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ENDP - Q1 2013 Endo Health Solutions Inc. Earnings Conference Call

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OVERVIEW:

ENDP reported 1Q13 total revenues of $709m and reported or GAAP EPS of $0.14. Expects 2013 revenue to be $2.80-2.95b and reported or GAAP EPS to be $2.10-2.40.

CORPORATE PARTICIPANTS

Blaine Davis *Endo Health Solutions Inc - SVP*

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

Alan Levin *Endo Health Solutions Inc - CFO*

CONFERENCE CALL PARTICIPANTS

Marc Goodman *UBS - Analyst*

Gregg Gilbert *BofA Merrill Lynch - Analyst*

Chris Schott *JPMorgan Chase & Co. - Analyst*

Corey Davis *Jefferies & Company - Analyst*

David Buck *Buckingham Research Group - Analyst*

Annabel Samimy *Stifel Nicolaus - Analyst*

Elliot Wilbur *Needham & Company - Analyst*

David Amsellem *Piper Jaffray & Co. - Analyst*

Ken Cacciatore *Cowen and Company - Analyst*

Michael Tong *Wells Fargo Securities, LLC - Analyst*

Shibani Malhotra *RBC Capital Markets - Analyst*

Andrew Finkelstein *Susquehanna Financial Group - Analyst*

Kevin Kedra *GAMCO Investors, Inc./Gabelli & Co. - Analyst*

Tim Chiang *CRT Capital Group - Analyst*

PRESENTATION

Operator

Welcome to the Q1 2013 Endo Health Solutions Inc earnings conference call. My name is Gary and I will be your coordinator for today. At this time, all participants are in listen-only mode. We will conduct a question-and-answer session towards the end of the conference.

(Operator Instructions)

As a reminder, this call is being recorded for audio replay purposes.

I would now like to turn the call over to Blaine Davis, Senior Vice President. Over to you.

Blaine Davis - *Endo Health Solutions Inc - SVP*

Great. Good morning, everyone. Thanks very much for joining us today. With me on today's call are Rajiv De Silva, President and CEO of Endo and Alan Levin, Chief Financial Officer. After our prepared remarks, we'll open the call to take your questions. I'd like to remind everyone 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 principle generally accepted in the United States and they 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.

With that, I'd like to turn the call over to Rajiv.

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

Thank you, Blaine. Good morning, everyone. I'm happy to have the opportunity to address all of you this morning. Since I joined Endo about two months ago, I have spent most of my time reviewing the Company's operations, speaking with shareholders and getting to know the people who run our major businesses and functions. My goal has been to understand the strengths and weaknesses, identify our best opportunities for growth, areas of streamlining our cost base and to determine how to best position Endo for this next phase of its corporate evolution. This review is ongoing. I expect to communicate its outcome before the end of the summer. Based on the early phases of this assessment, I do have some observations that I can share.

First, I am excited about the businesses we are in. For example, I'm particularly impressed with our generics business and see multiple opportunities for growth by expanding our capabilities at Qualitest. We have a strong presence and market share in controlled substances and liquids, which I believe will be a source of future growth for us in this segment. Second, in our Pharmaceutical business, we must continue to prepare for a future without LIDODERM, which is losing its exclusivity this year. This means that our remaining business must be made stronger and more efficient. I firmly believe we can improve our operating efficiency significantly. While I have not reached any particular conclusions or decisions, I believe that we have the opportunity to operate in a more nimble and lean fashion. Third, in urology, our AMS affiliate continues to be in a state of transition as we overcome the headwinds created by the FDA advisory related to the use of mesh implants as an intervention for vaginal prolapse. However, AMS continues to have great strength in the urology channel that we look to further leverage.

Finally, Endo is well diversified, which I believe is a point of great strength for the Company. I believe our best new opportunities for revenue growth will come from better execution within our current businesses, supplemented by selective accretive acquisitions of new assets. In addition to learning about Endo, I have also had a chance to get to know many of you. In recent weeks, I have met with a number of our shareholders whose candor and support have been extremely valuable and encouraging. I appreciate your feedback. I share your desire to see Endo succeed. I am wholly committed to creating sustainable value for you and all of our stakeholders for the longer term. Looking ahead, we are awaiting an important FDA ruling on the 10 of May, at which time, the Agency is expected to determine whether the old formulation of OPANA ER was discontinued for safety reasons.

It was our firmly held belief that the best interest of patients, physicians and other stakeholders is served by a strong -- by a show of strong support by FDA for the abuse deterrent formulation of OPANA ER through the removal of products that rely on non-abuse deterrent formulations. The FDA's decision will determine how we compete in the extended relief opioid market. So we are watching and preparing for this news accordingly. We have seen encouraging comments from FDA supporting the position we have taken on the issue, but we await their decision. In summary, I am optimistic about our Company's future, committed to making us more efficient and returning Endo to growth through efforts to enhance organic growth supplemented with accretive acquisitions. We expect to create growth for products such as OPANA ER and Voltaren Gel. We are focused on returning AMS to historical rates of profitability and growth. I appreciate your support. We'll have more to say about our plans in the months ahead.

