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ENDP - Q1 2014 Endo International PLC Earnings Conference Call

EVENT DATE/TIME: MAY 01, 2014 / 11:30AM GMT

OVERVIEW:

Co. reported 1Q14 revenues of $595m and adjusted diluted EPS of $0.92. Expects full-year 2014 adjusted EPS to be $3.60-3.85.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q1 2014 Endo International PLC earnings conference call. My name is Allison, and I'll be your operator for today.

(Operator Instructions)

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

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Thanks, Allison. Good morning, everyone and thank you for joining us to discuss our first quarter financial results. With me here in Dublin on today's call are Rajiv De Silva, President and CEO of Endo, and Suky Upadhyay, Chief Financial Officer. We have prepared a slide presentation to accompany today's Webcast, and that presentation is posted online in the investor section at www.Endo.com.

I would like to remind you that any forward-looking statements by management are covered under the Private Securities Litigation Reform Act of 1995, and Canadian securities legislation, 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 first-quarter results and revised financial guidance. With that, I'd now like to turn the call over to Rajiv.

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

Thank you, Blaine, and 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 start with a review of our recent accomplishments, and follow that with the highlights of our first-quarter 2014 financial results, and then we will discuss the key drivers that have resulted in the raise to our 2014 full-year revenue and adjusted earnings per share expectations. Following our prepared remarks, we look forward to taking your questions.

Moving on to slide 3. We continue to make solid progress towards our priorities, and achieving our goals to be a leading specialty healthcare Company. Let me quickly review some of the significant recent events.

First, we recently took several actions that we believe demonstrate a disciplined approach to capital allocation, highlighting our commitment to create shareholder value. Earlier this week, we announced the acquisition of Grupo Farmaceutico Somar, a leading specialty pharmaceuticals company based in Mexico City.

We also recently announced that Endo had entered into an agreement to acquire the global rights to Sumavel DosePro. The product expands our portfolio brand of product in the treatment of pain and management of migraines, and is highly synergistic with our current commercial expertise. Both of these deals are good examples of the types of acquisitions we have discussed previously, and well-aligned with our stated strategy.

In April, we entered into agreements to repurchase the majority of our 1.75% convertible notes, and a proportionate amount of the related warrants, in the limited number of privately negotiated transactions. This action reduces the dilutive effect of these securities, and we believe was an appropriate allocation of capital, given market conditions.

Second, we have plans to launch an authorized generic version of LIDODERM imminently. We will discuss this decision further later in the presentation, but we believe this launch represents the best opportunity to maximize the value of this franchise, as we continue to manage the loss of exclusivity of the brand.

Third, in March, we announced the FDA approval and launch of AVEED. It is still early in the launch, but feedback from physicians regarding AVEED has been positive.

Fourth, we remain on track, based on recruitment rates, for a mid-year readout of results from our second BEMA Buprenorphine Phase III study. Following success in the study of opioid-naive patients, we look forward to the results from the opioid-experienced group this summer.

If the results of the study are positive, we remain on track for a filing later this year or in early 2015. In addition, we are making progress on our clinical trials program for OPANA ER, in support of a label change application.

And fifth, we are focused on meeting our financial targets, and we have announced increases to our 2014 financial guidance for both revenues and adjusted diluted earnings per share. I would also like to take this opportunity to welcome a couple of recent additions to Endo's leadership team, both of whom I have had the pleasure of working with previously.

Dr. Susan Hall has joined Endo as Executive Vice President, Chief Scientific Officer, and Global Head of Research and Development and Quality. Sue's role is based in Ireland, and she will be focused on Endo's global R&D and enterprise quality activities. Sue will also be keenly focused on overseeing a strategic shift in branded R&D, to create a pipeline for future growth. We believe that late stage development projects, with relatively higher probability of success, will be an important source of organic growth, that will supplement our strategic plans.

Dr. Hemanthe Varghese has joined Endo as Executive Vice President of Corporate Development and Strategy. Hemanthe is an experienced corporate development and operations executive. Over his career, he has completed more than 40 corporate transactions, and is experienced in acquisitions integration.

In his new global role, he will lead Endo's enterprise corporate development efforts, including acquisitions, in-licensing, divestments, and alliances. He will also oversee integration efforts in support of the general managers of our business units.

Moving on to slide 4. As we announced last night, Endo has reached agreements in principle to settle a substantial majority of AMS litigation cases. These agreements were reached by Endo with several leading plaintiffs' law firms and are expected to resolve approximately 20,000 claims relating to vaginal mesh products sold by our AMS subsidiaries.

The agreements are subject to final documentation, and were entered into by way of compromise and settlement, and are not in any way an admission of liability or fault. Under the terms of the agreements, Endo estimates that AMS will pay an aggregate pretax amount of approximately $830 million, as claims are resolved over a period of time. Suky will cover more on the financial effects of the settlement in a few minutes.

I would like to take this opportunity to thank the Honorable Judge Joseph R. Goodwin of the Federal Court in West Virginia for his wise oversight of the settlement process. I would also like to recognize the many leading plaintiffs' law firms involved in the settlement for their constructive approach. Especially the leadership of the Motley Rice and Blasingame, Burch, & Garrard Law Firms.

We believe that these agreements are in the best interest of Endo, AMS, their respective employees, and our shareholders. While there are still risks of ongoing litigation, we are very pleased that we have resolved the majority of this legal overhang early in 2014, and continue to support the return to growth of the AMS business.

