as V Gel. So there's a couple of moving parts that can help you shape where 2017 cash might be. But again, we do expect over time to delever back into that 3 to 4 times range.

Jason Gerberry - *Leerink Partners - Analyst*

Great. Thanks.

Operator

David Amsellem, Piper Jaffray.

David Amsellem - *Piper Jaffray & Company - Analyst*

You might have mentioned this, so I apologize if I did miss it. But on Vasostriect, does the rebased guidance reflect any competition this year on the products? And just can you just remind us your latest thoughts on when you do expect to see competitors on that product?

Thanks.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Okay. David, hi, this is Paul. Regarding Vasostriect, right now we are well protected with our API source. From that standpoint we feel as though that we are well-positioned at least through 2017 on the exclusive basis. We are working very diligently with the PTO in order to get patent status, which you would then have our legal team immediately list the patent to the Orange Book. That has not happened yet; it is in progress. But at this point in time, our defense is really our API source; that should get us through at least 2017.

David Amsellem - *Piper Jaffray & Company - Analyst*

So no competition in the guidance this year?

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Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

No competition in the guidance.

David Amsellem - *Piper Jaffray & Company - Analyst*

Thank you.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

The first one is it just seems like things have gone very bad very quickly, a number of line items of your business over the last month and a half or so. What gives you confidence this round of cuts, captures, and accurate view of the business going forward? Has there been any change in approach to how conservative or not you're being with the guidance this time around? Or just addressing investors' concerns that things can continue to deteriorate in the business, can you just, at a high level, just address that question?

The second one was talking about the generic outlook in 2017. Just from our perspective, what do you think it's going to take to stabilize the legacy Qualitest business? And just how are you thinking about growth in the portfolio overall, once we get through this difficult 2016 and start to think about the longer-term portfolio?

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Sure, Chris, let me just start and I'm going to have Paul continue. Now, in terms of the things that have gone wrong this year, you're right, we've had several things that have not gone our way. And many of those things, an actually all of those things have played out over the course of the last four to six week, so in the second half of March, and in early April.

But I will point to the three things that have happened, so the three material things that have happened. First one is the earlier-than-expected launch of the Voltaren Gel generic. We clearly didn't see it coming as early as it did; we had forecasted toward the very, very backend of this year at worst and best case into 2017.

Now that being said, we knew that there was going to be a generic for Voltaren Gel at some point. Right? And in fact, the newly revised agreement with GSK and Novartis give us the right to an authorized generic, so we will have a tail of that product going through 2017 and beyond. So yes, there was bad news, it was earlier than expected, but not something that fundamentally impacts our longer-term growth trajectory.

The second event that Paul referred to was this delay in the 505(b)(2) programs, and again, our expectation while it is bad news for 2016, is that it will, in fact, manifest itself in 2017 and will, in fact, benefit 2017 as well as 2018, depending on when the FDA actually acts.

So then it comes down to the Qualitest-based business, right? And I'm going to let Paul pick it up. But basically, what we've seen is a real reset in Q1. Paul talked about the impact of the consortiums, the confluence of competitors that came in for some of our bigger products like the 325-milligram hydro APAP product, which is Qualitest's largest product that happened post mid-March.

All of those things have happened in a way that has reset that business. And the way we have thought about the guidance is that we've clearly taken a view of saying, how do we predict this erosion continuing through this year? So we do see continued erosion through this year, but by the



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same token, and Paul will elaborate on this, our view as we go into 2017, the continued erosion in this base business will moderate to what you would typically see in a commoditized generic business. And the future really is about the pipeline and segments like the sterile injectables segment.

So with that, let me just turn it over to Paul. Maybe you can talk a bit about our confidence about the remainder of the year and the moving parts going into 2017.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Thanks, Rajiv. Chris, your question really on stabilization and really why do we think it's going to get better? The first thing that we want to talk about is that historically, we've had successes with the Qualitest portfolio, but we've got to call it what it is. It is a mature portfolio that is susceptible to competition. With that, we are transferring the strategy from that high-volume throughput that historically had successes on economies of scale, to the more Par legacy success model of high-value products where we're having more technically challenging products, things that are more difficult to make.

Now, the first thing we have to do, we talked about the restructuring. So we need to take the portfolio, we've got to right-size it, we've got to be real smart about product selection and what we're going to continue to sell and market. We're making some very, very difficult decisions impacting some very talented people in our Charlotte and our Huntsville facility. That's been very difficult for all of us.

