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ENDP - Q4 2013 Endo Health Solutions Inc. Earnings Conference Call

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OVERVIEW:

ENDP reported 4Q13 revenues of \$585m and GAAP loss per share of \$6.74. Expects 2014 revenue to be \$2.50-2.62b, reported (GAAP) diluted EPS to be \$1.36-1.81 and adjusted diluted EPS to be \$3.40-3.65.



CORPORATE PARTICIPANTS

Blaine Davis Endo Health Solutions - SVP, Corporate Affairs Rajiv De Silva Endo Health Solutions - President & CEO Suky Upadhyay Endo Health Solutions - CFO

CONFERENCE CALL PARTICIPANTS

Dana Flanders JPMorgan - Analyst Marc Goodman UBS - Analyst Josh Riegelhaupt Stifel Nicolaus - Analyst Liav Abraham Citigroup - Analyst Gary Nachman Goldman Sachs - Analyst Greg Fraser BofA Merrill Lynch - Analyst Jim Dawson Buckingham Research - Analyst David Amsellem Piper Jaffray & Co. - Analyst Jason Gerberry Leerink Swann - Analyst Chris Caponetti Morgan Stanley - Analyst

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q4 and full-year Endo Health Solutions Inc. earnings conference call. My name is Adrian and I will be your operator for today.

(Operator Instructions)

As a reminder, this call is being recorded for replay purposes. I'd like to turn the call over to Blaine Davis, Senior Vice President Corporate Affairs. Please proceed, sir.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Thanks, Adrian. Good morning, and thank you for joining us to discuss our fourth-quarter 2013 financial results and 2014 financial guidance. With me on today's call are Rajiv De Silva, President and CEO of Endo, and Suky Upadhyay, Chief Financial Officer.

We have prepared a slide presentation to accompany today's webcast and that presentation is posted online in the investors section at www.endo.com. I'd like to remind you that any forward-looking statements by Management are covered under the Private Securities Litigation Reform Act of 1995 and subject to change, risks, and uncertainties described in today's press release and in our filings with the SEC.

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 filed with the SEC for Endo's reasons for including those non-GAAP financial measures in its 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.

Our prepared remarks will begin by briefly discussing our fourth-quarter and full-year financial results and financial guidance. With that, I'd now like to turn the call over to Rajiv.

Rajiv De Silva - Endo Health Solutions - President & CEO

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

On slide 2, you will see our agenda for today's call. We will first review our recent accomplishments and 2013 financial results. We will briefly introduce the new Endo, now known as Endo International, as we expect to close our transformative acquisition of Paladin Labs later today. Then we will discuss 2014 financial guidance. Following our prepared remarks we look forward to taking your questions.

Moving on to slide 3, we continue to make solid progress towards our goal to be a top-tier specialty health care company. In order to do that, we remain focused on optimizing our most promising assets and expanding in areas that offer above-average growth characteristics and attractive margins.

We are making good progress on all of our priorities and I will now quickly review some of the significant recent events. First, we recently announced the closing of the acquisition of Boca Pharmacal. We believe Boca to be an excellent example of the type of external growth opportunities that we are pursuing.

Boca has a strong presence in controlled substances, which complement Qualitest very well. We expect it to be immediately accretive to our adjusted diluted earnings per share and it represents a solid opportunity for value creation.

Second, sometime later today, we expect to close the acquisition of Paladin Labs. The acquisition of Paladin creates an international specialty pharmaceutical platform to drive future growth for Endo. And, it establishes a beneficial financial platform that we believe will enhance our growth prospects by redomiciling Endo in Ireland.

As a result, we believe Endo International is better positioned to generate sustained cash flow and earnings, which will accelerate our M&A agenda. The transaction is also immediately accretive to our adjusted diluted earnings per share, and it enhances our cash conversion. I will comment further in a few moments when I describe Endo International in more detail.

Third, we recently announced the divestiture of HealthTronics for an upfront consideration of approximately \$85 million. And the potential to receive an additional \$45 million in future milestones.

Fourth, we achieved our objective to reduce our adjusted operating expenses by \$150 million for full year 2013 when compared to full year 2012. We made significant changes to the organization and it performed very well by delivering solid top-line results as we implemented a new lean operating model. We also remain on track to achieve our annualized savings target of a reduction of \$325 million in underlying expenses versus 2012 adjusted operating expenses in 2014.

And, fifth, we are improving R&D efficiency by focusing on lower risk, near-term revenue-generating projects. In January, we announced positive top-line results from the Phase III clinical trials of BEMA Buprenorphine in opioid naive patients with chronic pain. And today is the action date for FDA to provide us with an update regarding our new drug application for AVEED.

I would like to take this opportunity to thank Ivan Gergel for his dedicated service and his significant contribution to the Company over the last six years. Ivan's tenure as head of R&D was successful, and he leaves us with two promising late-stage programs in AVEED and BEMA Buprenorphine.



Ivan has also built a strong foundation of capabilities and processes in R&D that we believe can support drug development as an organic growth driver for our business. We all wish him well in his future endeavors.

Moving on to slide 4, you will see that we had a solid fourth quarter, reporting \$585 million in revenues and \$0.96 in adjusted diluted earnings per share. I am pleased that we exceeded our expectations on these financial metrics, and as a result, we beat the high end of our guidance range for full-year 2013 adjusted diluted earnings per share by \$0.04. Suky will provide some more details about fourth-quarter results in just a few minutes.