Now, let me shift my focus towards some of our first-quarter performance highlights. In short, the first quarter illustrates many of the observations I just made. Our performance highlights the impact of our supply agreement with Actavis for LIDODERM, as well as the need for further improvements in our business. In total, Endo reported $709 million in revenues and adjusted diluted earnings per share of $1.09. First-quarter 2013 sales for our Qualitest business grew by 23% versus first quarter 2012, to $178 million. That is a record high for net sales for our generics business and is a solid first step towards our year-over-year growth objective for Qualitest. We expect low double-digit net sales growth versus 2012 from this business.

Within branded pharmaceuticals, our number one priority is the support of the long-term opportunity for OPANA ER. OPANA ER with net sales of $56 million performed to our expectations in the first quarter. Clearly though, there is a major decision by FDA pending that will strongly influence the future opportunity for OPANA ER.

Improved formulary access drove strong growth for FORTESTA Gel in the first quarter. Prescription volumes are more than double what they were in the prior year period. Net sales increased significantly to $15 million for the quarter. FORTESTA Gel has outperformed our expectations thus far this year, and, as a result, we now expect double-digit net sales growth for this product in 2013. Sales in our AMS segment declined 6% in first quarter 2013 versus first quarter 2012. Women's health drove the decline with a year-over-year 16% decrease in sales. US-based procedural volumes within the women's health business are still declining on a year-over-year basis. We remain committed to returning AMS to growth, while looking for ways to improve margins.

With that, I will now turn the call over to Alan to review more of the financial details. Alan?

Alan Levin - *Endo Health Solutions Inc - CFO*

Thanks, Rajiv. I'll focus my initial remarks on our first quarter results and then comment on our full year 2013 financial guidance. For the first quarter of 2013, we had total revenue of $709 million, up 3% over the first quarter of 2012. Our revenues reflect a number of changes to our business at the start of 2013. Net sales of LIDODERM were approximately $25 million lower during the first quarter, as a result of our supply agreement with Actavis, pursuant to which Endo provided an amount of branded LIDODERM as free goods for their wholesale affiliates' distribution. As Rajiv discussed, OPANA ER faced additional competition in the extended release opioid category.

On an adjusted basis, first-quarter gross margin for the Company as a whole was 66% of net sales versus 70.5% of net sales during first quarter 2012. Segment revenue mix, which is a product of higher growth rates in our generics business, is the major driver for this change. The first quarter was in line with our expectations for the full year. Total operating expenses for the quarter were $349 million. However, on an adjusted basis, total operating expenses for the quarter were $250 million. This decrease versus the prior year adjusted total operating expenses of $282 million is driven by a number of changes that we made to our organization in 2012 to increase our efficiency.

On an adjusted basis, total operating expenses as a percentage of revenue decreased to 35% as compared to 41% during the first quarter of 2012. Our adjusted effective tax rate for the first quarter of 2013 was 26.5%. Our tax rate for the first quarter benefited from the full year effect of the 2012 R&D tax credit that was passed retroactively in early 2013. That effect was assumed in our initial guidance of 28.5% to 29.5% for the full year of 2013. So, we would expect marginally higher adjusted effective tax rates for the remainder of 2013. Adjusted diluted earnings per share increased 25% to $1.09 versus $0.87 in the first quarter of 2012. Our reported or GAAP diluted earnings per share increased to $0.14 versus a loss of $0.75 in the first quarter of 2012. As a reminder, the reported loss in first quarter 2012 was primarily a result of establishing a liability of approximately $100 million related to our settlement agreement with IMPAX.

Our reported earnings for first quarter 2013 include a charge in the amount of $68 million for the period, reflecting accruals for certain legal contingencies. As a reminder, at the time of our fourth quarter earnings report, we accrued $92 million as an estimate for these matters. The incremental accrual for the period results in a total balance sheet liability of about $160 million for legal contingencies. Maintaining a strong balance sheet remains an important focus for Endo. To this end, we have also revised our credit agreement during the first quarter. The resulting new agreement significantly enhances our future flexibility. I'll be happy to discuss the new terms in further detail, but one key item is that, although we are currently at 2.5 times, we have a new ceiling of 3.7 times for our maximum permitted leverage ratio throughout the life of this agreement.

We reported a use of cash flow from operations of $59 million in first quarter 2013. As discussed on our fourth-quarter 2012 results call, we believe that the timing of certain working capital items helped to drive a strong performance last year and that they have reversed in the first quarter, consistent with our expectations. We updated our 2013 financial guidance in our press release this morning. We continue to expect 2013 revenues of $2.80 billion to $2.95 billion. We continue to expect our adjusted diluted earnings per share to be in the range of $4.40 to $4.70. As a result of updates to certain liabilities, we now expect reported or GAAP earnings per share to be in the range of $2.10 to $2.40. For additional details on our 2013 financial results and guidance, please review today's earnings press release.