That's the starting point to focus on the restructuring plan, and it gets back down to our core values of operational execution, something that we are really driving home at Par. Rajiv talked about it already, the pipeline is where we're going to be able to reset ourselves. Ultimately, 75% of our value coming is from two products, fourth quarter we've talked quite a bit about quetiapine and Zetia. Not going to spend a lot of time there, but we have to execute on the entire portfolio. And at the same time, we've got to continue to repopulate the products as we launch them.

So that coupled with, again, got to get the 505(b)(2)s, and we have other 505(b)(2) s across the portfolio. It's not just the two that we referring to, but we need to execute. We have a path forward. We have a good strategy. These are areas that are going to help us ultimately stabilize our base, and at the same time, we can't lose focus on our service levels and our quality and continue with diversification in our portfolio.

Chris Schott - *JPMorgan - Analyst*

Thank you.

Operator

Greg Fraser, Deutsche Bank.

Greg Fraser - *Deutsche Bank - Analyst*

It's Greg Fraser on for Greg Gilbert.

On the product rationalization efforts, do you expect those to start to help gross margins during 2016, or will those benefits, will the benefits from those efforts be realized more in 2017 and beyond? And then I just had a quick one on the amendment to the Stansfield agreement with TPG that's mentioned in the press release. Can you just give us more color on that change and what you know about TPG's intentions with respect to the stock?

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

I'll take the first one, Rajiv, on the gross margin on the restructuring. So the question on gross margin for 2016 will be about \$10 million.



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Suky Upadhyay - *Endo Health Solutions - CFO*

Yes. We've outlined that in the gross margin waterfall that you see in the presentation, Greg, in addition and we'd expect that benefit, net benefit to step up to somewhere about \$40 million to \$45 million in 2017, and we'll capture that full realization of \$60 million by 2018.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

And that's on a cumulative basis.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Greg, just to answer your question on the TPG stance. So when TPG first took shares when we acquired Par, there was a Stansfield agreement that prevented TPG from increasing their stake in the Company. So in this instance, with -- concurrent to Todd Sisitsky coming on our Board, our Board took the decision to release TPD -- TPG from the Stansfield agreement, subject to certain limits. And those are outlined in the 8-K that we filed with amended Stansvil agreement. But effectively, it allows TPG to purchase up to another \$250 million worth of shares, subject to a cap at 10% of ownership.

Operator

Liav Abraham, Citi.

Liav Abraham - *Citigroup - Analyst*

The pricing pressure that you talked about seemed to pertain primarily to the Qualitest business. Paul, can you talk about the pricing dynamics specifically in the legacy Par business? That's my first question.

And then secondly, just a quick question on the tax rate. Can you just remind us the accounting of your tax rate? Is this a GAAP tax rate or a cash tax rate, and what is your cash tax rate? Thanks very much.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Liav, this is Paul. In terms of legacy Par, in terms of the pricing pressure, for the most part, it's flat, maybe low single digits in terms of price, but for the most part, it's flat. And again, we're able to defend it because for the most part, that base business comprises quite a bit of modified release, sustained release; we've got injectables, as well. So a little less competition.

Suky Upadhyay - *Endo Health Solutions - CFO*

Liav, moving to the tax question, so our tax rate, adjusted tax rate is based on adjusted net income at a statutory rate. And then from there, we deduct the benefits that we have for inter-company debt for any IP and transfer price planning, as well as for acquired attributes. That ultimately results in our adjusted effective tax rate, which is and has been significantly higher than our cash tax rate. Our cash tax rate has been negative for a number of years, and is expected to be in the low single digits in our foreseeable future.

Liav Abraham - *Citigroup - Analyst*

Great. Thank you.



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Operator

Marc Goodman, UBS.

Marc Goodman - UBS - Analyst

I'm trying to understand these 505(b)(2)s and how significant they can be. I understand the amount of revenue that you're taking out of this year as guidance, because those two were delayed. But I'm trying to understand how big can those two products be in the first place? Are these going to be products like Vasostrict, which seems to be -- obviously going to break \$200 million this year, at least that's what it seems. So just give us a sense of that.

As well as the other 505(b)(2)s that you have, as you say in the pipeline, will we see others launching in 2017? Are they coming in 2018, 2019? When do they come and how big can they be? And then just one quick one, which is you mentioned 60 product discontinuations. What are the sales on those products on an annual basis and how much is that impacting this year?

Thanks.

Paul Campanelli - Endo Health Solutions - President, Par Pharmaceutical

Mark, I'll take the 505(b)(2). Now, starting with Vasostrict, we've disclosed we value of Vasostrict, and it's a little bit larger than you had indicated. It's in excess of around \$300 million.