Moving to slide 5, you can see the details of revenue performance for our segments. Managing the loss of exclusivity for LIDODERM obviously had an effect on our Branded Pharmaceuticals business. And so, I will highlight the progress we have made so far in driving organic growth in our core businesses.

Moving to slide 6, fourth quarter 2013 sales of \$198 million for our Qualitest business represented 22% growth versus prior year and closed out another strong year in which Qualitest sales increased 15% versus prior year. Approximately half of that growth is attributable to new product launches.

We are pleased to see continuing signs of improving trends in our AMS business in the fourth quarter. Fourth-quarter 2013 growth rates show improvement over the first half and were approximately level with prior-year sales. Growth for AMS, excluding women's health, was at 3% versus fourth quarter 2012 and 2% for the full year. The turnaround at AMS is continuing to deliver results while also improving profitability and EBITDA contribution.

As we expected, Branded Pharmaceutical sales declined in fourth quarter 2013 compared to fourth quarter 2012. However, we are pleased that our core portfolio of branded products increased 11% versus prior year. That core of growth products excludes LIDODERM and OPANA ER as well as royalties received from Actavis for the sale of generic lidocaine patches. And, if you factor in OPANA ER, our co-branded pharmaceuticals business had organic growth of 3% in the fourth quarter.

We believe we are effectively managing the loss of exclusivity for LIDODERM that occurred on September 15. We continue to evaluate the most effective way to manage the lifecycle of the product and are considering multiple options, including the launch of an authorized generic for LIDODERM.

With that, let me turn the call over to Suky to provide some more details of our financial performance for the quarter and the full year. Suky?

Suky Upadhyay - Endo Health Solutions - CFO

Thanks, Rajiv, and good morning to those joining us for today's presentation. This is clearly an exciting time to be at Endo. Before the day is over, we expect to close our acquisition of Paladin Labs, redomicile the Company to Ireland, and have the potential to receive approval for an important product which will add to our branded portfolio.

Moving to slide 7, the divestiture of HealthTronics has an impact on the complexion of our P&L. I'll cut through the accounting changes and focus on key measures of our performance. We had a good finish to the year in the backdrop of significant change across the Company. As Rajiv noted, we continue to make good progress around the core revenue growth of the Company, with positive trends in several areas of the business.

Through a disciplined approach to P&L management, we finished the year slightly ahead of our November guidance range. Implementing a lean operating model was a critical first step in Endo's strategy laid out early in June.

The full-year adjusted P&Ls we provided in our press release this morning show operating expenses excluding HealthTronics. If you factored operating expenses for HealthTronics back into both years for comparison, we exceeded our 2013 objective of \$150 million reduction in adjusted operating expenses versus 2012.



While there is more work that remains to fully realize our savings goals, we are on track to achieve our objective of \$325 million run-rate reductions in the third quarter of 2014. While we'll continue to look for opportunities to improve cash flow generation by reducing operating expenses, we will also look to improve performance across other value drivers, such as cost of goods, our effective tax rate, and working capital.

As we announced last week, our reported financial results reflect certain balance sheet adjustments. We recorded a pretax non-cash asset impairment charge of \$493 million, primarily related to goodwill attributed to the Company's acquisition of American Medical Systems. We also recorded a pretax non-cash charge of approximately \$316 million to increase the Company's product liability reserves to \$520 million for all known, pending, and estimated future claims related to vaginal mesh cases.

The change in the accrual for product liability claims is primarily associated with the Company's ongoing evaluation of American Medical Systems' vaginal mesh litigation, including the inherent uncertainty of this litigation and the potential liabilities and/or possible settlements. With those items factored in, Endo reported a GAAP loss of \$6.74 per share in the fourth quarter.

I'll make one last comment on AMS regarding an update on the mesh litigation. As we had expected, AMS count of filed cases increased in the quarter and now totals 22,000. Excluding the non-cash charges, on an adjusted basis we had a strong quality finish to the year with adjusted EPS of \$0.96, which was ahead of our expectations.

Moving to slide 8, as I just mentioned, we exceeded our expected expectations for earnings per share in the fourth quarter. This was in the backdrop of increased share count dilution that resulted from strong performance in the price of Endo shares through the fourth quarter.

Financial reporting requires that we factor in fractional dilution from our outstanding 1.75% convertible notes and a related set of warrants when shares of Endo trade above certain levels. One way of looking at that effect would be to look at the full-year performance without those incremental shares. Under that assumption, full-year 2013 adjusted diluted earnings per share of \$4.79 could have been approximately \$0.17 higher.

We've included an additional table in the back of today's presentation that outlines the dilutive accounting impact of our convertible notes, which mature in 2015. For additional details on our 2013 financial results, please review today's earnings press release.

Again, we are pleased with our solid finish to 2013. I would now like to turn the call back over to Rajiv to introduce the new Endo International. I'll be back to cover 2014 guidance in a few minutes.

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Suky. On slide 10, you will see that the strategic direction of the Company remains unchanged. The closing of our acquisition of Paladin Labs and the creation of Endo International is very exciting and significantly accelerates our goal of becoming a top-tier specialty health care company.

In order to do that, we will focus on optimizing our most promising assets and expanding in areas that offer above-average growth characteristics and attractive margins. We are committed to serving our patients and customers. And we believe that we can maximize shareholder value by adapting to both market realities and customer changes.

