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ENDP - Q2 2013 Endo Health Solutions Inc. Earnings Conference Call

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OVERVIEW:

ENDP reported 2Q13 total revenues of $767m and reported diluted EPS (includes the effect of $60m increase this qtr. to reserves, mostly for product liability related matters) of $0.30. Expects 2013 revenue to be $2.7-2.8b and GAAP diluted EPS to be $1.47-1.77.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the second quarter 2013 Endo Health Solutions Incorporated earnings conference call. At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of this conference.

(Operator Instructions)

As a reminder, this conference is being recorded for replay purposes. I would now like to turn the call over to Mr. Blaine Davis, Senior Vice President of Corporate Affairs. You may begin.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

Good morning, everyone, and thanks very much for joining us. 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. In addition, we've prepared a slide presentation to accompany today's webcast, and if you'd like to follow along with that presentation, you can find it within the Investors section at www.endo.com.

I'd like to remind you that any forward-looking statements by management are covered under the Private Securities Litigation Reform Act of 1995 and subject to change, risks and uncertainties described in today's press release and in our filings with the SEC. In addition, during the course of this call we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the

United States and that may be different from non-GAAP financial measures used by other companies. Investors are encouraged to review Endo's current report on Form 8-K filed with the SEC for Endo's reasons for including those non-GAAP financial measures in its earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in our earnings press release issued prior to today's call.

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

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

Thanks, Blaine. Good morning, everyone, and thank you for joining us today. I hope that you have all had a chance to review the Company's earnings press release and access our presentation that we have posted on our website. We had a solid performance in the second quarter, as a result of strong demand trends for our products combined with effective expense management. We continue to expect strong performance for our business through the remainder of 2013, and having increased our 2013 financial guidance for adjusted diluted earnings per share and have narrowed the range for revenue guidance.

I will start by providing an outline of today's call that you can find on slide 3 of our presentation. To begin, let me review some of the progress we have made since the strategy update we provided in early June. After that, I will turn the call over to Alan to cover more of the financial details related to the second quarter. I will then wrap up with a review of our full year 2013 guidance. Moving on to slide 4. In our strategy update, we set forth our aspiration to be a top-tier specialty healthcare company. In order to do that, we will focus on optimizing our most promising assets and expanding in areas that offer above-average growth characteristics and attractive margins.

On slide 5, we have listed our near-term priorities in support of our new strategic direction. And on the slides that follow, I will focus on a few of these and highlight our progress thus far. First, we intend to reinvigorate organic growth through more focused and disciplined execution. Second, we are exploring options for assets that do not fit within our new model, including exploring strategic alternatives for our HealthTronics business, an early-stage pharmaceutical discovery platform. We have received interest in both; and for HealthTronics, we have engaged an investment bank to assist us with the process.

Third, we are implementing a new, lean operating model designed to generate significant cost savings, drive greater accountability and better decision-making, and allow us to focus more effectively on key priorities. Fourth, we are improving R&D efficiency by concentrating our spend on lower risk, near-term revenue generating projects. Fifth, we are pursuing select accretive and value creating external growth opportunities. Sixth, we are continuing to look for ways to optimize our capital structure. And seventh, we are continuing to strengthen our talent base and organizational capabilities. On this last point, I would like to take this opportunity to welcome Don DeGolyer, whom we recently appointed to the role of Chief Operating Officer of Pharmaceuticals, which includes Endo Pharmaceuticals and Qualitest. He is a strong and experienced leader with nearly three decades of experience in the branded and generic pharmaceutical industries, most recently serving as President and CEO of Sandoz in the US. The addition of Don strengthens our senior team, and we look forward to his contributions.

Moving now to slide 6. I will highlight the progress we have made in driving organic growth in our four businesses. Second quarter 2013 sales of $171 million for our Qualitest business is in line with our expectations and we remain on track to deliver low double-digit net sales growth versus 2012 for the full-year. Year-to-date 2013 sales for Qualitest are up 14% versus prior year, and approximately half of that growth is attributable to new product launches. Demand is strong for existing products as well, and we believe that strong demand combined with our diverse product offerings will continue to create new business opportunities and deliver strong growth for Qualitest. To capture most of that opportunity, we have initiated a multi- year capital expenditure program that we expect to significantly increase our manufacturing capacity and efficiency.

Moving to slide 7. As we expected, branded pharmaceutical sales declined in second quarter 2013 compared to second quarter 2012. However, we are pleased that our branded products, excluding Lidoderm and Opana ER, increased 5% versus prior year. These growth assets continue to be our focus. One of those growth assets, Fortesta Gel, continues to generate strong growth as a result of improved formulary access and targeted promotion. Prescription volumes were more than double what they were in the prior year period and net sales increased significantly, to $17 million for the quarter. The decision to focus on our current set of opportunities led to many of the actions we announced in June, and we believe we are well-positioned to manage the loss of exclusivity for Lidoderm that we expect to arrive on September 15.