Now, the 505(b)(2)s that we are working with the FDA, we have not, for competitive reasons, disclosed specifically the value. I would say they're not on the magnitude of Vasostrict; they're material, but nowhere near the magnitude of Vasostrict. I think for competitive reasons, I think at this point, that's about as far as we can really go on the two products that we're working with with the agency.

Additionally, we have, we do have a 505(b)(2) strategy to take unapproved drugs, run the requisite clinical trials, and bring them to market. And we do have a handful of additional products that are at various stages across the entire portfolio of either injectables, or solid oral dosage forms. But at this point, we're just not advanced enough to go into any more detail. And hopefully in another quarter or two, we'll be able to provide a little bit more visibility.

Rajiv De Silva - Endo Health Solutions - President & CEO

Marc, just to add to that, this is certainly one of the core capabilities of the Par team. And as we look further into the future, we do expect this to be one of the core drivers for the business. Certainly, we're encouraged by the success that the Par team has had with Vasostrict so far. In terms of the impact of the product rationalization, Suky, do you want to talk about the revenue impact?

Suky Upadhyay - Endo Health Solutions - CFO

Yes. For this year, we would see that revenue impact is about \$20 million. And then on a cumulative basis into 2017, we'd see that about just under \$90 million, so it steps up by about \$70 million in 2017. And again, our benefits that we talk about for the plant rationalization are net of that revenue reduction. So we do still expect to see \$60 million margin improvement on a full run-rate basis net of the sales reduction.

Operator

Annabel Samimy, Stifel.



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Annabel Samimy - *Stifel Nicolaus - Analyst*

I wanted to understand the gross margins a little bit better. It sounds that from the rationalization, gross margins could possibly come back up in 2017 forward. But are we ever going to see the levels that we saw before you had taken this cut down? And what component of the Qualitest business is commoditized? How much of that 60 -- how much of the product rationalization is part of that commoditized business? And once that gets out, how do you see gross margins recovering after this? Thanks.

Suky Upadhyay - *Endo Health Solutions - CFO*

Sure. So for -- Annabel, if I miss something there, just please weigh back in. But overall, we would see the gross margins, all else being equal, improve into 2017 given the rationalization of our products -- sorry, our plants that we talked about, as well as because of the reduction in the lower margin SKUs for products that we're rationalizing.

Other drivers to think about into 2017, as we continue to grow the Par portfolio, which we see as one with products with a margin profile above the existing gross margin average, we could see improvement from that driver. And then in addition, as we see growth from branded within Xiaflex as well as BELBUCA, we would also see those as potentially expanding margins into 2017. So again, we're not in a position to provide full 2017 or beyond guidance, but we do see a path to recovering gross margins above where 2016 are going to land.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Ever recovering to the level that they had been at?

Suky Upadhyay - *Endo Health Solutions - CFO*

It's too early to tell at this time, Annabel.

Operator

Louise Chen, Guggenheim.

Louise Chen - *Guggenheim Securities - Analyst*

Just to follow up on an earlier question on your 2016 guidance, just curious where you think there is further possibility for downside risk to your 2016 guidance? Or do you think that this now incorporates the bear-case scenario as well? And then, this is not to be an antagonistic question, but people have been asking us at what point you would consider strategic options for Endo if you can't create shareholder value on your own.

Thanks.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Thanks, Louise. So let me touch on both questions.

Look, in terms of guidance, we do not take a reduction in our guidance lightly. It is disappointing for the Company and personally disappointing for myself, as well. So we have done an exhaustive assessment over the course of the last few weeks to ensure that we put as much thought as possible into how we assess the remainder of the year. And I would say our guidance range for the full-year is a realistic range. Right?



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So no business is without its risks, and I think you know that, but we have taken a substantial downward revision in the base business in generics. We have commented on how we are treating Voltaren Gel. We have also taken the opportunity to address some other parts of our branded business because of the continued pressure in the pain market. We've rebased some of those products as well, so we've really taken the opportunity to take a hard look at the forecast in this rebasing.

So we don't take this lightly, and it's not something that we want to do more than once. So that's of approach that we've taken. We are confident in this guidance range, and we have a team that is going to work extremely hard at executing against this range. But as in all businesses, at a point that there is always risk.

And then Louise, I was also just going to answer the second question you asked. Look, for us and our Board of Directors, our goal is longer-term shareholder value creation. So certainly there is -- the last -- what's happened with the business over the course of the last few weeks and months is a disappointment and a setback.

But I would point out that our future growth drivers remain unscathed in terms of these particular events that we've talked about. So we point to Xiaflex, the Xiaflex pipeline. We talked to BELBUCA, which even though there is potentially a delay in terms of the launch trajectory of the product, we continue to believe in the future of that product.