This concludes my prepared remarks. Now I'll turn the call back over to Rajiv. Rajiv?

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

Thank you, Alan. In summary, we look at 2013 as a year of transition for the Company. As I mentioned, we are in the midst of a full strategic and operational review of the Company and all its businesses. We should be in a position to conclude that review in the first half of 2013. I look forward to communicating its outcome internally and externally, latest by the end of the summer. Let me conclude by thanking all of those shareholders who very generously provided their time and feedback to me over the last few weeks. This input is very valuable to us as we go through our assessment.

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 Health Solutions Inc - SVP*

Great. Thanks, Rajiv. This concludes our prepared remarks. We'd now like the to open the line to take your questions. So, operator, can we go to the first question, please?

QUESTIONS AND ANSWERS

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

First on Qualitest. Can you talk about the first quarter? How much it takes away from the rest of the year, given that you really didn't change your low double-digit guidance? I'm curious whether you knew there were going to be some big launches? If so, could you call them out? Why they won't be sustainable kind of going forward? Then second on AMS. Can you talk about what's changed in that business with respect to driving profitability? Since we have new Management there for the past six months, that's probably long enough to at least start to talk about the changes and what's been done. Thanks.

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

Perfect. Thanks, Marc. So on your -- on the question, let me take Qualitest first. As you can imagine, in a generic business, things do tend to be a little lumpy. The competitive dynamics change quite rapidly. We have a very large portfolio of products and SKUs. So we had a pretty good cough, cold season for example in the first quarter that drove those results. That being said, we want to be prudent that we don't assume that we will continue that level of trajectory over the course of the year. So we expect some ups and downs. We are quite comfortable with the low double-digit guidance we put forward. We can obviously get more granular and then clear on that as the year progresses. But we certainly are quite happy with our Qualitest business.

With AMS, as you pointed out, we've had a new general manager in charge of the business for six months now. A lot of what has happened is that we've essentially turn over the Management team, so we have a new Management team across most key functions and sub businesses within AMS. We've also restructured, in terms of -- particularly in terms of our support functions. But what I would I say is that it's not yet completed. That is still ongoing. As you can imagine, as part of my own strategic and operational review, AMS is part of that review as well. We expect to continue to make changes with respect to improving the margin structure. I expect to be able to provide a bit more clarity on that when we can talk about it towards the back end of the summer.

Marc Goodman - *UBS - Analyst*

Have costs already started to come out of that business pretty significantly? Obviously, expenses were pretty under control in the first quarter. So was AMS a big part of that?

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

Let me have Alan answer that question.

Alan Levin - *Endo Health Solutions Inc - CFO*

Yes. Yes, they were, Marc. We had done some restructuring on G&A support for the business toward the tail end of last year and some restructuring and field course realignment earlier this year. So the first quarter results reflect our target to get back to at least the high 20%s, low 30%s contribution margin from that business that it enjoyed prior to our acquisition.

Operator

Gregg Gilbert, Bank of America.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Two strategic questions for you, Rajiv. Hopefully, you can touch on them at least preliminarily. My first one is on the brand side. If OPANA doesn't work out the way you hope and generics destroy the franchise -- I know you're not saying it will -- but can a case be made that Endo shouldn't have significant commercial presence for brands? Or is it important in your mind to maintain some sense of franchise due to where your pipeline is and where BD opportunities might be? On the generic side, with the very large companies becoming bigger and more global, et cetera, do you see an opportunity for a Company like Qualitest to play a more active role in consolidating the smaller and medium sized players? Thanks.

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

Thanks, Gregg. So, yes. Both good questions. On OPANA, as you might imagine, we don't expect to make any commentary as to outcome until we've heard what the FDA response is, which we will hopefully get this Friday -- by this Friday. But suffice it to say that -- I view our cost structure as a flexible cost structure, which needs to be managed to fit business realities. So, depending on the outcome, we will continue to move to make changes. Obviously, by the time that we make some announcements with respect to strategy and cost structure, the FDA action will be known. That will be incorporated into whatever we roll out in a few weeks to come. With respect to the question on Qualitest. Absolutely, I view generics as a strategic area for us. I think frankly, there is a lot of potential within the Qualitest business itself that we can further unleash, in terms of building our Endo pipeline, in terms of increasing manufacturing efficiency and some of the things that can kind of fall in the category of operational improvements. But certainly if there are opportunities for us to acquire other smaller players, particularly businesses that give us complementary products to what we already have, we would be very open to that.

Operator

Chris Schott, JPMorgan.

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

Just a couple ones here. First, as you think about just Endo's overall positioning, as we can see about business development, how important is improving the Company's tax rate as you think about the longer term evolution of the Company? The second question was just coming back to the mesh liability. I know, just -- can you talk a little about that in more detail now that you've had time to consider the issue? How much of a challenge do you think this is for Endo? How much does this factor into your long-term vision of the Company? Thanks very much.