AMS will continue to focus on the safety and efficacy of its products. We continue to support the FDA's recommendations that physicians be well trained and patients fully understand the risks associated with the use of mesh products. And finally, AMS will continue to invest in developing clinical evidence to support the restoration of quality of life that their mesh solutions provide.

Moving on to slide 5. You will see that we had a solid first quarter, reporting $595 million in revenues, and $0.92 in adjusted diluted earnings per share.

We are off to a good start in 2014, with solid commercial performance leading the way. Suky will provide more details about first-quarter results in just a few minutes.

Our underlying performance is on track and if line with our expectations. Managing to the loss of exclusivity for LIDODERM obviously has 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. As we expected, branded pharmaceuticals sales declined in first quarter 2014 compared to first quarter 2013. Our core portfolio of branded growth drivers increased 2% versus prior year.

That core of growth products excludes LIDODERM, royalties received from Actavis for the sale of its generic Lidocaine patches, and OPANA ER. We remain confident in our full-year expectation for low single digit growth from our four products. We continue to invest behind our three growth drivers in this business, as we also explore opportunities to add additional products to our branded business through acquisitions, partnerships, or licensing.

Moving to slide 7, first-quarter 2014 sales of $212 million for our generics business continued to deliver impressive results, delivering 19% growth versus prior year. Our generic business benefits from inclusion of Boca Pharmacal results, following the close of that acquisition at the start of February.

That growth is aligned with our expectations for Qualitest in 2014. Qualitest's strong start to 2014 was led by its controlled substance business, where we continue to see strong volume growth and pricing power for the category overall.

Moving to slide 8. We are very pleased to see improving trends in our AMS business in the first quarter. In total, AMS grew 1% in first quarter 2014, and growth rates continue to show improvement.

Growth for AMS excluding women's health was at 4%, versus first quarter 2013, after growing 3% last quarter. The turnaround of AMS is continuing to deliver results, while also delivering profitability and EBITDA contribution.

During the first quarter, AMS acknowledged the receipt of a warning letter from FDA following an inspection of its manufacturing facility in Minnesota. AMS has a collaborative approach with the agency and they are addressing their concerns, and agreed upon plan, and is making very good progress.

Moving to slide 9, our international pharmaceuticals business is performing well. Following the close of our acquisition of Paladin labs on February 28th, that business performed well in March, and is on track to meet our expectations.

We also set forth on an accelerated program to build a presence in Ireland, following the close of the transaction. The key functions we have in place now include a President of Ireland business, known as Endo Ventures, Executive Vice President of R&D and Quality, as well as supply chain and finance. We are in the process of adding senior staff, and investing in infrastructure, to enhance our capabilities in Ireland.

Moving to slide 10, we continued to make good progress towards our acquisition objectives. Last week, we announced the acquisition of worldwide rights to Sumavel DosePro from Zogenix, Incorporated. Earlier this week, we announced the acquisition of Grupo Farmaceutico Somar, a leading specialty pharmaceuticals company based in Mexico City, and I will provide more details for each opportunity in a moment.

We believe these deals are well aligned with our strategic objectives, and represent the type of acquisitions we have discussed with you previously. We remain keenly focused on acquisitions as a core tenet of our future growth, and we remain open to a broad range of opportunities across the pharmaceutical spectrum.

We also have significant flexibility with our balance sheet to do additional deals, and are open to all forms of financing. We will also continue to be disciplined in the allocation of capital.

Moving to slide 11, we believe Sumavel DosePro is an excellent fit with Endo's experience in pain therapy and migraine management. The product is on the market in the US, with $32 million of sales in 2013, and we will support the growth of the product with existing resources. We are focused on completing a seamless commercial transition, as we expect the transaction to close sometime in the second quarter.

Moving to slide 12, the acquisition of Somar is well-aligned with our goal of pursuing accretive transactions, and this transaction provides us with a platform in Mexico that we believe can support further expansion into attractive Latin American pharmaceutical markets. Somar has a highly diversified portfolio which generated approximately $100 million of sales in 2013, by targeting Mexico's non-patented pharmaceutical market through three primary segments: Generics, branded generics and OTC. They have a robust pipeline, which currently includes over 60 products expected to launch over the next three years.

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

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

Thanks, Rajiv, and good morning to those joining us for today's presentation. This is clearly an exciting time to be at Endo, as we delivered solid first-quarter results, and as a result, we are raising our full-year 2014 expectations.

Let's move on to slide 14, and I'll walk you through some of the financial details. While revenues declined versus the first quarter of 2013, underlying growth, excluding the effects of LIDODERM, royalties from Actavis, Boca Pharmacal, and Paladin was about 1%. We expect that to improve as the year progresses, and we annualize this loss of exclusivity of LIDODERM.

Rajiv covered revenues earlier in the presentation, so I'll move on to the rest of the P&L. Moving to slide 15, gross margin was slightly better than expected in the quarter, primarily driven by higher LIDODERM royalty revenue.

For 2014, we expect each segment to broadly maintain or improve their gross margin profile, in the backdrop of a dynamic pricing environment. However, we continue to expect a decline in the overall corporate average, due to a shift in business mix. Regarding operating expenses, we continue to track to our overall cost target of a $325 million reduction versus the 2012 baseline, and that is reflective of the 25% reduction in year-on-year operating expenses in the first quarter.