And the Par pipeline, which was the primary driver of that acquisition is robust as ever; it continues to grow. The sterile injectables business is robust and growing. And I have every confidence in Paul and the team in terms of getting the generics business back on track.

So from that standpoint, we believe that in the hands of our management team, with appropriate rebasing that we've done in 2016, that there is a path to returning to organic growth, improving our margins, and delevering, and therefore, to creating shareholder value going forward. That being said, we've also been very clear that our Board is a shareholder-friendly board. And if there is ever any strategic alternative that presents itself, our Board will, of course, evaluate it.

Operator

Andrew Finkelstein, Susquehanna.

Andrew Finkelstein - Susquehanna Financial Group - Analyst

Could you talk -- I'll give you a couple things you can focus on. But at a high level, as you talk about the new strategy and you've reassessed the environment, I think you highlighted where the growth drivers you currently have. But as you look longer term at trying to incubate additional drivers, where are the opportunities in this environment and the types of products that are going to have the right risk reward to pursue?

And then as you go about managing that, could you talk a little bit about how you're thinking about balancing cash generation in the near term, particularly with regard to leverage ratios versus investments you may want to make in longer-term opportunities? And just specifically on that, as you talk about rationalizing some of the legacy products, were these loss-making or is some cash flow being given up? And if so, what's the benefit in doing so at this point?

Thanks.

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Andrew.



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Let me just take your three questions, and I will let Paul talk about the product rationalization question at the end. So from a long-term standpoint, I think what we continue to be very optimistic about is following the Xiaflex pipeline. So we've pursued the cellulite indication; our phase 2b trial is in the clinic and currently recruiting patients. We feel positive about that.

And you've also seen that we have increased confidence in being able to move forward, at least for other indications into the clinic. And they fall generally into the areas of aesthetics, as well as other therapeutic indications around the non-collagenase. So it's one core priority for us is continued and increased investment in that R&D pipeline.

In the pain market, clearly in terms of public policy and regulatory pressures is increasing the market. As we said before, BELBUCA has a real profile that would really benefit in terms of some of the current concerns around schedule II opioids, so we do think there's a future there.

But as we look further out into the future, building on our portfolio across our branded business, we could see ourselves in multiple areas that have similar characteristics to other specialty areas where with a smaller focus on marketing footprint, that we can be successful. And following some of the therapeutic areas where Xiaflex is going to get us to is going to be the best way for us to pursue that.

Now leading to your next question in terms of cash and our priorities for using the cash, as Suky explained, when we talked about delevering, we do expect to continue to prioritize delevering, and delevering back to the 3 to 4 times is an important goal for us. Now, that is delayed from 2016 into 2017, but continues to be an important goal for us.

At the same time, investing in our R&D pipeline, both in Xiaflex as well as Par, are going to be very important priorities for us, which we will balance as we go. So those are going to be the most important uses of cash. And beyond that, obviously, once we get into a position where we have excess cash and have the opportunity to look at perhaps bolt-on acquisitions, either for the generics business or the branded business, we will certainly look at those as they come. Our preference would be to do so in the branded space, but that is a ways out. We want to make sure that we execute against our growth plan and delever as our primary priorities, and we always keep the option of returning cash to shareholders as an alternative, as well.

Now, let me just turn this over to Paul, because I want him to talk to you about some of the new areas that we might expand the Par pipeline into, as well as the question that you had on product rationalization and the profitability impact of that.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Thanks. It's obviously a very broad question, and I want to start by saying this: the decision in terms of culling the portfolio, as I said, very, very difficult for us. But as you look at legacy Par, and as part of normal course, it really is an evolution where you need to consistently look at your portfolio. You have to make some tough decisions. You have to take your unprofitable products, or products that you're feeling pretty pain and pressure on.

That being said we're the fourth largest generic Company. We are incredibly relevant, we will continue to be relevant in the industry, and I want to make that statement. And when you -- if want to be able to compete with the four large consortiums, add Walmart in, those five companies representing in excess of 90% share, you really need a well-balanced portfolio.

And what I mean by that is you need your fair share of paragraph 4s, you need hard-to-make -- technically challenging solid oral dosage products. You need injectable products, and you do need commodities that are profitable. So that's going to be very important for us in terms of the Qualitest portfolio on a go-forward basis.