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

Great. Thanks, Chris. So on the issue of the tax rate, obviously, we have a relatively high tax rate. That being said, I believe there are a lot of opportunities for us to create value with our existing business that is not dependent on finding a lower tax structure. Obviously, we will continue to make changes in our business such that it optimizes tax structure. Certainly, if there is a transaction that allows us to move to a preferred tax structure, we would be very open to that. But certainly our strategy, as I see it, is not dependent on being able to do that.

Alan Levin - *Endo Health Solutions Inc - CFO*

I think the only other thing I'd add to that is, we do have a history through our acquisitions of taking on some tax attributes in terms of net operating losses and other attributes of acquisitions that have allowed us to ratchet down the tax rate over time by 7 percentage points. I suspect that other BD activity will likely continue to provide opportunities in that regard.

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

Then onto your next question on mesh. So my view on mesh is that obviously, first of all, it is still early days. We are still beginning to understand the nature of the potential claims that have been filed against the Company. We obviously, as the months and weeks progress, we have a better and better handle on the magnitude. As you know, we already have a reserve on the books that reflect our current understanding of that liability. We've just taken an increase on that reserve as well in this quarter. The way that we will manage this is in a prudent way, which is, as we progress and as we get to know more about some of the trials in cases where it makes good business sense, we will settle certain cases. At the same time, we're not going to rush into anything either because our expectation is that this is an issue that will evolve over time and potentially over years. As such, I'm not predicting that this is a challenge that will hinder the execution of whatever strategy we come up with, but certainly it is a factor that we need to keep in mind as we plan for the future.

Operator

Corey Davis, Jefferies.

Corey Davis - *Jefferies & Company - Analyst*

Can you say whether or not you've submitted anything formal to the FDA for a label change on OPANA similar to what Purdue had submitted in anticipation of a similar positive ruling like Purdue had?

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

Yes, Corey. So we have submitted a request for a labeling change. Obviously we will let the FDA run its course, in terms of how they respond to our Citizen's Petition. But yes, we have submitted a request for a label change.

Corey Davis - *Jefferies & Company - Analyst*

Second question is, if you get a positive outcome and even if IMPAX comes off the market and generics are never there or not there for a long time -- I'm not convinced that the presence of IMPAX is kind of impeding OPANA's growth. So even if they do come off, what's the key to returning OPANA to a more acceptable trajectory? Is this just simple blocking and tackling? Or is there something that's going on that we're not really aware of?

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

No, I think a lot of it, Corey, will fall in the category of blocking and tackling and commercial strategy. As you can imagine, over the course of the last few years, we had a -- we've built a lot of efforts on LIDODERM which is a much bigger product. As we look forward to the future, OPANA is going to be the primary product for our field organization. So we can structure it and optimize it with a view to maximizing that brand's potential. As you also know, we've been through a very tough year on OPANA with the supply disruption, the launch of the abuse deterrent formulation now with IMPAX on the market. So there have been many shocks to the system. But my belief is, after the FDA response, assuming it's a positive one, that we will have a clear path to really focusing commercially on the brand. With that being said, and I don't expect that we will change the trajectory dramatically in the very near term because this is a prescriber base that is very broad. It will take time to -- for the brand to regain its growth trajectory. But we do feel very positively about it, particularly given the strong intellectual property estate that we have that could take it through 2029.

Corey Davis - *Jefferies & Company - Analyst*

Okay. The last question, how much visibility, if any, do you have on whether and/or when Voltaren generics may appear?

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

We don't have a specific view on it, though as you know, this is a product that is partnered with -- we're with Novartis. That particular supply agreement will have a decision point in 2014. But this is something that we continue to work with Novartis.

Alan Levin - *Endo Health Solutions Inc - CFO*

That would be consistent with the provision of product guidance that the FDA provided in 2012 and the lead time to do the kind of clinical work that's implicit in bringing generic formulation to market, which we believe also puts us into a mid-2014 time frame before that's likely.

Operator

David Buck, Buckingham Research Group.

David Buck - *Buckingham Research Group - Analyst*

A couple questions for Rajiv. Rajiv, if I look at the changing mix of the Company from 2013 to 2014, you obviously had some expense control year-over-year in keeping a combined adjusted operating expenses to about 35% of sales. What's the right number to look at? Or what's sort of the amount of cost savings that you might be able to achieve as LIDODERM goes generic? Have you spent any thoughts on that in terms of what the right percentage of sales is for SG&A and R&D combined as we look at a more generic and more medical device type Company for next year? Then secondly, as you looked at the OPANA issue and the decision on May 10, can you talk about whether you have any type of contingency plans or profit protection plans to allow you to reaffirm the guidance ahead of Friday's decision. Thanks.