Moving to slide 11, at Endo International we will continue to aggressively move forward with the implementation of our operating model. Let me quickly run through the key elements of our operating model as I think they are important to highlight and reinforce.

First, we will continue to operate our business, and those we acquire, with a lean and efficient operating structure. Second, we will align our international -- internal performance metrics with shareholder interests.

Third, we will continue to actively pursue M&A as an important component of building the business longer term. With the creation of Endo International and the redomiciling of our business in Ireland, we believe M&A, coupled with a focus on organic growth, will deliver superior performance.



Fourth, we will remain agnostic on therapeutic areas we invest in, but will focus on specialty arenas with a focused precision and customer base. Fifth, we will continue to invest in R&D that is focused and lower risk, with programs like AVEED and BEMA. And finally, and perhaps most importantly, we will operate this diversified organization in a streamlined manner with quick decision-making that we believe is a competitive advantage for Endo in the marketplace.

Moving to slide 12, Endo International will establish its global headquarters in Ireland and we will explore opportunities to create value through this presence. Paladin Labs will become a subsidiary of Endo International and will continue to be led by its current management team. Paladin will maintain its current headquarters location in Montreal and operate in Canada under the Paladin Labs name.

I would point out that, while the majority of Paladin revenues are generated in Canada, further expanding its international footprint, particularly in Latin America, is a key strategic imperative. Finally, the new Company will trade on the NASDAQ under the ticker symbol ENDP and will also be listed on the Toronto Stock exchange under the ticker symbol ENL.

Moving to slide 13, we are adopting some new naming conventions for our reporting segments. For example, if we refer to Generic Pharmaceuticals US, we are discussing the combination of Qualitest and Boca Pharmacal. And, if you were to add additional assets or companies that expand our generics presence in the US, then we would track that performance within that segment.

That concludes a brief introduction of Endo International. And now, let me turn to our expectations for 2014. Moving to slide 15, I would like to share with you some of the objectives of the organization for 2014. We believe that if we focus on meeting or beating these objectives that Endo will prove to be a strong creator of shareholder value.

In 2014, we are focused on: meeting our financial targets; driving organic growth through our core business; establishing a new corporate structure; implementing a lean operating model; completing at least 2 to 3 near-term accretive and value-creating transactions; increasing the value of pipeline and launch products; maximizing balance-sheet flexibility; developing an organization and culture aligned with the new strategy; and, enhancing our continued focus on quality compliance and risk management.

Let me focus on just one of those for a moment. I believe the organic growth story for Endo in 2014 is a good one. If we exclude the additions of Paladin Labs and Boca Pharmacal, as well as LIDODERM, the revenues for our core business are expected to grow in 2014 in low single digits.

We believe we can improve upon that, over time, towards our longer-term objective of low to mid-single-digit organic growth, but it is a good starting point for 2014. All in all, the organic growth of the business looks solid, while we are also enhancing our overall profitability.

Let me now turn the call back over to Suky to review the details of 2014 guidance. We will then close out the prepared remarks and move on to Q&A. Suky?

Suky Upadhyay - Endo Health Solutions - CFO

Thanks, Rajiv. Moving to slide 16, the focus of our US Branded Pharmaceuticals business is on growing a core set of products while managing the loss of exclusivity for LIDODERM. We are more optimistic about the viability of Voltaren Gel and OPANA ER as we head into 2014. And, our assumption is that we will continue to invest to promote these brands.

That said, we have less room in our ranges to cover some scenarios where the market conditions are less favorable for OPANA ER and Voltaren Gel. With respect to LIDODERM, while we assume the arrival of a second generic in the first half of this year, we are considering multiple options, including the launch of an authorized generic.

Moving to slide 17, our US Generic Pharmaceuticals business remains a source of strong organic growth in 2014. We believe the base of Qualitest products will continue to experience low double-digit revenue growth.



That growth is primarily driven by increase in demand for products, but is also the result of selected pricing opportunities within the higher barrier to entry categories. The addition of Boca Pharmacal at the start of February is expected to add significantly to the growth rate of this business.

Moving to slide 18, in 2014 we are focused on continuing to improve the operating performance of our Medical Device business. As discussed during the review of 2013 results, we see continued signs of improvement in revenue growth. And, with the changes put in place last year, we have seen improvement in efficiency and operating margins. We expect that trend to continue into 2014.

Moving to slide 19, for International Pharmaceuticals, our approach would be to support the continued execution of Paladin's historic and ongoing strategy. We believe Paladin Labs will pursue the in-license of innovative products and the acquisition of under-promoted or mature brands and will supplement that with the development of low investment and lower-risk products for Canada and other select world markets.

Paladin's presence in Mexico and Brazil will be a valuable platform for Latin American growth. Similarly, we look for ways to maximize the value of our partnerships in the Litha business.

Moving to slide 20, we have some key assumptions that support our 2000 financial guidance. First, we do not assume future M&A, but we have highlighted the timing of the M&A that has been completed, or that we expect to complete today.

Our diluted shares outstanding will increase when we close the acquisition of Paladin, as we will create 36 million shares in Endo International to fulfill the terms of the arrangement. And, as I discussed during the review of 2013 results, diluted shares outstanding are also dependent on a share price assumption. For guidance, we've assumed an average share price based on recent trading. The fully diluted average share count for full year 2014 under this assumption is 164 million shares.