Now, on discontinuation products, hard decisions, but by culling the portfolio in areas that's going to help us, products that are ultimately being sold at losses and we make the tough decisions, it's going to help us on the cash side. We're going to have a reduction in our operating costs. We'll have a reduction in working capital. And we'll also not need to invest as much in certain facilities from a CapEx standpoint. So from that standpoint, generally speaking high level, those would be areas that we would have savings in.



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Suky Upadhyay - *Endo Health Solutions - CFO*

And I want to just come back to Annabel's question just playing off of what Paul just said there around gross margin outlook, I think I was answering maybe a little bit too narrowly and just thinking about 2017. But given the growth drivers that we have that Rajiv outlined earlier, and given the focus on execution and efficiency that Paul and his team have around our manufacturing network, I think we do see a path to get back into the mid 60s over time.

We're not going to time bound that at this point yet. We're going to let more of 2016 play out, and as we move into 2017, we'll have a better view into that. But I do think the growth drivers are at a gross margin level that are higher than our overall corporate average. And again, through efficiency that Paul and his team will drive, there could be a pathway there over time.

Operator

Douglas Tsao, Barclays.

Douglas Tsao - *Barclays Capital - Analyst*

Just first, in terms of Voltaren Gel, when do you anticipate launching an authorized generic? And then I have a quick question on BELBUCA.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

I will -- let me just address that on Paul's behalf. We're not going to talk about when we might launch an authorized generic, for competitive reasons. And a lot of it is going to depend on how the competitive environment evolves with our one competitor on the market. So far, we are very happy with the strategies that we have put around mitigating erosion of our branded product.

Douglas Tsao - *Barclays Capital - Analyst*

Okay. And then just in terms of BELBUCA, obviously, the initial launch, the first few weeks has gone a little more slowly, as you acknowledge. Just curious from your perspective, when do you think we should start to see an inflection point in the scripts?

And then just also, obviously you noted that very good coverage -- default coverage exists right now. When do you anticipate finalizing that and how are those talks going? And the pricing that you expect to get, is that in line with your expectations, better, or perhaps a little bit more challenged, given the dynamics in the pain market right now?

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Great, thanks, Doug.

So as we said, it's still early days of BELBUCA, right? And the last week for which we have data, I think is the week of April 21st. And we had roughly 650 prescriptions. And we continue to see momentum, right?

And it's difficult to predict exactly when the inflection point is going to be, but what I can say is that the anecdotal feedback and the qualitative feedback from physicians has been very positive. I myself have spent time in the field. And the fact that this is a schedule III product, at this point, all the new pressure there on physicians with the new CDC guidelines and everything else, the message resonates.



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But that being said, from the very beginning, we pointed to something that would likely lead to requiring more time to educate physicians, and that is the tapering and titration required with this product. So, to the extent that you are trying to move a patient from other therapy onto BELBUCA, you are to taper that patient down, per our label, and then titrate the patient back up.

And for most physicians, what they are trying to do is to figure out their own gut feel for how this works. Clearly, from a promotional standpoint, we have to stand behind what's on the label, but every physician will figure out what he or she is comfortable with.

I would also say another encouraging sign is that the repeat prescriptions from those who prescribe is progressing very well, so we have as many repeat prescriptions now as we have new RXs. These are all good indicated. I'm going to hesitate to give you an exact time frame of when there's going to be inflection point, but I would point to the second half of this year in terms of when we would expect to see continued improvement in it.

And Doug, I'm afraid I've forgotten the second part of your question. Oh, it was on the managed care. It is progressing very well. As we have said before, we have roughly about two-thirds of commercial lives covered at least with default coverage. We made very good progress in terms of converting the default coverage into actual coverage.

Many other plans, they require -- have confidentiality agreements that prevent us from talking about these things in a public way. But one that we can point to where we have permission to talk about is Express Scripts; that has been a very good win for us. We are continuing our discussions with other plans. And so far, it's going exactly as we had expected.

Now, the one piece that we would expect to not get to until 2017, is the Medicare Part D coverage. But that is on par with all other situations where a product launch is midyear. We've also implemented a co-pay program that basically puts our product on par with competitive products. So from all aspects, from access standpoint, we are making good progress.

Douglas Tsao - *Barclays Capital - Analyst*

Great. Thank you.

Operator

Ken Cacciatore, Cowen and Company.

Ken Cacciatore - *Cowen and Company - Analyst*

Just reiterating what you all said that you're going to be going through some really painful and difficult restructuring. So I'm still a little bit confused why there isn't a lot of contemplation about letting your business merge with another to allow for a total restructuring, maximize all aspects of the business.

And the question, again, is why stay standalone? You could take equity in a pro forma company, realize the benefits of a larger entity, while the value is extracted. And for your shareholders wanting to know, are there indeed options on the table? And why isn't this very, very high on the list of options?