In addition, we have an improving tax rate as a result of the Paladin transaction, and remain on track to realize our post tax synergies on an annualized basis. These improvements in our cost structure and overall tax rate will ultimately lead to adjusted net income growth of 9%, despite a revenue decline of 10%.

Adjusted EPS of $0.92 is ahead of expectations, as a result of stronger than expected operating performance. On a year-over-year basis, adjusted EPS declined, due to the overall revenue decrease, and a higher share count related to our convertible notes.

However, we believe our actions as a management team have positioned the Company for sustained earnings power and enhanced underlying cash conversion, with improving operating margins, and a more favorable effective tax rate. The fundamentals of the business remain solid, and we are excited about additional opportunities to improve revenue growth, margin expansion and cash conversion by executing our strategy.

On a reported basis, our results include a pretax non-cash charge of approximately $625 million, to increase the Company's max liability reserve to approximately $1.1 billion for all known, pending, and estimated future claims. The change in the accrual for product liability claims is primarily attributed to agreements in principle that the Company's AMS subsidiary has reached, to resolve approximately 20,000 claims.

This represents a substantial majority of claims relating to vaginal mesh products. For your reference, AMS has approximately 23,505 filed cases as of the end of April. We expect the liability to be paid through 2016, and remain confident that the cash call can be managed, while continuing to execute our growth strategy.

I would also echo some of Rajiv's comments made earlier, in that we are very pleased to have successfully resolved the majority of the mesh liability early in 2014. We feel that the removal of this overhang is a positive step for our business, and we'll continue to execute deals and support our organic growth. We have a strong balance sheet and broad access to capital to finance future deals. I would also remind you that the charges are pretax amounts, so the net result of these settlements would be favorably adjusted by US tax shields. For additional details on our first-quarter 2014 financial results, please review today's earnings press release.

Moving to slide 16, let me make a few comments on full year guidance. I won't spend time going through all the items of guidance but will highlight a few key considerations.

Before I move into the details, as consistent with last quarter, we do not include M&A transactions that have not closed within the current period. We are excited about the opportunity to close Sumavel DosePro and Grupo Farmaceutico Somar, both of which we expect to finalize in the coming months.

Also, regarding our convertible notes and the impact on shares outstanding, we assume a share price that reflects recent trading when estimating forward-looking weighted average fully-diluted shares. Given our better than expected performance in the quarter, we are tightening our guidance range on revenue, while increasing the top end by $20 million.

We are also raising our adjusted EPS guidance range by $0.20. Adjusted EPS is now expected to be $3.60 to $3.85. The increase in our adjusted EPS range is driven by a stronger operating performance, as well as a lower share count related to the repurchase of approximately $240 million of convertible notes.

One additional comment to consider for 2014, relating to our repurchase of outstanding 1.75 convertible notes. As we discussed in detail on the last earnings call, financial reporting requires that we factor in fractional dilution from the notes and a related set of warrants, when shares of Endo trade above certain levels. In the first quarter of 2014, that effect was about 13.3 million shares, based on an average share price of approximately $70.

Recent market conditions as wells as the repurchase of notes and related warrants are expected to significantly reduce the dilution effect we will report going forward, as we can now exclude the dilutive effects of the securities we have repurchased. As Rajiv stated earlier, we believe the decision to repurchase a large portion of the outstanding notes was a good capital allocation decision, based on favorable market conditions. The detailed aspects of our former P&L guidance are broadly in line with what we provided in February, and therefore I will not cover this in detail.

Overall, we had a solid first quarter and continue to deliver the proof points of our ability to execute against the strategy. To summarize, we are increasing our revenue and adjusted EPS guidance ranges, resolving a majority of the mesh liability, executing two value-creating transactions, efficiently deploying capital to delever our balance sheet, and continuing to enhance our leadership team. These actions continue to build a foundation for long-term value creation, and we are excited about our outlook.

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

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

Thank you, Suky. Moving now to slide 17.

In closing, I would like to focus on three of the priorities for 2014. Let me start with our objective to meet our financial targets. We had a very strong close to first quarter, and we are tracking favorably year-to-date, and we beat consensus expectations for adjusted diluted earnings per share. While Endo management still has much to achieve in 2014 in pursuit of this objective, our strong operating performance in the first quarter has us off to a good start, and supports the raise in our top and bottom line.

Second, we have an objective to complete at least two to three near-term accretive value-creating transactions. The additions of Sumavel DosePro and Grupo Farmaceutico Somar are solid examples of our acquisition program for 2014. We continue to look for new opportunities, as we complete and integrate these transactions.

Third, we are developing an organization and culture aligned with our strategy. We are attracting new talent to Endo, and at the same time, we have existing leaders taking on new and challenging responsibilities, that will be key to our future success.

Finally, we are making good progress in addressing some of our historical challenges, such as the litigation burden on our AMS subsidiary, managing through the loss of exclusivity of LIDODERM, and the dilutive impact of our convertible notes. We are pleased that we have been able to reach resolution on the substantial majority of our vaginal mesh liability early in the year. The removal of this overhang is a very positive step for our business, and we remain focused on supporting the organic growth of each of our segments, while continuing to explore additional M&A opportunities.

In conclusion, it is an exciting time at Endo. We continue to execute against our turnaround plan, as we transform the Company into a leading global specialty healthcare 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. Let me now turn the call back over to Blaine to manage our question-and-answer period. Blaine?