Moving to slide 21, I will summarize our 2014 financial guidance that we announced earlier this morning. We expect revenues between \$2.5 billion and \$2.62 billion. On an adjusted basis, we expect our corporate gross margins as a percentage of revenues to be between 63% and 65%.

The reduction in year-over-year gross margin is driven by the mix of our business as we continue to diversify beyond LIDODERM and OPANA. On an adjusted basis, we expect operating expenses to decline year over year by a low double-digit percentage as we successfully complete our cost-reduction initiatives that we started in 2013.

We anticipate an adjusted effective tax rate of approximately 23% to 25%. This is consistent with an annualized underlying rate of approximately 20% for Endo International, which we expect to achieve by the end of the year. This represents a significant improvement over the underlying corporate tax rate of below 30% prior to the Paladin transaction.

Moving on with guidance, we expect adjusted interest expense of approximately \$210 million. We estimate adjusted diluted earnings per share in a range of \$3.40 to \$3.65. And, we project reported, or GAAP diluted earnings per share, to be within a range of \$1.36 to \$1.81.

The GAAP EPS estimates may change as we finalize the Paladin purchase price allocation over the allowable measurement period. Finally, as I just detailed, our fully diluted per-share estimates assume a weighted average number of common shares outstanding of approximately 164 million shares.

There are a number of moving parts in 2014 that may create a lumpy growth in earnings profile as we progress through the quarters. At a high level, we expect revenues and adjusted EPS to be slightly weighted towards the back half of the year. Before I hand the call back over to Rajiv, I'd like to summarize the highlights of our full-year 2014 financial guidance, which I believe demonstrate early favorable proof points around our strategy and our execution.

First, our transformational acquisition of Paladin Labs and strategic acquisition of Boca Pharmacal will help offset significant declines in the branded business due to the loss of exclusivity of LIDODERM and OPANA, and will further diversify our revenue base into higher-growth platforms while expanding our geographic footprint. In addition, our operational focus to drive revenue growth will sustain an underlying organic growth rate in the low single digits in 2014.



Second, by reducing our OpEx base by about a third since 2012, we have created a lean operating model that is projected to broadly hold overall profit margins despite a material gross profit decline as we diversify beyond LIDODERM and OPANA. Third, our strong EBITDA profile, in conjunction with our improved underlying tax rate, will lead to a favorable step change in our overall cash conversion performance.

And, finally, we have increased our balance-sheet flexibility, while locking in financing at attractive rates to provide the capacity to take advantage of strategic value-enhancing opportunities. While 2014 will be a year of transition, we're excited about the continuing to build a platform for long-term value creation.

Let me turn it back to Rajiv to close out. Rajiv?

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Suky. In closing I would like to focus on two of our priorities for 2014. I will start with our objective to meet our financial targets.

We have provided our financial guidance for 2014 and we have done so in a way that adheres to a principle that I believe is fundamental for building a high-performance culture and aligning management and shareholder interests. Endo Management must achieve or exceed that guidance in order to realize its incentive compensation.

And, second, we have an objective to complete at least 2 to 3 near-term accretive value-creating transactions. We are starting 2014 with ample capacity to meet or exceed those objectives. And, if we were to do so, I'm confident that our focus on creating value through a disciplined approach, coupled with our new platform that increases the efficiency with which we can convert operating performance into cash, will put us in a position to continuously replenish our firepower to support M&A and organic growth.

In conclusion, it is an exciting time at Endo. Later today, we expect to close the acquisition of Paladin Labs, redomicile the Company, and enter into the next stage of transforming Endo into a leading global specialty health care company.

Let me also take this opportunity to thank our patients and customers for their trust in us, our employees for their hard work, and our shareholders for their support. That concludes our prepared remarks, so let me now turn the call back over to Blaine to manage our question-and-answer period. Blaine?

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Thanks, Rajiv. This concludes our prepared remarks and we'd like to now open the line to take your questions. Just 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'd greatly appreciate it. Adrian, if we can go ahead and take the first question please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Chris Schott.



Dana Flanders - JPMorgan - Analyst

This is Dana Flanders in for Chris. Rajiv, just a couple questions here on business development. With the Paladin deal closing today, do you see Endo as poised to do substantial business development immediately or do you need a period of digestion to more fully integrate, get the infrastructure in Ireland set up, things of that nature? Just trying to understand the priorities here for Endo on that front.

And then secondly, with some of the charges being taken and the recent debt raise, can you just remind us how much gross cash you have on the balance sheet and what you view as your capacity today to go out and do a deal? Thanks.

Rajiv De Silva - Endo Health Solutions - President & CEO

Sure. So I will have Suky answer the cash question but let me start with the first, on your timing. As you know M&A is a very important part of our growth agenda. And as with any point in time we have a pretty robust pipeline of ideas we continue to look at.

As Suky will elaborate on, we have -- we will begin this year with a pretty good cash balance that is available for M&A. And so from that standpoint, really, there is no major limitation on when we would be able to do transactions. Our Irish structure is being set up as we speak and we would -- we expect to have a presence in Ireland in the coming weeks.

And in terms of the types of transactions we like, I'd reiterate what we said in the past which is that we like the small to medium term transactions, particularly private transactions, so we continue to look actively for assets in the \$250 million to \$500 million range. That being said, we're also always opportunistic and look at transactions of any size that we think will create value for our shareholders.