Thank you.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Thanks, Ken.



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So let me refer back to my previous answer to a similar question, and I'll answer your question. End of the day, what is most important for our team and for our Board is to ensure that we right the ship operationally, address the challenges that we've seen, and make the progress that we know we can make as a team. Right? That being said, we've also always been clear that we are shareholder-friendly management team, or a shareholder friendly board, and we will always look at strategic options that present themselves.

One of the things that I've said in the past is although from a debt-market perspective, as well as where our own equity is trading, we are not in a position to do substantial acquisitions. But I have pointed out that mergers are certainly options that we would consider if they present themselves, particularly where either on a relative value basis it's something that makes sense or we conclude that it's the best interest of our shareholders. So certainly we remain open to those options, but our primary focus and priority is on operationally executing against our plan.

Ken Cacciatore - *Cowen and Company - Analyst*

Thank you.

Operator

Irina Koffler, Mizuho.

Irina Koffler - *Mizuho Securities - Analyst*

I wanted to go through the 505(b)(2) again. It sounds like it's a big part of your going forward strategy, and I just wanted to understand, how competitive is this space? Are you going to get any additional players in the market based on your setback and delay into 2017? And then going forward, we have to rely on your execution of these programs, and yet we had a delay this year already. So what can you say to give us more conviction in your execution of these products?

Thanks.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

I will let Paul answer it. I think I would just point to Vasotrist as an example of why you should have confidence in Paul's ability to execute. It's been an extraordinarily successful product strategy and one where I don't think we've seen the final chapter yet; Paul continues to work on it.

But Paul, why don't you answer the rest.

Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Irina, again, at the end of the day, we have a broad strategy in terms of getting unapproved drugs through the FDA through the 505(b)(2) process. Historically, these are typically older drugs which we have to run requisite clinical trials in order to get NDA status.

When we can change a product and when we can get intellectual property, obviously we're going to do that aggressively. On certain products we're able to do that, and certain products we are unable to do that.

In the case of the products that we're referring to at this point in time, I would tell you that I don't believe that intellectual property is as strategic as we would like it to be. However, there are other things that we would be working towards at this point in time I would not want to disclose for competitive reasons. But we're hopeful this is not going to be a one-year and out type of 505(b)(2) whereby we spend the requisite PDUFA fees, build up a product, and then invite competition.



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So we do have strategies outside of intellectual property that hopefully will gain us longevity. But we're not talking compound patent IP where you're typically seeing multiple years. That's not what we're talking about here.

Operator

David Risinger, Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

A couple questions. So with respect to the generic pricing and competitive pressures that hit your generics guidance, could you just help us understand how much of that is from the Qualitest business and how much is hitting the Par business? So I'll make up a number. Let's say that the hit was \$10. Of the \$10 hit, was it two-thirds to Qualitest and one-third to Par, or was it half and half to each? Just trying to understand that.

And then second, with respect to Xiaflex, how should we think about that product sales sequentially in coming quarters? And then finally, actually, and this one is for Suky, you had mentioned moving parts in 2017. Could you just talk about the big, big moving parts that are uncertain? Obviously, there's some certainty with Zetia and Seroquel. But what are the moving parts for revenue that are uncertain for 2017 at this point?

Thank you.

Rajiv De Silva - Endo Health Solutions - President & CEO

David, let me hit your Xiaflex questions and then I will go to Paul on the pricing question and the moving parts in 2017. Look, I think on Xiaflex, we had a very good first quarter. We had growth of about 21% when you're looking at the US. And as we laid out in our presentation and my comments, our expectation for the full year is product growth should be somewhere in the mid to high teens range. Right?

Now, clearly we are working to accelerate the product, but that is a view of where our best current thinking is. So if you take a look at the 21% and the full-year at mid to high teens, there will be a slight moderation as we head into the next few quarters. But this is still going to be well within the strong double-digit growth profile that we predicted for the product.

Paul Campanelli - Endo Health Solutions - President, Par Pharmaceutical

David, your question on the price and the pressure, when we look at the Qualitest portfolio, which had served us well for so many years, as I said before, it is a mature portfolio, which is subject to more than normal competition. We were very strong in pain; a big portion of our portfolio is directed towards pain. It's not quite the barrier that it once was, and as a result, the pricing pressure that we saw was about 80% tied to legacy Qualitest and about 20% tied to legacy Par.

Rajiv De Silva - Endo Health Solutions - President & CEO

And then let me start on your 2017 question, and I'll ask Suky to jump in.