With Opana ER, we continue to believe that the development of abuse deterrent formulations is an important part of the future for prescription drug products containing long-acting opioids. We are actively working with the FDA to cross the clinical program to support a potential label change. We will also continue to vigorously assert the patents that we believe are infringed by generic versions of the old formulation of Opana ER. We continue to assume in our financial guidance that multiple generic versions of the old Opana ER formulation will arrive in 2013, having a substantial impact on the brand; however, we have initiated court actions to enjoin such launches in light of our patents, and we believe that our case has strong merit. We continue to promote Opana ER through our field force and will continue to do so as long as it remains economically viable.

Moving to slide 8. We are pleased at seeing the early signs of improving trends in our AMS business. Second quarter 2013 growth rates show an improvement over the first quarter. Growth for AMS, excluding Women's Health, was at 3% versus second quarter 2012. We are hopeful that these trends will continue through the second half of the year. The Women's Health business continues to be challenging and we remain focused on managing that business through a declining market. We are hopeful, though, that the market will begin to recover now that the two-year anniversary of the publication of the FDA's public health notice on mesh has passed.

As the emerging trends show, AMS has a number of growth drivers that we believe can lead the turnaround of this business to offset the weakness in Women's Health. For example, AMS is growing in international markets across all lines of business. And in May, AMS announced the results of the Go Live study that compared GreenLight laser treatment head to head with [Terp]. The results were impressive, equally safe and effective, but with a faster recovery time and with fewer complications. AMS believes this data supports continued steady adoption of GreenLight as a treatment for BPS. And finally, Men's Health, the largest business within AMS, continues to be a leader in the areas of erectile restoration devices and urinary incontinence.

Moving now to slide 9. Implementing a lean operating model is a critical first step in supporting the strategy that we unveiled in early June. I am pleased to say that the Company has made excellent progress in implementing our restructuring program. We have largely already completed the structural changes to the organization that resulted in a 15% reduction in head count, and we are also making good progress on optimizing external spend related to SG&A and R&D. We are on track to meet the 2013 objective of $150 million reduction in adjusted operating expenses versus 2012 actual spend. First half 2013 adjusted operating expenses were $84 million lower than those in 2012. I am confident that we will achieve our objective of a $325 million run rate reduction by mid-2014.

Moving to slide 10. We have sharpened our focus on R&D, and I will share some highlights from our diversified portfolio of opportunities. AMS recently announced the launch of MiniArc Pro for the treatment of female stress urinary incontinence. As with all its products, AMS will support MiniArc Pro with robust physician training and we encourage physician-patient conversations on the risks and benefits of these therapies. In Branded Pharma, we remain on track to complete our phase three trials for BEMA Buprenorphine by early 2014. We are also on track to submit a revised REMS proposal for AVEED to FDA by the end of third quarter 2013, and are planning for a potential launch in 2014. At Qualitest, we have assembled a new team to lead our ANDA development and provide future organic growth drivers for this business. This team has already begun to file important new additions to the approximately 40 ANDAs that we have currently under review at FDA.

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

Alan Levin - *Endo Health Solutions Inc - CFO*

Thank you, Rajiv. I'll focus my remarks on our results and then turn the call back over to Rajiv to comment on our full-year 2013 financial guidance.

Turning to slide 11, in total Endo reported $767 million in revenues, down 2% compared to the second quarter of 2012. Our revenues reflect a number of changes to our business at the start of 2013. Opana ER faced additional competition in the extended release opioid category and net sales of Lidoderm, though up slightly versus 2012, faced pressure versus the prior-year period, as a result of our supply agreement with Actavis pursuant to which Endo and the manufacturer of Lidoderm, Tycocu, provided an amount of branded Lidoderm as free goods for Actavis' wholesale affiliate.

Our reported diluted earnings per share of $0.30 include the effect of a $60 million increase this quarter to our reserves, mostly for product liability-related matters. The incremental accrual for the period results in a total estimate of $216 million for product liability contingencies. The increase in the reserve is primarily attributable to the number of vaginal mesh cases filed, and that we currently expect to be filed, against AMS. We expect that the number of cases filed will continue to increase through the fall months, beyond the two-year anniversary of the FDA public health notice, which occurred a few weeks ago, as a result of an agreement in the MDL between the majority of the defendants and plaintiffs' attorneys. However, we expect the volume of cases filed to begin to slow as we approach the end of the year. Our first MDL case is scheduled to be tried in December of this year. I would also add that we expect that it will take an extended period of time to fully understand the outcome of this ongoing litigation. Adjusted diluted earnings per share increased 12%, to $1.42 versus $1.27 in the second quarter of 2012.