From an overall deal capacity standpoint, what we've said in the past is not changing very much which is that we believe that we have capacity in the current range for between \$2 billion to \$2.5 billion of deals. As long as we're doing the kind of accretive deals that we expect to do. Maybe Suky you can elaborate on the cash position and the specifics a bit more?

Suky Upadhyay - Endo Health Solutions - CFO

Sure. So we ended the year December 31, with about \$500 million of cash on the balance sheet. And a gross leverage ratio of just under three turns. But as we close the first quarter and we close the Paladin deal, the \$700 million of high-yield financing that we took out at the end of last year will now become available to us.

So we're looking at cash balances at the end of Q1 or at the close of the transaction of about \$1.3 billion available to the company and that represents a gross leverage ratio of about three turns. And so as Rajiv mentioned, we'll have that \$1.3 billion available to us.

We've also talked publicly about the tolerance to go up to about four times on a leverage ratio and so when you think about that opposite about \$1 billion of EBITDA, that provides another \$1 billion of capacity on top of the \$1.3 billion of cash we have. And still keeps us well within our overall corporate ratings.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Great. Thanks, Dana. Can we go to the next question please?

Operator

Marc Goodman, UBS.



Marc Goodman - UBS - Analyst

Two things. First, can you talk about why you increased the reserve for the mesh liability? What was the strategy there and how we should think about that overall? And just give us a sense of how you see the year progressing just on that front and all the news flow and how we're thinking about it?

And second maybe you could just get into the device business a little bit and talk about how you're thinking about this year and talk about the individual three pieces and your expectations for growth in the quarter. Like what's turning around? What did well? What didn't do well relative to expectations? Thanks.

Rajiv De Silva - Endo Health Solutions - President & CEO

Thanks, Mark. Let me start with the question on mesh. Overall, the mesh liabilities is progressing as we expected, which is we knew that as the year drew to a close in 2013 that we will have an increase in the number of filed cases.

And we also knew that our first trial set cases for our MDL process which is most important part of the process for us would be beginning in April. So the Company has been working very hard to prepare for those cases and we are ready.

With respect to the mesh accrual, the strategy around it and the methodology behind it remains the same, which is an estimate of our liability based on an overall estimate of cases out there as well as other factors that go into determining what the company believes its liability could be. So in terms of the overall cases, that number really has not changed in our estimates. Although the number of filed cases keeps increasing, our accrual is based on an estimate of total cases that we extrapolate through some methodologies.

Secondly, as we get closer to 2014, we have a clearer view of what our longer-term and medium-term legal expenses are expected to be. So when you add all of these together, it gives us several factors that allow us to think about the liability accrual in perhaps a different light than we have in the past which is enhance the \$500 million.

I would just though continue to reinforce what we've always said, which is that it is a number that could certainly go up. There's no guarantee of a settlement now or in the longer-term. Our primary strategy is to defend ourselves in court and we continue to believe in the safety and efficacy of our products. So again, the facts are not that different than we have described in the past.

With respect to the business itself, I think we have been seeing some very encouraging signs of turnaround at AMS, which, as I described in previous earnings calls, we've seen quarter-on-quarter improvement and that improvement is coming in multiple areas. So first of all, we've seen a return to stability and growth in our men's health business which is roughly about 60% of our revenues and therefore our most important business.

And also we are beginning to see some stabilization in women's health, particularly in the stress urinary incontinence part of our business and continued performance in our BPH business. Also keep in mind this is one part of our historic business where there is a reasonable proportion of our sales outside the US which have been growing well in excess of US growth rates.

So actually as we enter 2014, we are seeing good performance across all segments, including women's health where we expect to see a real stabilization in 2014. And as we fast forward, we expect the business in its entirety to swing into organic growth at some point in the year. And to end the year with something around low single digits in terms of organic growth.

So I think it's been a good story of turnaround and we've also done this in the backdrop of increasing our margins. We expect these margins to be in the low to mid-30% this year.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs Thanks, Mark. Can we go ahead and go to the next question please?



Operator

Annabel Samimy, Stifel.

Josh Riegelhaupt - Stifel Nicolaus - Analyst

This is Josh Riegelhaupt in for Annabel. In your guidance for 2014, at least EPS seems to be a little bit lower than what we were expecting. With everything pretty much else above it, what's affecting this? Is it the pricing of debt which is a little bit higher than we expected? Is it just continuing reconciliations?

And then second, are there any updates on negotiations with Novartis for V-Gel? I know we're kind of getting close to that April deadline. Thanks.

Rajiv De Silva - Endo Health Solutions - President & CEO

So let me have Suky answer your question on guidance and I'll come back and talk to you about V-Gel.

Suky Upadhyay - Endo Health Solutions - CFO

Yes. Relative to guidance and what we put out there from an earnings per share perspective, I think the two key variables to think about year-over-year that are headwinds going to 2014 are one, our overall interest expense which will be a step up about \$50 million to \$60 million year-over-year. And again, the reason we did that was to secure very favorable interest rates at the end of last year to create the capacity to execute the forward-looking strategy that Rajiv's been talking about, so that's one element.

I think the second is really around the dilution of the additional shares. The way to think about that is the addition of Paladin. As I mentioned in my script, we talked about 36 million approximately shares being added by Paladin.

On an annualized basis for this year given the 10 months it will be about 30 million. And then the remainder of additional shares year-over-year is driven by the increase in the share price and the accounting impact that comes from our convertible notes.