So let's take the following view on 2017, so let's talk about what's changed since we last put in our expectations for 2017. So the three main changes have been a resetting of expectations for our Qualitest base business; the delay in the 505(b)(2) program, as we talked about, which is going out of 2016 but will be impacting positively 2017 and 2018, for that matter; and then we talked about V Gel, which we fully expected to be genericized as we headed into 2017. It just happened much earlier than we expected, and we do have authorized generic as an option for us to use going into 2017. So the real major downward revision there is the impact of the Qualitest base business.



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Now, there are other moving parts that will impact what our final guidance in 2017 is though, right? We will have to take a view on exactly how BELBUCA is going to do. It all depends on where the inflection point is going to be. Obviously, tailwinds behind Xiaflex will continue to grow. We will know more by the middle of this year in terms of what's happening with OPANA. We have a July 29th PDUFA date for our ADF relabeling request with the FDA. And we will also know more in terms of some of the other pipeline launches and other programs that Paul's pursuing in the Par business and exactly where they will fall in 2017. Right? So those are some of the real moving parts we have.

We've also signaled that we expect to increase our R&D spend, particularly behind the Xiaflex pipeline, and to the extent that Paul has new ideas from an R&D standpoint we will try very hard to meet any additional funding requirements in the Par pipeline as well.

So those are some of the moving parts. I don't know, Suky, whether there's anything else that you would point to?

Suky Upadhyay - *Endo Health Solutions - CFO*

I think the only other thing is the strong growth we've been seeing in the injectables portfolio. We continue to see that momentum into 2017. It's just understanding where our exit is in 2016 before we make that final call.

Operator

Elliot Wilbur, Raymond James.

Daniel Sanchez - *Raymond James - Analyst*

This is Daniel Sanchez on for Elliot Wilbur. I just wanted to get your latest thinking in regards to the eventual resolution timeline and expected 2016 payment liabilities as you work to push the mesh settlement issue behind you? And if you think the worst parts and the claims with the highest value are over?

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Sure. So let me just comment on the overall status of mesh, and then I'll let Suky talk about the financial aspect.

So as we talked about in our fourth-quarter call, we took a new approach to how we're dealing with the tail, which is that we took steps to resolve the higher-quality claims, which is what led to an increase in accrual that we announced in the fourth-quarter call. Since then, the situation has not changed. There is alleged potential for another 8,000 cases in the tail that we disclosed, but we were also very quick to point out the expectation is that a large proportion of those cases could be of lower quality. We don't have all the facts around them.

We also point to the fact that there is a potential fraudulent scheme that is running through many of these cases, which we are investigating currently. As we pointed out before, these are typically the types of things you see at the tail end of a mass start situation. We can't give you a precise projection of what the end date is, but we have confidence that we're seeing the real tail here.

Maybe Suky, you can talk about the cash expectations in 2016.

Suky Upadhyay - *Endo Health Solutions - CFO*

Sure.

At the end of first quarter, we will have a total product liability accrual of about \$1.9 billion on the balance sheet. You'll see that in our 10-Q, which will be issued in the very near future. Of that \$1.9 billion, the amount of restricted cash or cash that's already been put into qualified settlement



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funds was about \$0.5 billion, which leaves a residual of \$1.4 billion on a gross basis to be paid. We'd expect of that remaining \$1.4 billion, about \$750 million on a gross basis to be paid between -- for the rest of 2016. And then about \$600 million \$650 million into 2017, or the residual of that \$1.3 billion balance.

So that's where we stand from a cash call basis. As we talked about earlier, we did receive the federal tax refund that we pointed to earlier this year; that came in early April. We continue to look at ways to provide a shield around future liabilities.

Daniel Sanchez - *Raymond James - Analyst*

Thank you. And any line of sight as to the magnitude of potential fraud cases or is it still too early to tell?

Rajiv De Silva - *Endo Health Solutions - President & CEO*

It's an active investigation, we have issued subpoenas in the case. And are also working with the judge in the NDL case, as well as other parts of the law enforcement infrastructure in the country. So we really can't comment more on it.

Daniel Sanchez - *Raymond James - Analyst*

Thank you.

Operator

Rohit Vanjani, Oppenheimer.

Rohit Vanjani - *Oppenheimer & Company - Analyst*

Sorry, I maybe missed some of the commentary on Voltaren, to Doug's questions, but how much did you reduce your Voltaren estimates by or how much share do you anticipate the new competitor taking? And then same thing with Frova, are you seeing a new competitor there? And if so, how much did you reduce estimates by?