Turning to slide 12, on an adjusted basis, second quarter gross margin for the company as a whole was 67% of net sales versus 70% of net sales during second quarter 2012. Segment revenue mix, which is a product of higher growth rates in our generics business, is the major driver for this change. And second quarter gross margin was in line with our expectations for the full year. Total operating expenses for the quarter were $357 million; however, on an adjusted basis, total operating expenses for the quarter were $219 million. This decrease versus the prior year adjusted total operating expenses of $271 million is the result of a number of changes that we made to our organization in 2012 to increase our efficiency.

In addition, second quarter adjusted operating expenses benefit from a partial quarter of implementation with a lean operating model described in our June strategy update. On an adjusted basis, total operating expenses as a percentage of revenue decreased to 29%, as compared to 34% during the second quarter of 2012. One final note regarding our performance. The Company produced approximately $175 million of cash flow from operations in second quarter 2013.

Let me now turn the call over to Rajiv to wrap up with a discussion of full-year guidance.

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

Thank you, Alan.

As you can see on slide 13, we have updated our 2013 financial guidance. Based on the strong second quarter 2013 performance, we have increased the bottom end of the range for our financial guidance for 2013 revenues. We now expect revenues be in the range of $2.7 billion to $2.8 billion. We have also increased guidance for adjusted diluted earnings per share, and now expect those to be in the range of $4.25 to $4.55 a share. And finally, we now expect reported our GAAP diluted earnings per share to be in the range of $1.47 to $1.77. For additional details on our 2013 financial results and guidance, please review today's earnings press release.

In summary, we have made significant progress in the first half of 2013, and I am looking forward to the remainder of the year. This is a year transition for Endo, and as an important first step, we unveiled our new strategy in June. It is still early, but we believe that the actions we have taken and our focus on the commitments that remain will allow Endo to evolve into a top-tier specialty healthcare company. And as we do so, we believe we will be better positioned to maximize shareholder value.

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, Corporate Affairs*

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

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Gregg Gilbert, Bank of America Merrill Lynch.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Thanks. Good morning. I have two for Rajiv, and a quick follow-up for Alan. First, Rajiv, how's the business development process going and are you still confident you can get a few deals done in the next year or two? And secondly, as your R&D portfolio in Generics grows, can you share some color as to how it's growing, in what direction, what types of products? And are you considering vertical integration into APIs at a high level for some portions of your Generic business? And for Alan, it looks like DSOs bounced back to a more normal level, but inventory turns declined. Can you offer any color on that? Thanks, guys.

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

Thanks, Gregg. Let me just answer your first two questions. First, on business development, we remain confident that we can execute the types and the number of transactions we talked about before, which is, I think we've said two to three transactions in the $250 million to $500 million range in the next 18 months. We remain on track. We have a very active pipeline of transactions, and I am hopeful that we will be able to execute at least one transaction in the near-term.

In terms of R&D in Generics, our general approach in Qualitest is to play to its strengths. The two areas that we believe we have a substantial competitive position are controlled substances and in liquids and semi-solids. So many of our R&D programs, our new R&D programs and new ANDAs, are focused in those areas. In terms of your question around vertical integration into the API space and beyond, those are all options that we have in front of us. I think for reasons that we have talked about before, we remain very bullish about Qualitest and remain open to thinking about strategy in a very broad sense for that business. But there's nothing very specific I can talk to today about the API element of it. Alan, any answers on the other question?

Alan Levin - *Endo Health Solutions Inc - CFO*

Sure. Gregg, with regard to DSOs, we do see some cyclicality in wholesaler inventory levels. And Q2 wholesaler inventories at the end of the quarter tend to be typically a little bit lower than Q1, which generally means that we've got a little bit more inventory on hand on the branded side. And then within our Qualitest business, we've also been building some inventories. And some of that is a function of product mix in the second half, with the arrival of the cough/cold season.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Thanks.

Operator

David Amsellem, Piper Jaffray.

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

Thanks. Just a question on the mesh litigation. You have a sense of where the reserve over time could be taken up to, as more cases get added? And I guess the question, this is more of a commercial question on the mesh business, what are your thoughts about continuing to have a presence in this business, given that sales continue to get pressured? Thanks.

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

On the two issues, with respect to the reserve, the current increase that we've taken has been something that we expected as we got to the two-year anniversary of the FDA public advisory on the product. Our expectation is as the year unfolds that the rate of new cases will decline after this big bolus. And this is a process that's going to unfold over time. Our first MDL case will not be heard until the back end of the year. And until then, we will continue to be prudent in terms of how we treat this reserve and we will continue to take increases as we need. But again, this kind of bolus increase we would not expect every quarter.