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Thanks, Rajiv. That concludes our prepared remarks. We'd now like to open the line to take your questions. Operator, if we could please go to the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from Chris Schott of JPMorgan. Please proceed, sir.

Chris Schott - *JPMorgan Chase & Co. - Analyst*

Congrats on the settlement here. A couple questions. First, could you talk about your capacity, financial capacity for further transactions, once we factor in the settlement and the convert repo? I think before you said at least $2 billion, just an update on that number.

Second question was on the mesh settlement. How much of an overhang was this liability on your business development strategy, and now that you have some clarity on this, do you consider looking at maybe larger transactions than in the past, just with the certainty?

And the final question, can you talk about this decision to launch a LIDODERM AG, just how are you balancing the lost royalty revenues, versus the prospects for your own product there? Thanks very much.

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

Thank you, Chris. So let me start with the first question with the capacity question. You're right, we have previously talked about having capacity for between $2 billion an $2.5 billion of transactions.

When we talked about those estimates we always had in mind that we had to at some point redeem our convertible notes by mid-2015. We also had an expectation of either settling or dealing with the mesh liability over a period of time.

Those types of things were already in our calculations as we thought about it. Obviously we have a more refined [read] now that we reached a settlement on the vast majority of the cases, and we have also done a couple of transactions. So what I would say is in general we remain very optimistic about our transaction capacity.

I think the ballpark that you talked about is not unexpected, and a lot of the capacity is also related to the types of companies we will buy, because to the extent that we are buying EBITDA-heavy companies, we can obviously lever the balance sheets of the companies that we're buying as well. So we feel good about the capacity for M&A going forward.

In terms of the overhang of the liability, in general, for us, I think this is a great step forward in turning the AMS business around. It also resolves management share of mind issues for us.

I would say that the mesh liability was not something that was a hindrance to our acquisition strategy. That being said, now that we can focus even more on it, I would certainly expect our level of commitment to our R&D program to increase.

In terms of LIDODERM authorized generic, it's a very calculated decision. In terms of, if you look at the share position that we currently have, roughly about 80% of the molecule share is now in the generic, about 20% in the brand. And based on our assessment, we can certainly do better than that, with an authorized generic out in the market.

As we pointed out, yes, we do lose the royalty. On the other hand we believe we will actually have more competitive pricing opportunities with an authorized generic as opposed to depending on rebating and discounting our branded product. Ultimately, we believe that this will be a rational marketplace, and we look forward to being a competitor, both with the branded product as well as the authorized generic.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

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

Operator

Certainly. Thank you. Our next question comes from David Amsellem of Piper Jaffray. Please proceed.

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

Just a couple. So on the mesh settlement, does that -- getting that out of the way, make it potentially more likely that over time you may look to divest the AMS business? And then secondly, on generics, just a high level question.

Are you focusing primarily your acquisition strategy in the generics and brand generics space on ex-US emerging market assets, or are you also looking at US assets in the generics space? Thanks.

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

First, to answer the question on AMS. Our primary focus is on turning AMS around, and as we showed in our -- in the information that we just shared with you, we are seeing very encouraging business performance, and resolving the overhang of the mesh litigation is also a positive, and we are looking forward to seeing continued growth out of AMS, they're a very important contributor to our progress in our turnaround.

But that being said, I think we've always been very clear that as a shareholder-friendly Company and management team, we are always open to thinking about the value of our assets, and we would always want to make sure that the value is maximized in our assets. If someone else will value any of our assets more than we do, we are always opened to a discussion. That being said, no decision has been taken around the future of AMS.

In terms of your question, the generics. We are firm believers in generics and branded generics. As you see further acquisitions from us, certainly outside the US, you should continue to see us looking at attractive generics, branded generics, and OTC assets. They tend to be more durable assets and they're certainly things that tend to in those markets be much more reliable, so growth for us going forward.

And in the US, Qualitest has been an outstanding performer for us, and we continue to want to put more assets in the hands of that management team. So we will look for the acquisitions in the US, as well, but most often we are looking for assets with either some niche type of capability, either barriers to entry, something that makes it different, as opposed to your typical run-of-the-mill solid oral dosage form generics.

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

Thank you.

Operator

Thank you. And your next question comes from Marc Goodman of UBS. Please proceed.

Marc Goodman - *UBS - Analyst*

So, a couple things. First, on AMS, can you actually talk a little bit about the fundamentals of the business and profitability, and what's going on behind the scenes, so we can understand that? It's still a part of your Company. Second of all, generics, can you talk about Boca, the impact Boca had in the business, and what's going on behind the scenes? Obviously the important controlled substance market and stuff like that, and whether you are able to take pricing and things Just in general, what is happening there.

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

Sure.

Marc Goodman - *UBS - Analyst*

Thanks.

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

Absolutely, Marc. Thank you. First on AMS, I think the -- so there are two or three major drivers to our continued turnaround.

First and probably most important is the continued recovery of the men's health business. So the men's health business has always been a traditional source of strength for AMS, and something that clearly over the course of the last three years, there was insufficient focus. So that's been where most of our managers and leadership team's focus have been, and that's return to growth, and it's a highly profitable business for us. We are also seeing growth in our BPH business, and also our ex-US business is also contributing very well to growth.

The women's health business, I would say, is in the process of recovery. We have not yet seen it bottoming out. The market trends are still some negative, perhaps not as negative as they have been in the past.