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

Thank you. So on the issue of the cost base, as you can imagine, this is one of the main pieces of work that's currently ongoing with assessment of the Company, so I'm not in a position to opine on exactly what our target margin structure will be, but certainly we are looking at all different avenues to control costs in the Company. So we will be in a position to answer this question once the assessment is completed. But certainly I can assure you that it is an area of clear focus for us. With respect to OPANA, again, we have a lot of work that's gone in assessing how we will respond to different outcomes based on what FDA says. Again, at this point, as you've seen, we have reaffirmed guidance for the year. We will -- so we will not say anything further with respect to what we may or may not do, depending on the outcome of the FDA response. Obviously, we are hoping for the best. If that does not turn out to be the case, then we will come back with another announcement.

Alan Levin - *Endo Health Solutions Inc - CFO*

I would just add that while our guidance does contemplate the assumption that generics will come off the market in the second half of the year as Rajiv alluded to earlier in the call, we do have a flexible cost base. We do have a history of adjusting that cost base consistent with our revenue trajectory. I would expect that as we move forward, we continue to manage in a financially disciplined manner.

Operator

Annabel Samimy, Stifel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Just a couple here. One on AMS, you're obviously going through strategic review here. You're doing a lot to improve the operating efficiencies of the business. But you said that you wanted to return the segment to growth. So have you identified those areas that you can sort of target as a return to growth? Will that require further investment in the future?

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

Good question. I actually think there is a lot of possible -- there's a lot of possibilities within the AMS business as it stands even without additional investment. So let me pick a couple of areas. So we've been very encouraged by the performance in our international markets. So those businesses are actually growing. So as we continue to put more efforts behind those businesses, we will hopefully begin see an overall impact on the AMS growth rate from the international business. The other area is men's health and BPH. We just had a -- we just announced a pretty positive outcome from our go live trial, which we expect to have some positive results in our BPH business.

Then obviously at some point, the negative implications or negative impact of the FDA advisory on mesh implants would also begin to work its way out. Because fundamentally, our belief is that our products make a big difference in the lives of patients. For the appropriate patient in the hands of a well-trained physician, we have very, very good product interventions in most cases, patients have few options by the time they come to the point of needing one of our products. Demographics is in our favor because these are all diseases of aging. So we think there are strong fundamentals that drive the business once we get over this -- the challenges that we've had over the last 12 months.

Annabel Samimy - *Stifel Nicolaus - Analyst*

What stage is the vaginal mesh declines in the process of working its way out in terms of the decline?

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

It is honestly difficult to tell because one would have thought by now it would begin to flatten out. We have not yet seen it. So I can't make a clear prediction, but we would expect hopefully sometime in the next 12 months to begin to see a flattening out of the trajectory.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay. Then on OPANA, you had mentioned that I guess some of the pressure you're seeing is competitive pressure. But we haven't really seen that much impact from the generic. So can you characterize that competitive pressure on OPANA?

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

Not quite sure what you mean by competitive pressure. What I was referring to was the challenge that the product had last year because of the supply disruption. Then obviously with IMPAX coming on the market, there's been some impact, you're right. It's not been dramatic. But it's still early days, as you can imagine. I think -- with the product, we continued to sell competitively versus MSER and OxyContin. We, in general, get more business than we lose to those two products. But in the first quarter, with IMPAX coming on the market and taking some share away, some of those positive implications have been negated because of IMPAX, right? Obviously, as we expect, the FDA rules in favor of our Citizen's Petition and IMPAX is no longer on the market, that issue will go away. Then the positive dynamics that we see in terms of taking share from the competitive products should continue to be -- to work in our favor.

Operator

Elliot Wilbur, Needham & Company.

Elliot Wilbur - *Needham & Company - Analyst*

Just first with respect to FORTESTA Gel and the strength in the quarter. In the press release where you reference or attribute the strength to a change in formulary status that resulted in increased uptake. Obviously, a small product but fairly impressive sequential gain. I'm just wondering if the level of sales in the quarter represents sort of a new baseline resulting from the change in formulary positioning for the product? Then, as just a follow-up, the most recent correspondence with FDA regarding OPANA ER, I believe was submitted by the Company on April 23. It looks like there's just extensive reference to the recent development around FDA's decision on OxyContin. I'm just wondering if there's anything really new in there in terms of quantitative metrics or surveillance data related to Oxymorphone that you think is directly tied to the FDA's recent decision on Oxycodone? Or if you're just basically citing a somewhat similar development? Thanks.

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

Thank you. So, on FORTESTA, first of all, we are quite delighted with the performance of that brand. I think the commercial team has done a great job with that product. We've moved to contract that brand in a more comprehensive way than we've done in the past. What you see reflected in the first quarter is two major contract wins that we had. So we do expect to see a good full year performance on the product. Obviously, there's been a very sharp uptick based on contract wins. So that particular percent growth, it may or may not be sustained. But certainly, we see a strong trajectory for the product. It's one of the products that we are quite excited by.

With respect to the supplement to the Citizen's Petition that we submitted, as you pointed out, the main gist of that supplement was to point out the similarities between the OPANA ER situation and OxyContin with respect to the recent decision that FDA took. We believe that we have a very strong facts on our side. If you look at our filings over the course of the last year, surveillance data alone shows that there's been a very sharp decrease in abuse of the brand with the launch of the abuse deterrent product. Depending on which time period it looks at, it's -- it could be an almost 60% reduction. So we do believe that we have a very strong data on our side. Obviously, every company has a slightly different twist on it.