I think those are probably the two key drivers that will probably reconcile you back from where you may have been to where our guidance is currently. At the end of the day I think fundamentally our guidance still represents a very high quality plan.

If you think about the erosion in Lidoderm and Opana we're essentially offsetting that through the acquisitions of Pharma Boca -- Boca Pharmacal as well as Paladin. And in that backdrop we're essentially holding margins relatively flat year-over-year, potentially slightly improving in the backdrop of lower gross margins, and improving our overall cash conversion profile. So hopefully that gives you a little bit more color and context.

Rajiv De Silva - Endo Health Solutions - President & CEO

Thank you, Suky. The only additional comment I would make on that is, if you think about the impact of our interest expense, frankly, this is a good news impact as far as I'm concerned because when we went to the market at the back end of 2013 we had very favorable conditions and both of our debt offerings were [also] by quite a big margin and we were able to add some extra dry powder.

Obviously, our guidance does not reflect any future deals. And as you know we don't intend to stand still on our M&A program so we're actually glad that we have this extra debt on our books at this point.



In terms of your question on Voltaren Gel I think the situation again is as we had described on the previous earnings calls, we have a very productive dialogue with Novartis which is led by Don DeGolyer, our Chief Operating Officer of Pharmaceuticals. And it's a partnership that we have with Novartis that goes through 2015.

The only uncertainty historically has been around timing of other strategic moves that Novartis might make with Voltaren Gel as well as the potential arrival of a generic for Voltaren Gel. We had previously thought about that as being potentially an early 2014 event in terms of either of these outcomes making Voltaren a less important product for us.

However, as time has progressed, and our dialogue with Novartis has progressed, we've become increasingly optimistic that we will continue to promote Voltaren Gel well into 2014. And obviously there's limits to how much we can talk about this topic since the product is Novartis' product and their strategy is proprietary to them, but we are very cautiously optimistic about our ability to continue to benefit from Voltaren Gel through 2014.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Great. Thanks. Can we go ahead and go to the next question, please?

Operator

Liav Abraham.

Liav Abraham - Citigroup - Analyst

Rajiv, can you talk about the pipeline, broadly about the pipeline of transactions that you're looking at and your view on the level of competition for these assets and consequently valuations given the increased pace at which inorganic growth seems to be being pursued by players in the industry at the moment?

And my second question is regarding your tax rate. Can you talk a little bit about the dynamics around the tax rate following the closure of Paladin and the redomicile to Ireland and how you see this evolving over time? Thank you.

Rajiv De Silva - Endo Health Solutions - President & CEO

Sure, Liav. Let me have -- I'll have Suky talk about taxes and let me talk about the deal flow and the deal pipeline. So our deal pipeline is probably as robust as it has been over the course of time.

We continue to look at a reasonable mix of transactions between US branded, US generics and within that, a reasonable mix of private companies or asset deals as well as public market transactions. And obviously now with the Paladin transaction closing today, we also have a fairly robust set of international opportunities that we are looking at as well, which again, fall in the same categories of deal type, which is private as well as public, though probably more private than public. So in terms of the types of opportunities we're looking at in the pipeline, it's actually very robust.

In terms of competition, I wouldn't say that I -- that the competition has fundamentally changed. We've seen the same level of competition for assets as we have historically. While you may say there's more activity, not every player is looking at the same assets that we are looking at. And obviously, the larger you are, you look at a different set of assets. I think we are small enough that we can still benefit from transactions that are in the small to medium-size. So in terms of deal flow and valuations, we're not looking at a fundamentally different picture.

So let me, with that, maybe have Suky talk about the tax rate dynamics over the course of this year and the longer-term.



Suky Upadhyay - Endo Health Solutions - CFO

Sure. Thanks, Rajiv. If you remember when we closed the Paladin transaction we talked about \$75 million of post-tax synergies as part of the deal, primarily generated by tax synergies.

Right now where we're sitting today we expect to achieve that \$75 million of tax synergies, which will ultimately translate into an annualized run rate of about 20% over the midterm. And the way that breaks out into 2014 guidance of the 23% to 25% we quoted is, one, we're getting a partial year benefit from Paladin, so of course the transaction is expected to close today and it will take some time to fully realize those benefits.

As with any year, there's always going to be a lot of moving parts around tax when you think through NOLs, R&D tax credit, other discrete items. Also there are elements of our capital structure that could ultimately impact our overall tax rate.

Again, we're still very pleased with the synergies that we expect to get through the Paladin transaction. We still expect to be somewhere around 20% on an annualized run rate basis. And when you think about that opposite our underlying tax rate of about 30%, it represents a significant improvement.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Great. Thanks, Liav. Can we go ahead and go to the next question, please?

Operator

Gary Nachman, Goldman Sachs.

Gary Nachman - Goldman Sachs - Analyst

Rajiv, in your operating expense guidance it sounds like you're assuming the full effect of the restructuring initiatives by 3Q. I would have thought expenses overall would have come in a little lower. Could you talk about what the big drivers for expenses are? And I guess the operating cost synergies from your deals and how much flexibility that you have there? And then also, what's your comfort to use equity for a more material sized deal beyond the \$2 billion to \$2.5 billion that you've characterized?

Rajiv De Silva - Endo Health Solutions - President & CEO

Sure. Let me have Suky talk to you about your question on the expense and I'll come back and talk about the equity.