But the totality of it, just given the size of the men's health and BPH business and the growth potential basically allows us to power through the negative trends in the women's health business. So that's fundamentally what is going on there.

With generics, we have had a lot of success integrating Boca. It's been seamless integrated, and in general, the hydro-APAP product and our broader suite of APAP products are doing very well. We took an early strategy to converting the market from high dose APAP to low dose APAP, and that's paid a lot of dividends.

We have one of the leading market shares in that category at this point, and obviously, we don't expect our competitors to stand still. We believe that will continue to be a very competitive place for us, but we are very pleased with how the market share progression has gone there for us, and we have been able to take advantage of some pricing opportunities, but if you look in its totality, Qualitest is performing, because of substantial volume growth, not simply price.

Marc Goodman - *UBS - Analyst*

And instead of just talking about the top line, could you talk about the bottom line a second in each of those businesses, how much is profitability improving?

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

Sure. So if you look at our AMS business, we have made some substantial profitability improvements, given the cost restructuring program that we implemented last year, and we expect the EBITDA margins of that business to be in the low to mid-30s this year, which would make is one of the better performing device businesses out there, in terms of a -- from a margin standpoint. I will ask Suky to comment a bit on Qualitest margins, because we're also seeing some good improvements there, coming through from a gross margin standpoint as well.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

Absolutely. So on the top line, you saw really nice growth with the AMS business, and that was also replicated on the bottom line. We've made several improvements to our overall cost of goods profile there, and as we've quoted before, we expect gross margin in that business to approach the mid to high 40 level. That's playing out quite well. Again, profitability growing right in line, maybe slightly better than revenues.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

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

Operator

Certainly. Thank you. And your next question comes from Gary Nachman of Goldman Sachs.

Gary Nachman - *Goldman Sachs - Analyst*

A few on the mesh settlement. Rajiv, how did you come to terms with the plaintiffs' attorneys so quickly, I'm curious if it was a hard-fought negotiation. You said in the past a lot of the cases could turn out to be frivolous.

Could the payment number actually come down meaningfully, if that turns out to be the case? And then Suky, how should we think about these payments, how should they be staggered over the next few years? Is it spread out evenly or is it more back-end loaded?

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

Let me take the first couple of questions and I will have Suky talk about the payment, expected payment schedule. So, I think in terms of, you always found us, I think not only in mesh, but more broadly to be a very fast paced and practical management team. We've long taken the view that certainly this is a liability which we could certainly fight in the courts, and do so over a long period of time, but that obviously comes at the expense of a lot of legal expenses, and substantial drain on management share of mind, so we hired settlement consultants last year, and we've been very practical about how we approached the settlement.

We had a good relationship with the judge, Judge Goodwin in West Virginia, who was in charge of the process, and in the end, although we were in adversarial positions, we also managed to find a constructive dialogue with some of the leaders of our process. I do have to say, I have to give a lot of credit to our General Counsel, Caroline Manogue, and her litigation team, as well as our outside attorneys at [Holland and Porter], who are outstanding, as well as Reed Smith, our litigation counsel. I would say, while we have made outstanding progress here, we do have some remaining

liabilities to settle, and we intend to fully defend ourselves in those cases, and continue to look for settlements with the remaining plaintiffs, plaintiffs' counsel.

In terms of your question on the frivolous lawsuits, one of the elements that we have included in this settlement in principle is that in order for payments to be made, we do have a requirement that we verify that AMS product was actually used, and we also will have access to pertinent medical records, before final payments are made. So if there are frivolous lawsuits, which there may well be, those will be weeded out in this process. And, look, we will continue to shepherd the settlements through to their final resolution, and we will also vigorously defend ourselves in court, if we have to, for any of the remaining cases, should the need arise.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

And Gary, it's Suky. Relative to the payment pattern on this, so the one thing I'll say is that it's still very fluid, and so we are in agreements of principle with plaintiffs' counsel. As we move into the final negotiations on the final contracting, that could ultimately drive the timing of payments.

Also, as part of the adjudication process of this settlement, that could also drive the timing and change the timing. The way we broadly see this is about $400 million pretax payment in 2014, and again, recall from my scripted comments, that will be insulated by a 35% US tax shield, and then we would see broadly of the remainder of that, the majority of the remainder happening in 2015 with the tail into 2016.

Gary Nachman - *Goldman Sachs - Analyst*

Thanks a lot.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

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

Operator

The next question comes from Shibani Malhotra of Sterne Agee. Please proceed.

Shibani Malhotra - *Sterne, Agee & Leach - Analyst*

Congratulations on the great quarter. Can I just ask a couple of questions related to your Paladin and Endo tax structure? You commented that this deal would now be -- that shareholders will now be subject to tax, so could you just explain the mechanics behind this?

And then, does the current structure preclude you, or are there any considerations for you, when considering the size of acquisitions in the US going forward? I know you said, Rajiv, that you could do -- you can lever up a different Company, and so just wanted to get some clarity on, again, what size are you looking for, and what would fit your criteria, given the current structure? Thank you.

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

Sure, let me have Suky answer the first question, and I'll come back and answer the second question.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

Relative to the taxability of the transaction, it's a very complicated tax ruling here but essentially has to deal with the aggregate shareholder gain of our US stockholders, vis-a-vis the capitalization of the former Endo, opposite the new Endo. Again, some very complicated rules in there, but basically, if your shareholder gain is larger than that capitalization, ultimately, the deal becomes taxable.