But I do think that the way that the FDA looked at OxyContin, we would certainly applaud that decision. We merely wanted to point out one more time, the similarities between the two situations with FDA as they deliberated on our own file.

Operator

David Amsellem, Piper Jaffray.

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

I have just a couple. First, on Voltaren Gel. Rajiv, in your review on the business, what are your thoughts on the risk around potential generics for that product over the medium to long-term? Realistically how long do you think you'll get to keep exclusivity on it? Then, my second question is on your presence in the urology space, particularly from a brand pharmaceutical perspective. Rajiv, is this an area that you'd like to continue to have a real presence in? Maybe just high level, what do you think are some of the aspects of that business that you like and don't like? Thanks.

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

Sure. So, on Voltaren Gel, as we've just mentioned, it is a product that's partnered with Novartis. That particular arrangement will come to an end sometime in 2014, probably in the early part of the second quarter. That's our operating plan. Obviously, we continue to discuss this with Novartis, since this is a brand that's doing quite well. But from our own planning standpoint, we don't expect to have the brand beyond the second quarter of 2014. So, therefore, if there are generic or other competitive actions beyond that, it doesn't particularly factor into our plan at this point. If we do change the nature of our agreement with Novartis, obviously, that will factor into it. At that time, we can opine on it.

Now with respect to the urology channel with respect to our pharmaceutical business. The short answer to this is that, I do like the urology pharmaceutical business because this -- again, lends itself to the kind of business that I think is great for a Company like Endo, which is basically specialty areas where with a relatively small footprint you can commercialize brands. I also like smaller brands. I'd much rather have a collection of smaller brands than one big blockbuster that drives the Company for obvious reasons. So FORTESTA and VALSTAR for example, I think certainly fall in the category. As you seen our results on FORTESTA, it continues to show why urology is a good category for us. So certainly, I'd be -- I'm certainly very committed to it. I don't want to opine on what our areas of focus will be until we completed our strategic review. But early indicators are that certainly that urology business is a strong one. One that's here to stay.

Operator

Ken Cacciatore, Cowen and Company.

Ken Cacciatore - *Cowen and Company - Analyst*

Just a couple questions, one on vaginal mesh. I was wondering if you could update us on the actual number of cases accumulated? Then maybe discuss a little bit how we're arriving at those numbers? I know, last time we talked about a little bit of art and science. But maybe -- should we be expecting another charge this quarter? Then lastly, Rajiv, it sounds as if there's potential here to be expanding into generics. So, just wondering if you could help us get a better understanding of your background in generics? What's informing you of these decisions to maybe push into an industry that is often found to be quite difficult? Thank you.

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

Thank you, Ken. So on -- let me start with mesh. So as of the end of April, we had just a little bit shy of 7,700 cases. With respect to how we're managing it and how we're making our estimates, as I said, we know relatively little about these particular allegations, until and unless things get

of to the point where we're able to look at the medical records and other factors, which is the case when you typically get trial set cases. The approach that we're taking is, we make a business judgment as to the merits of settling cases, as we come close to that, which is what we've done. If you look at the increase in accrual that Alan referred to, that reflects a business decision that we made to settle certain trial set cases, plus a broader inventory of cases that the same plaintiffs attorneys have. Again, let me stress, this is a tentative settlement. It is not completed yet. That's how we're going to manage it. In certain quarters, as we have certain settlements that come up, we will reflect those as we move forward. In certain cases, we will have none. Obviously, some parts of our increase in accrual also reflects the higher number of cases that we now have versus what we had at the end of the fourth quarter as well.

Alan Levin - *Endo Health Solutions Inc - CFO*

I would just say that from a quarter-to-quarter basis, you wouldn't necessarily see increases in the mesh related liability every quarter going forward. We obviously have to think about not only the increase in the number of cases filed, but potential future cases. But the primary driver for the increase this quarter is, as Rajiv said, a tentative agreement that we've reached. So it's a discrete event that drives the increase this quarter.

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

With respect to -- one final comment on mesh. Obviously, we intend to vigorously defend ourselves. So any settlements that we make will be only ones where we think there is business logic that drives it. With respect to generics, it clearly is a segment that is important now from an industry standpoint. The importance of lower cost medication is only going to grow, certainly in the US, but certainly outside the US as well. In the different companies that I have spent time in over the course of my career, there have been very important generic businesses. I have a clear appreciation for it. As I pointed out, there are certain aspects of the generic business which requires very careful Management.

You are to also keep in mind that we are in certain segments of generics right now, which are actually quite attractive, like controlled substances and liquids. So as we continue to expand, we will look to stay in niche areas as opposed to broadening out in the more classic, traditional, solid oral dosage from generics. Obviously, one of the things that we will continue to work on over the course of the next little while is also to supplement our capabilities in generics. We have a very good team in Qualitest. But we are constantly looking for ways to supplement that team. I'm hopeful that as the months progress that we can update you on some of those things that we're working on.