And then secondly, for the generics unit, could you help me understand the business a little bit better. Do you have contracts primarily at the beginning of the year and that's where you get the renegotiations happening? Or are the majority of the contracts staggered throughout the year, or are you seeing [rophirs] where you are choosing not to engage? Or are most of the products sold ad hoc or at will, where your customer can move pretty freely?

Rajiv De Silva - *Endo Health Solutions - President & CEO*

So let me just talk about briefly about V Gel and Frova, and I will pass it on to Paul. With respect to Voltaren Gel, we have pointed to, in the materials for today's call, the relative impact on the rebasing of our 2016 guidance. We are not going to discuss market's expectations anymore, just other than to say there's a single competitor on the market. And we are effectively defending the branded product at a level that we would expect to do.

With respect to Frova, yes we do have a new competitor, that is Glenmark, and currently Par has also launched our authorized generic. So that is also in the market. Maybe you can address the other question?



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Paul Campanelli - *Endo Health Solutions - President, Par Pharmaceutical*

Sure, in terms of the consortiums, the cycling, I think you had that exactly right. So they are staggered, so each consortium has a different timeframe that we bid against. So it's not like you come in, in Q1 and have to deal with 3 of the consortiums. Reddo does not actually put out bids; their expedition is that there going to be guaranteed best pricing. So their style is a little bit different as opposed to the one-stop program or the [weedbad] program or even the ECONDISC program.

Regarding rophirs, that is exactly what it is. So after you go through the consortium bid cycle, that does not mean that you are still not exposed for rophirs. That being said, we defend against rophirs and we have our fair share of wins. You have your fair share of losses, and at the end of the day, I think on a go-forward basis, this is an area that we're fairly strong in, in terms of at least to protect ourselves from the legacy Par standpoint. And we are, in essence, right-sizing the Qualitest business legacy side in order to be able to defend against rophirs on a go-forward basis.

Rohit Vanjani - *Oppenheimer & Company - Analyst*

Great. Thanks.

Operator

Kevin Kedra, Gabelli.

Kevin Kedra - *Gabelli & Company - Analyst*

Just wondering, when you think about that strategically, how much sense does it still make to keep the generic and the branded business together? Are there any thoughts about maybe separating those businesses? And then actually, I'll take that and I'll be good.

Rajiv De Silva - *Endo Health Solutions - President & CEO*

Okay. Thanks. Look, it's a strategic question.

One of the things that our Company has benefited from over the course of the last three years since my arrival, when we really started to transform the business, is in fact the diversity of the business. Right? So the generics business, especially with the addition of Par, despite the rebasing that we are taking, is a highly diversified business with multiple growth drivers. And we've also taken the steps to build critical mass in our branded business.

But I have been also open that from a forward-looking standpoint, at a certain point in time when we have critical mass in both our branded business, as well as our generics business, these can be both two very viable standalone businesses. So from a strategic standpoint, we remain open to thinking about creative ways of creating that shareholder value.

But as I pointed to earlier in my comments, our primary focus right now is operational execution. We have a full plate in Par in terms of restructuring that needs to be done, progress on the pipeline, as well as in the branded business growing Xiaflex and growing the BELBUCA and investing in the pipeline. But certainly, we keep all strategic options open to us as we think about the future.

Operator

I would now like to turn the conference back over to Rajiv DeSilva, CEO and President.



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Rajiv De Silva - *Endo Health Solutions - President & CEO*

Thank you, and I want to thank all of you for your attention today. There have been a lot of very good questions. And we've talked a lot about the different factors that have impacted our 2016 guidance, as well as other financial updates.

But what I hope that you will take away from this call today is that despite the rebasing of our 2016 guidance, Endo is a fundamentally different and stronger business than it was in 2013. And it is also a more compelling investment and growth story.

In 2013 we had two primary and declining assets at that time and a very fragmented base of business across healthcare solutions divided in pharmaceuticals. You fast-forward to today, we've rebuilt our branded portfolio and pipeline with the acquisition of Auxilium and particularly Xiaflex. We divested non-core businesses. We've achieved scale and differentiation in our generics portfolio with the addition of Par, and frankly, that is what the future is going to be about. Particularly, as we see the rebasing of our legacy Qualitest business. We established an international structure and footprint for growth and expansion. We narrowed the mesh tail, and we have built a business generating significant EBITDA, even after this rebasing, and free cash flow that we expect to grow going forward.

So no one likes to rebase guidance more than I. But we have now reset our business so that we can move forward and effectively drive growth and value. And we thank you for your continued support. Thank you very much.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for your participation and have a wonderful day. You may all disconnect.

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