Now, when we first did the transaction, a share price of $45, we thought that the aggregate gain was in fact lower than that capitalization, but as the stock price increased between signing and closing to somewhere in the $79 range, that shareholder gain then outpaced the capitalization, so the deal actually became taxable. But again, it's a very complicated subject and topic, probably more so for this conversation. I will refer you to our filed S-4 on the transaction, which goes into more detail on the mechanics of this.

Shibani Malhotra - *Sterne, Agee & Leach - Analyst*

Okay.

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

On the question with respect to size of transactions, our preference in terms of transaction size has not changed. We've been very consistent that we like transactions in the $250 million to $500 million range. We like private transactions. Somar is a very good example, as is Boca Pharmacal.

That being said, our primary focus is shareholder value creation. In that context, we will certainly look at deals of any size. If we think they will create shareholder value, and we will be opportunistic.

Shibani Malhotra - *Sterne, Agee & Leach - Analyst*

I guess just the follow-up is, does your current tax structure put any restrictions on the type of deals or the locations of companies, the domicile of companies that you acquire?

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

None whatsoever.

Shibani Malhotra - *Sterne, Agee & Leach - Analyst*

Okay.

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

One of the reasons why we did this transaction, was to increase our corporate flexibility. So frankly, we now have a lot more flexibility in terms of how we think about transactions, both US as well as ex-US, it also gives us a lot more flexibility in terms of moving and managing our cash on a global basis.

Shibani Malhotra - *Sterne, Agee & Leach - Analyst*

Thank you.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

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

Operator

Thank you. Your next question comes from Chris Caponetti of Morgan Stanley. Please proceed.

Chris Caponetti - *Morgan Stanley - Analyst*

Congratulations on the settlement. I have three quick questions for you. First, what is the net cash cost of repurchasing the $240 million face value, just because the converts were deep in the money?

Second, when do you expect additional entranTs, generic entrants on LIDODERM and how does that impact your thinking on whether to launch an AG? Finally, if you could just add some chore on what drove the year-over-year decline in FORTESTA sales during the quarter? Thank you.

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

Sure. Let me just answer your questions on LIDODERM and FORTESTA. And then Suky will talk about converts.

So with respect to LIDODERM, we do expect another generic launch sometime this year, and that is anticipated to be the launch from Mylan. The timing is unclear to us, but we have been expecting it sometime in the first half of this year. But obviously, we have no further information that can back that up, other than public commentary made by that Company.

There are also two other generic filers, [TWI and Novin], which we expect to launch sometime in early 2015. And certainly one of our calculations in terms of early launch of the authorized generic is that we do believe there are some advantages towards establishing contracting relationships, ahead of another generic launch in the category.

In terms of FORTESTA, there's been a general slowdown and decline of the low T market. What you see in terms of FORTESTA volume declines is in keeping with the market declines, which are in the low single digits.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

Chris, it's Suky. Relative to the total cost of the convert retirement, so as you noted, the principal amount was $243 million. In aggregate, it was about $450 million, when you consider the note conversion, as well as the unwind of the related warrants.

Chris Caponetti - *Morgan Stanley - Analyst*

Great. Thanks so much.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Thanks, Chris. Could we go to the next question, please?

Operator

Thank you. The next question comes from Annabel Samimy of Stifel. Please go ahead.

Annabel Samimy - *Stifel Nicolaus - Analyst*

I just wanted to confirm with you the guidance that you have put out does not include the Somar acquisition, as well as Sumavel DosePro. If you could talk about gross margins going forward, it looks like some of the acquisitions that you've done tend to be in a lower gross margin business.

How should we be thinking about where you want your gross margin goals to be a few years down the road? are you trying to balance that going forward, with some additional acquisitions of higher margin products? And also just last question regarding the cost restructuring program, where are you in that, and have you identified any further cost synergies through the various business development deals that you've done? Thanks.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

Regarding your first question, regarding guidance, we do not include Somar or Sumavel in that forward-looking guidance. It's our policy not to include deals that have not closed. So the numbers we have quoted exclude both of those.

Regarding gross margins, overall, I talked a little bit about it, where the overall corporate average we expect to decline year-over-year, primarily due to the mix of our business. Again, each one of our segments is performing really well, and actually holding margins, or improving in the backdrop of a very challenging pricing environment. So we feel really good about that.

You're right, and we talked a little bit about platform deals, particularly in emerging markets or perhaps in our generics business, which might have a lower gross margin profile than the overall Company. However, we'll balance those in a portfolio approach with higher synergy and higher margin deals in our branded -- in the branded segment. Relative to these deals, specifically on gross margin, because they're in emerging markets and more or less a platform deal with Somar, they're slightly dilutive to overall gross margins, but the size and scale of the deal is relatively small. So we don't see a major impact, a material impact to what we've guided already for this year.

And then relative to our cost savings target, we're right on track with the underlying reductions that we spoke about last year. And a way to sort of quantify that in is, if you looked at the $325 million target, vis-a-vis the 2012 baseline, that would call for about $171 million run rate quarterly OpEx target.

If you look at where we are in the first quarter, we've done about $180 million. However, if you were to back out the Paladin transaction, as well as HealthTronics on an apples-to-apples basis, we're essentially right on target with the overall savings goals. So very good progress made against that.