Operator

Michael Tong, Wells Fargo.

Michael Tong - *Wells Fargo Securities, LLC - Analyst*

Two quick questions for you, Rajiv. As you think about acquisitions in the branded pharmaceuticals segment, are you thinking more along the lines of pain management? Or urology? Or will you entertain thoughts about entering into a new therapeutic category in order to further broaden out Endo's therapeutic reach? Then, secondly, with respect to generics. The commentary you just made in terms of expansion of capabilities, are you referring both to Management capability and/or generic assets in terms of dosage form capability? Thank you.

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

Thank you, Michael. With respect to the two questions. On acquisitions, I'd look at things fairly simplistically, which is that, I think, what our shareholders at this point will value are accretive -- near term accretive transactions. Which -- one we are doing that obviously is to make sure there is a reasonable and material amount of cost synergies in transactions that we do. So obviously if those transactions are in common areas that were already present, the chance that we can find material cost synergies is much higher, right? So those are logical areas for us to look. That's being said, I don't believe we are going to be constrained by therapeutic areas. If there are good acquisition opportunities that come up, that allow us

the opportunity to move in to a new area and are able to do that on the basis of a financially attractive transaction that is near term accretive, we will certainly look at it. So I would not rule out anything.

With respect to Qualitest, I think our capability enhancements are going to come in multiple areas. So first of all, in -- one of the things that we need to spend more time is building our own internal Endo pipeline. We already have a reasonable pipeline. But we recently hired a Head of R&D. We're just in the process of qualifying a pilot plant down in Huntsville. We're building a formulation group to help create the future for us from an Endo pipeline standpoint. Commercially, we will continue to look for additional talent. Where again, as I said, we have a very, very good team in Qualitest. But we would love to supplement that team. We have a very active business development effort ongoing, looking at the purchase of new Endo's or other complementary products. There's a whole host of improvements that we can make in the manufacturing footprint that we have in Huntsville and in Charlotte to essentially create more efficiency in that plant and get more capacity out of our existing footprint and equipment.

Operator

Shibani Malhotra, RBC Capital.

Shibani Malhotra - *RBC Capital Markets - Analyst*

So quick question on OPANA, Rajiv. Assuming that the FDA decision goes in your favor, I guess you made two comments. One was that, you believe you could grow the brand given that you can return to taking share from OxyContin. I just wanted to understand how that dynamic would work, given that it's likely the abuse deterrent label will be stronger than that of OPANA's? Then second, you also mentioned the importance of generics in terms of having the availability of low cost generics for consumers. So how does that play in with keeping OPANA branded, especially in light of OxyContin's -- the decision to settle on OxyContin with Actavis? We understand this was driven in part by political pressure. Just a question for Alan on the DSOs. We notice these are a bit higher than usual this quarter. Anything we should look out for? Or is it just a timing situation?

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

So let me just start with the OPANA question. So with respect to label, we don't have a new label yet. So I'm not going to enter into a hypothetical discussion as to any label differences. But what I can say is, right now, we have more switches to OPANA ER from OxyContin than switches away. So that was the dynamic that I was referring to. Our expectation is that we will continue to focus our commercial efforts to maximize that trend, right? Again, if there are different labeling decisions that are made, we will deal with those at that time. With respect to lower cost medications. Again, clearly from a healthcare industry structure standpoint, generics are -- as a broad category, are here to stay. I was not referring in particular to generics of extended release opioids when I made that comment. I was making a more macro comment.

But at any given time, we obviously need to balance the patient's safety factor along with our commitment to low cost medications. I think in the case of OPANA ER, we have a very clear fact base and a very firm point of view, that what is in the best interest of patients and society, in general, is a continued reliance abuse deterrent formulations of extended release opioids in a way that is protective to the broader population in terms of reducing abuse. That is our point of view. It will continue to be our point of view. I think in other categories where the FDA is permissive of generics, we would love to compete in those. Because with our capabilities, we think we can provide very competitive offerings when it comes to generics in the areas that we compete in. Alan, you want to address the other question?

Alan Levin - *Endo Health Solutions Inc - CFO*

Sure. On the question of days sales outstanding, we have seen a modest increase since the end of the year by about 2 days. I really think it's a function of the product mix in the top line, as you look at either the international side of the AMS business, which is growing faster than AMS overall or the generics business which is growing faster. Those are segments that can tend to have slightly longer DSOs.

Operator

Andrew Finkelstein, Susquehanna Financial Group.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

I was hoping you could just talk a little bit about the outlook for the rest of the year? If you look at the business ex-LIDODERM, what areas should we be looking at for revenue run rates to increase sequentially? So that we can think about what the right level for the business is -- for the current business, ex-LIDODERM? Where that might put you relative to your range for the year? How it can get closer to the higher end if possible?