Suky Upadhyay - Endo Health Solutions - CFO

Yes. So Gary, the first thing is, I'll just ground this in 2013, we said we which achieve about \$150 million of savings worth versus a 2012 exit rate. That would translate into about \$180 million on a quarterly run rate basis. And I think you'll see that we achieved that in the fourth quarter of 2013.

As we move forward into 2014, using the same dynamics, you would expect a run rate of about \$180 million to \$185 million in OpEx going into 2014. So we believe we're largely there.

Now, while you might not see as big of a reduction than the underlying expenses might show, is because we're adding in the Paladin base as well as Boca Pharmacal and then we're also going to put some nominal investments into creating our overall Irish infrastructure. So the way to think



about this is that we are achieving a \$350 million run rate savings -- sorry, \$325 million, thank you, with the addition of Paladin, Boca, as well as some costs for Ireland.

Rajiv De Silva - Endo Health Solutions - President & CEO

So on your question on equity, our view of it is that we are still in a very attractive interest rate environment. And therefore debt continues to be our preferred source of capital for transactions. We believe that we should take full advantage of locking in low interest rates at this point in time for the longer-term. So that philosophy has not changed very much.

At the same time, our primary goal is shareholder value creation. So we do remain open in the longer-term for utilizing all forms of capital that is available to us. And as we saw with the Paladin transaction, we are not afraid to use our equity for the right type of transaction that we believe will create shareholder value. So in the longer-term, certainly we will keep our options open but in the near-term we'll continue to focus on the use of debt.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Thanks, Gary. Can we go ahead and go to the next question, please?

Operator

Greg Fraser, Bank of America.

Greg Fraser - BofA Merrill Lynch - Analyst

This is Greg Fraser on for Gregg Gilbert. Two questions. One, what are your latest thoughts on the recent Opana ER share trends and your ability to stabilize or perhaps even return Opana to share growth? And then second question is, does the 2014 guidance include a partial or a full year of contribution from V-Gel?

Rajiv De Silva - Endo Health Solutions - President & CEO

So with respect to the question of, on Opana first, we've been very pleased with how the product has performed. The share split between the branded product and the generics has remained roughly around 80/20. And has not changed dramatically with the launch of the full range of the Actavis non-AB-rated generic.

I would say there are a couple of reasons for that. One is that we do continue to actively promote Opana ER for its label. Secondly, there's been no change in terms of how managed care views the product from a tiering standpoint and that's largely due to the fact that the generics are non-AB-rated. So those two things are by far the biggest reasons in terms of why the share remains stable.

I think from a long-term perspective, we have -- there are two things we're doing in parallel. One is that we have active clinical program that we're pursuing in conjunction with the dialogue with the FDA which would hopefully allow us to apply for a label change sometime in the recent future -- near future. And then secondly we continue to vigorously defend ourselves in terms of our patents in court.

So in the near-term unless FDA approves a full range of other generics and managed care formulary status change dramatically we're hopeful that we continue to hold the brand where it stands today. And if all goes well, we may have a situation in 2015 with a stronger label where we could look at this brand again as a growth asset but that's obviously a medium term opportunity for us.



In terms of your other question on Voltaren Gel we're not going to be specific in terms of when in 2014 we believe the promotional agreement may or may not come to an end. All I can say is that we are optimistic that we will have the benefit of V-Gel for the majority of the year.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Thanks, Greg. Can we go ahead and go to the next question, please?

Operator

David Buck, Buckingham Research Group.

Jim Dawson - Buckingham Research - Analyst

It's Jim Dawson in for David Buck. What assumption are you making for royalties on Lidoderm in 2014? And what about expectations for Opana ER and Aveed?

Also just on the tax rate, you discussed the tax rate for 2014. What about for the first quarter of 2014? Is there a one-time benefit in that quarter? And then lastly, just the pricing environment for Qualitest or generics in the fourth quarter and what's the expectation for pricing and volume in 2014 and 2015?

Rajiv De Silva - Endo Health Solutions - President & CEO

A lot of questions. Let me see if I remember all of them. Let me start with the last one which I obviously remember the best, which is your question on generics pricing.

So by and large if you look at our performance in 2013, the growth is driven by volume and mix, mix related to the launch of new products. We have a very extensive portfolio of products where we do have opportunistic pricing events. Which we have a team that's very nimble and dynamic and we make use of market discontinuities and/or competitor pricing actions that allow us to take advantage of these events.

So as we go into 2014, we would expect a similar outlook, which is, we are planning our growth based on volume and new product launches. But obviously we will take advantage of price events as they come.

I will have Suky answer the question on tax. On Aveed, today is the PDUFA date. We have had an active dialogue with FDA. But that being said, until we hear definitely from the regulators, we don't want to comment on the likelihood of approval, but we remain cautiously optimistic given all of the effort that has gone into the brand.

In terms of the royalty from Actavis, we will continue to enjoy the benefit of a royalty as long as there is no other generic on the market. Obviously, that time period is subject to uncertainty around when the first generic would launch. We really can't predict how long it would last, but certainly we continue to enjoy the benefits of that royalty currently. Do you want to talk about the tax question, Suky?

Suky Upadhyay - Endo Health Solutions - CFO

Sure. Thanks, Rajiv. So going through the quarters throughout the year the tax rate could be lumpy as you have changes in discrete items opposite changes in operating income from quarter-to-quarter, but the way we think about it is we would expect to see our highest tax rate in the first quarter, primarily because you only have a partial benefit in that quarter. Then as we fully realize our overall tax synergies throughout the rest of the year, that tax rate will start to migrate back down.



Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Great.

Jim Dawson - Buckingham Research - Analyst

Thank you very much.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Could we go for the next question, please?

Operator

David Amsellem, Piper Jaffray.

David Amsellem - Piper Jaffray & Co. - Analyst

Couple of Qualitest questions. Can you give us some color on how many ANDA filings you have pending and give us a sense of how many of these filings are maturing, say older than 24 months?

Then on business development in the generics business, how are you thinking about what alternative dosage forms and complex generics interest you the most? And then just lastly a quick follow-up on Lidoderm, just to be clear, I want to make sure that the guidance does or does not reflect the launch of an authorized generic on Lido. Thanks.

Rajiv De Silva - Endo Health Solutions - President & CEO

Let me answer the Lido question first. So our potential launch of authorized generic is something that is still uncertain, we have not yet decided. But the guidance does reflect expectation of a second generic sometime in the first half of this year.

On your question on Qualitest, so with the addition of Boca Pharmacal, we have roughly about 55 ANDAs that have been filed. And we expect to see approvals of those ANDAs over the course of the next two to three years.

In terms of our acquisition strategy, for obvious reasons I'm going to stay away from being very specific on the types of things we're looking at, but suffice it to say that we continue to enjoy the benefits of being in controlled substances. We like our liquids capability, and there are others. For example, semi solids would be an area of interest.

You can obviously extrapolate from that in terms of what others you think we might be interested in. But in typical we're looking for areas that stay away from the typical solid oral dosage form generics and focus on areas where there's some niche benefits, either in terms of difficulty in formulation or fewer competitors.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Just in the spirit of time, I think we can go ahead and take two more questions. And then we'll try to wrap at the bottom of the hour. So can we go ahead to the next question, please?



Operator

Jason Gerberry, Leerink Partners.

Jason Gerberry - Leerink Swann - Analyst

Just a question on gross margins. If you can talk about with the two new acquisitions, how A, Boca impacts your ability to reach your aspirational Qualitest gross margins, which I think were in the mid-40%. And then Paladin, I think your pharmaceutical gross margins were in the high 70%s. Just kind of curious how Paladin fits into that overall margin structure.

Then just on Qualitest, anything you'd specifically want to call out on 4Q that drove the top line strength? Thanks.

Suky Upadhyay - Endo Health Solutions - CFO

Okay. Hi, Jason, first on gross margin, your question around Qualitest and how we exited the year and our ability to get to our aspirational goal there. We actually had a good strong quarter with Qualitest. Roughly just below 40% overall on a gross margin basis. And given our overall capital plan and process improvements that we plan to put into that business going forward, as well as the ability to take some opportunistic pricing, we think we'll get very close to our goal in 2014, if not fully there. And again, that goal that we put out there was a longer-term aspiration.

Relative to Paladin vis-a-vis branded, so you're right, branded was a higher gross -- the highest gross margin segment for the business, and given the loss of exclusivity on Lidoderm and Opana we're going to see an overall unfavorable mix impact on the company. The way Paladin fits in that, and while it offsets a good deal of that revenue loss, Paladin's got a margin profile somewhere around the mid-50%s to upper 50%s, so there is a little bit of erosion there. And again you see that manifest into the overall corporate guidance for 2014.

Rajiv De Silva - Endo Health Solutions - President & CEO

So on your question on the fourth quarter of Qualitest, it was probably a confluence of things that are all good trends for us. One is that we had some good volume trends in our controlled substance business. For example, we took an early approach to the conversion of the high-dose APAP products and the low-dose [APAP] products so therefore our combination APAP products performed quite well and continued to perform quite well. We had some new product launches.

So overall, we had a lot of positive events in the fourth quarter. And again, the good news is that we expect some of these trends to continue to hold going into the new year as well.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Great. Thanks. Can we go ahead and go to the last question, please?

Operator

Chris Caponetti, Morgan Stanley.



Chris Caponetti - Morgan Stanley - Analyst

I have two quick modeling clarifications and a higher level question. First, specifically when in the first half of the year do you guys model generic competition on Lido -- or additional competition on Lidoderm? And then second, could you remind me the 2015 gross margin target for Qualitest including Boca?

Then on my high-level question, excluding future M&A, should we think about 2014 as a trough year for earnings per share? Or is there a risk to out year EPS growth from potential generic competition to Voltaren Gel or the new Opana ER? Thank you.

Rajiv De Silva - Endo Health Solutions - President & CEO

On your question on Lidoderm, I'm not going to give you any specifics on when in the first half. The launch of a generic is inherently uncertain. The best I can say is that we expect it sometime in the first half of the year.

Now, your question in terms of longer-term margins and longer-term EBITDA, we're not going to focus on those today other than to say that we do have a view of our company to be an organically growing company in the medium to longer term. And we expect that our M&A program coupled with the improvements that we are making in terms of operating margins, as well as organic growth drivers like Aveed and other things that are going to happen this year will all contribute going into 2015.

Chris Caponetti - Morgan Stanley - Analyst

Great. Thank you.

Blaine Davis - Endo Health Solutions - SVP, Corporate Affairs

Just want to take the opportunity to thank everybody for joining us on the call today. Jonathan Neely and myself will be available for additional follow-up questions. And thank you very much.

Operator

Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. Good day.

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