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

Let me just add to Suky's answer. I think when you think about the acquisition like Somar, the recent we think about it as a platform acquisition is that, A, it has the potential to allow us to really expand in Latin America. And while in some of these markets the gross margin profile is lower, we believe that the long-term growth outlook and the durability of these assets are actually superior to Western markets.

And secondly, one of the other attractive aspects of Somar is that they have some new manufacturing capacity that they built up in Mexico City, a brand-new facility. It is not yet FDA approved, it is approved by COFEPRIS. But it is something that could be a real source of strategic value to our Qualitest business, because currently we lack a source of low-cost manufacturing outside the US.

And the other thing I would say on the cost part of it is that looking for cost improvements will be an ongoing effort. It's never going to stop. And also, one of the things that we are focused on in the US is looking for transactions that are heavy in cost synergies, and those are the ways in which we will continue to improve our cost structure and improve our margin structure, as well.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay, great. If you I could just ask one more, with regard to, I guess, the profile of the Company. You look like you're becoming extremely diversified between generics, branded generics, international.

Is there anything in terms of the branded side that you're trying to leverage, in terms of area? You had significant pain expertise. You obviously have a lot of urology expertise. Anything you could leverage there that you should continue to focus on, or you're willing to continue to focus on?

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

We are completely therapeutic agnostic, so we are not tied to those two areas. Obviously, our capabilities in pain and urology can be easily leveraged, if we do acquisitions in those areas. We are more driven by finding opportunities for true shareholder value creation, in all therapeutic categories that are more likely to provide sustainable and durable growth as well.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Great, thanks.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

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

Operator

That comes from the line of Corey Davis of National Alliance. Please proceed.

Corey Davis - *National Alliance Securities - Analyst*

A couple questions. I think you said in your remarks that you were open to all forms of financing, and you talked about debt capacity, but assuming that your stock gets back to where its was sometime in February or so, are you open to using your equity as a currency to do acquisitions?

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

What I would say is our first preference is use the debt markets, because despite all the movements over the course of the last few months, the debt markets are at all time low rates, and this is a great time to put on long-term debt on our books in support of acquisitions at very competitive rates. But that being said, we are open to all forms of creative financing, but what I would say is that debt is still our preferred form of financing.

Corey Davis - *National Alliance Securities - Analyst*

Okay. Thanks. And then secondly, can you just give us an update on the insufflation study on OPANA ER, where that stands, and the chances of someday ending up with a label that has more abuse deterrent language, or should we continue to model OPANA as a slow decline, or maybe someday turn that around and turn it into a growth product?

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

From an internal plan standpoint, we've modeled exactly as you described, a flat to declining molecule. That being said, we are making progress in three fronts with OPANA. First of all, we are defending our new patents vigorously in court, and that process will continue.

We continue to detail the product and since it is still not AB-rated in managed care formularies, we still get the vast majority of the products where the script is written for OPANA ER. Thirdly, we are engaged in a clinical program, so we have agreed a protocol for the insufflation study with FDA. And we have begun the study itself.

We expect to have results somewhere in the second half of this year, and if all goes well we will be able to file our data with FDA by the end of the year, or early in 2015. And obviously as -- you obviously follow this very closely, so you know it's the insufflation study where we also need to continue to provide evidence from the epidemiology databases, as well. So we are cautiously optimistic. It will not be until sometime in 2015, until we know how the FDA will view this.

Corey Davis - *National Alliance Securities - Analyst*

Great. Thanks, Rajiv, and congrats on all the progress you've made so far.

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

Thanks, Corey.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Go to the next question.

Operator

Your next question comes from Tim Lugo of William Blair. Please proceed.

Tim Lugo - *William Blair & Company - Analyst*

I guess following up on the branded side as well, can you tell me when you expect the second study to read out, and can you comment on potential peak sales, given the move of hydrocone APAP products to schedule 3, hopefully by the time this product launches?

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

I'm sorry, can you repeat the second half of your question? I'm not sure I fully got it.

Tim Lugo - *William Blair & Company - Analyst*

I believe the timing of hopefully a launch of BEMA Buprenorphine should coincide with the hydrocone APAP products being rescheduled from schedule 3 to schedule 2.

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

Understood. In terms of the timing, it's mid-year, so I would say in the July time frame is when we expect the study to read out. Which has been where we predicted last quarter as well, so no change in that.

In terms of peak sales, we have not made any public commentary about that, and we're not going to at this time either, but I think as we said, our current expectation is that this will likely be a schedule 3 product, and should the current plans with the FDA pan out and the hydrocodones move to schedule 2, there would be potentially some advantage for the product. So we are encouraged and optimistic about it, but we tend to be very conservative about how we think about these things, and we don't really want to get ourselves too excited about peak sales until we see the clinical data and are convinced the product is launchable.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Thanks, Tim. I think we have time to take three more questions. If we can go to the next question, please?

Operator

Certainly. Thank you. Jason Gerberry is the next question from Leerink. Please proceed.

Chris Kingley - *Leerink Swann - Analyst*

It's Chris Kingley in for Jason. Couple of quick follow-ups on the mesh litigation. Could you discuss the number of unsettled cases? I think in February you mentioned it was around 22,000 cases in total. Is the number around 2,000, or has it grown since then? If you could remind us of the cutoffs for litigants filing new cases? Thanks.