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

So I think I would -- let me take a crack at the question. I'll ask Alan to add to it as well. First of all, we just reaffirmed our revenue guidance for the year, right? We are not in particularly opining on which end of the range we will be by rather, committing to that range. As LIDODERM begins to have competition from Actavis, pretty much all other aspects of our portfolio are going to become important. Qualitest -- we've already seen the early part of the year where on the basis of our cold business and our oral contraceptive business, we've actually done quite well. We will expect to see good results on Qualitest for the rest of the year. With OPANA ER, with our assumption that IMPAX will be withdrawn from the market based on the decision by the FDA.

You would expect to see some improvements in that trajectory. FORTESTA Gel, as you saw, is on a very good run for the first bit of the year -- Voltaren Gel. We would also expect to see some positive impact on our men's health business in AMS from the go live trial. Overall, I think in AMS, we would expect that a lot of the turnaround efforts that are put in place over the course of the last six months should begin to start showing positive results. Those are some of the positive factors that we expect. Again, we'll have a better sense obviously, once we have another quarter under our belt, as to how all of that is going. But as of this point, we are comfortable with the guidance range that we have put forward.

Alan Levin - *Endo Health Solutions Inc - CFO*

Yes. I would add to that. If you step back and look at the full year picture, we've been guiding to low single-digit growth rates in AMS over the course of the year. So we would expect the AMS performance to strengthen year-over-year as the year unfolds. We've guided to a low double-digit growth in Qualitest. So we would expect continued strong performance from that business going forward. Then within branded, we talked about it being year-over-year down on LIDO given the loss of exclusivity this year, coupled with OPANA given the pace of recovery from the supply disruption, coupled with generics. That being said, we're seeing some very attractive growth in the double-digit range in FORTESTA year-over-year and V-Gel is performing quite well. So branded side, I think you've got very product specific performances. But net-net, we're pretty pleased with where things have unfolded so far.

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

I think the only other comment I would make is, obviously a big part of the ongoing assessment of the business is also taking a full look at the P&L, not only for this year but the P&L going forward. So we will -- we'll continue to really understand the dynamics of how the brands are performing. As we make announcements about our strategy and cost structure going forward in the next few months, we will have a much better sense of how we see the near to medium term trajectory of the business evolving.

Operator

Kevin Kedra, Gabelli & Co.

Kevin Kedra - *GAMCO Investors, Inc./Gabelli & Co. - Analyst*

Two quick ones, first on Voltaren Gel. Just wondering, since you've said, Rajiv, that you expect to not have that product, by the end of 2014, will you be managing that as sort of a latent life cycle product from a standpoint of pricing? Or from the sales force effort that you'll put behind that? Then secondly, on the women's health business in AMS. What sort of studies are you guys doing right now to reaffirm the safety of the mesh products? Can you maybe give us some sense of time lines? Whether or not that's going to play any role in your strategy from legal standpoint going forward?

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

Sure. So with respect to Voltaren Gel. To be clear, what I was talking about was the fact that our current arrangement with Novartis will come to an end in 2014. That was not so much a statement on the end of the life cycle of the brand. It is a product that is both important to us and is meaningful to Novartis, our partner, as well. So we will continue to maximize our commercial efforts on that brand until that partnership is no longer in effect. As I said, if the partnership continues, obviously we'll continue to invest behind the brand. Again, as we continue to tweak the sales and marketing model of the business, we will being optimize resources. But it will continue to have resourcing behind it.

With respect to your question on the women's health products. First of all, we believe, we strongly believe in the safety and efficacy of the mesh products. We have a number of 522 Studies that are currently ongoing. We would expect those studies to read out over the course of the next several years. So it is an ongoing effort. I think, again, the fact that we are undertaking a number of these studies should reflect our belief in the product as well as the importance that they play in the lives of our patients.

Operator

Tim Chiang, CRT Capital.

Tim Chiang - *CRT Capital Group - Analyst*

Rajiv, how much focus are you planning to put on reducing operating costs this year? Is it more focused on growing the business? On the top line? Or is it going to be more focused on cutting costs?

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

My personal view is, we're taking a longer term view of Endo. We want Endo to be a growth Company; therefore, finding avenues for growing the Company is our primary priority. That being said, I believe there's an opportunity to move the Company to a leaner, more effective operating cost base. I can't opine on what that means in terms of specific numbers. That's a question that I know that many of you have. But I will be in a position to clarify that once the assessment is done. But I would say it will be a meaningful contributor to our near term plan. But certainly, it's not a -- cost cutting is not a long-term growth plan, as you can imagine. So there, our focus is on returning aspects of our business to a more robust growth trajectory and doing some accretive transactions. But that will be on the back of a cost base that is going to be more competitive for us.

Blaine Davis - *Endo Health Solutions Inc - SVP*

I just want to take the opportunity to thank everybody for joining us today. This completes the conference call. Jonathan Neely and myself will be available today for additional follow-up questions. Thanks very much.

Operator

Thank you very much, ladies and gentlemen. That now concludes your conference call for today. You may now disconnect. Thank you.