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

In terms of the case numbers, there are different definitions for the different cases. So what we have disclosed in the past in our filings and earnings releases, are number of filed cases. You referred to 22,000. The number of filed cases right now are 23,500 filed cases.

The 20,000 settled cases, they'll refer to both filed and unfiled cases, in the portfolios of these plaintiffs attorneys. In addition to this 23,500 cases, there are potentially some unfiled cases out there. We do expect that to be in the single digit thousands.

So we still believe that we have settled the vast majority of these cases. And was there another part to your question?

Chris Kingley - *Leerink Swann - Analyst*

Yes.

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

The statute of limitations. By and large, the statute of limitations has expired in most states, where it's two years. There were a series of cases that were subject to a tolling agreement, some of which are still in process potentially. So we've been conservative in terms of some of our assumptions around unfiled cases. There are a few states, though, where the statute of limitations does extend longer, but at this point, our anticipation of new cases is at a very low level, which is where it was before, and at a very manageable level.

Chris Kingley - *Leerink Swann - Analyst*

Thank you.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Can we go to the next question, please?

Operator

Certainly. Which comes from David Buck of Buckingham Research. Please proceed.

David Buck - *Buckingham Research Group - Analyst*

Yes, thanks. Just a couple of quick ones. Looking at the Qualitest business, can you give us a sense of what Boca contributed in the quarter? And can you talk about the expectation for competition on the large liquid product, that has been the growth driver for that business?

Secondly, if I look at AMS and the recent settlements announced, does that go to cost basis of that business, and eventual sale? And was this a sticking point in any parties looking at an acquisition previously of AMS? And then finally, from Endo's Board perspective, does the Company view it as appropriate in the acquisition strategy to be teaming up with financial buyers and potential acquisitions? Thanks.

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

Let me have Suky answer the first two questions. I'll start out the first one by saying that we don't give line item guidance on any of our businesses, so we're not going to talk specifically about any of the Boca products, in terms of size. What I would say is that we are very pleased with the performance of the Boca products and the low dose APAP Hydrocodone combination has been one of the primary drivers of our growth in the quarter.

You referred to a liquid product. It's actually the main driver is the solid oral dosage form of the product. But suffice it to say that we are very pleased with the progress of Boca.

Suketu Upadhyay - *Endo International PLC - EVP & CFO*

And so, David, on your question relative to basis from a book perspective, this will result in a reduction in the overall book basis of AMS, commensurate or one for one for the increase in the accrual. From a tax basis perspective, it will also decrease our overall tax basis to the effect that there are favorable tax impacts from the US tax shield. So, hopefully that answers your question.

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

And on your last question, being a Company whose primary strategy is M&A, we obviously view with interest things that are going on in this environment. Our Board has not had a specific reason to opine on any transaction, where we may or may not contemplate a partnership with anyone.

What I would say is that we are open to a wide range of transactions. We enjoy partnerships with many people, on many aspects of our business. But there is though no specific plan for us, along the lines you just talked about.

David Buck - *Buckingham Research Group - Analyst*

Okay, thank you.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

Can we go to the last question, please.

Operator

Thank you. And that comes from Elliott Wilbur from Needham & Company. Please proceed.

Elliot Wilbur - *Needham & Company - Analyst*

First, real quick for Rajiv. You had mentioned in response to an earlier question, alluding to your preference for private company transactions, and I'm just curious if that's based perceptions of maybe better relative value and less dollars chasing those assets? Or maybe more a function of just perhaps leaner cost structures, less inherent leverage, and maybe more easy to integrate into, or to take advantage of tax attributes in the current model, or maybe some combination of all those factors?

And then real quickly on Sumavel DosePro, obviously an asset that's been in a couple of different parties' hands over the years and there's been a lot of resources put behind it, and it's been a bit of an underperformer. Just curious what your expectations are in terms of actually being able to drive unit growth of that product? Thanks.

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

Sure. So let me catch the Sumavel question first. As you pointed out, this is a product that is in the market, or has been in the market for a period of time.

Our general belief is that the product is a good product. It is one that fulfills a need among migraine patients. That being said, we don't have overly optimistic views, in terms of the growth of the brand. We do expect that in our hands with the very experienced pain field force that is experienced in selling Prova, that we will be able to get some traction from a volume standpoint.

We also believe that we have the opportunity to work with Zogenix to continue to improve the margin profile of the brand as well. From an economics standpoint, I think we expect the asset to become a more attractive asset in our hands, going forward. But we don't have unrealistic expectations in terms of volume growth.

And then on your first question, actually I do apologize, I may have forgotten your first question. Can you repeat your first question again?

Elliot Wilbur - *Needham & Company - Analyst*

I may have forgotten it as well. Just with regard to transactions and the preference for private companies.

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

In terms of the private companies, it's actually to some extent a combination of all of the reasons we mentioned. First of all, you don't have public Company expectations, when you're dealing with private companies. Many of these are negotiated transactions outside of formal processes. They can be relationship-based.

Many private Company transactions, the owners and sellers have motivations that go beyond just price. And especially in the current equity markets, we prefer private transactions a great deal. That being said, we're certainly open to public transactions too, but we do have a pretty deep pipeline of private transactions that we look at.

Blaine Davis - *Endo International PLC - SVP of Corporate Affairs*

So to wrap the call with that, I want to thank everybody for joining us today. As you have additional questions, both Jonathan Neely and myself will be available to take those questions. Thanks very much for joining us.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the presentation. You may now disconnect, and good day.