With respect to the commercial business, I think I will reiterate the comments I made before, which is that our mesh products meet a very important unmet clinical need for women with stress urinary incontinence and pelvic prolapse. There are very few options to women when they reach this point and require medical intervention. And we continue to believe in our products and we'll continue to make the products available to our physicians to use. In terms of the market, again, what we've said before is certainly being borne out, which is that as this two-year anniversary of the FDA advisory passes, we are hopefully going to see fewer plaintiffs' attorneys out there advertising for patients and things like that, that create fear in the minds of potential patients. And we expect the market to stabilize and recover going into 2014. Now time will tell if we are right or wrong, but that is our expectation. And for those reasons, we continue to believe in the commercial viability of this business.

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

Just a quick follow-up on the Qualitest business. This is a BD question. Can you give us a sense of what formulation technologies are you looking at in terms of expanding your generic footprint? And then are you looking at businesses that in terms of ANDAs are more litigious than what Qualitest has focused on historically? Thanks.

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

In terms of specific formulations, I'm going to stay away from that question, basically for competitive reasons. But our belief is that the future of our Generics business is going to be best served by investing in difficult to manufacture formulations, controlled substances, things where we have a specific strength. I've talked about liquids and semi-solids before. So those are the types of areas where you ought to be seeing new ANDA investments from us. In terms of the profile of the types of ANDAs that we'd be [prosecute] in the future, it could very well change. I think in the past, we've had a strategy that's been focused on Paragraph III filings, but we may well pursue Paragraph IV filings with our new R&D strategy and our R&D capability that we put in place.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

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

Operator

Chris Schott, JPMorgan.

Jessica Fye - *JPMorgan - Analyst*

Hello there. It's Jessica Fye on for Chris. Question on Lidoderm as we think about 2013 and 2014, what type of share do you think you can maintain in a market with a single generic player? And then, if another generic is approved in 2014, what type of Branded share do you think you could hold onto in that type of market? Thanks.

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

Thank you, Jessica. So as you can imagine, the Lidoderm scenario will unfold very shortly. So I think you will have the answer to your question in a few months. But from a planning standpoint, we do expect to see Actavis lunch their generic in mid-September. And our presumption is that that will lead to a 30% of net sales for us. And with the launch of a second generic, which again, for planning purposes, we assume sometime in the first half of 2014, would result in a 20% of net sales, in terms of market share. But obviously, as you can imagine, there are lots of things that we are doing currently in terms of the commercial strategy from the brand. It will also depend quite a bit on the behavior of the generic products when they come to market, as well.

Jessica Fye - *JPMorgan - Analyst*

Thanks.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Good morning. First, on AMS, can you just give us a little more color on what's going on overseas and why the business is doing so well, and maybe, of the three businesses, just growth rates OUS? Second, can you talk about the tax rate and why the change, and how we should think about that for the next year or two? And then third, has there been anything as far as an update on your conversations with your partner for Voltaren? Thanks.

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

Thanks, Marc. Let me take the AMS and Voltaren questions, and Alan will talk about tax. With respect to the AMS international business, there is trends across all segments of the business. Men's Health, BPH and Women's Health all grow -- continue to grow outside the US. We have some pockets of strength in Western Europe, for example, in Australia, Canada. And essentially, the demographic shifts continue to favor the use of the brands. And despite austerity measures in Western Europe, for example, we continue to see mid- to high single-digit growth across all of our businesses. I think overall we grew about 6% in our international markets, and we expect to see that trend continuing towards the second half of the year.

With respect to Voltaren Gel, there is nothing new that I can comment on. It's an ongoing dialogue with our partner. And for obvious reasons, we can't really disclose any details of the conversations, but rest assured, we are in active dialogue. Alan, you want to talk about the tax?

Alan Levin - *Endo Health Solutions Inc - CFO*

With regard to the effective tax rate, Marc, we do have a portfolio of net operating losses and other tax attributes that have come from our historical acquisitions. That's a fixed portfolio. And as you see an increase in taxable income, which is a function of the stronger overall business and our raising guidance, that fixed portfolio has a smaller relative benefit on the tax rate, which results in the increase in our effective tax rate guidance

for the full year. Going forward, we would expect some of those NOLs to fade away. But by the same token, tax rate planning remains a key focus for the Company going forward.

Marc Goodman - *UBS - Analyst*

Okay.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

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

Operator

Annabel Samimy, Stifel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Hello. Thanks for taking my question. Just a few. First, on the Qualitest business, I couldn't help but notice that the growth came down to 7%. So what makes you comfortable about the double-digit growth for the year? Is the 7% just typical variability in the business, or is there any kind of impact from the increased operating efficiencies? And the second question is, you mentioned that one of your goals is to drive organic growth. I guess it's pretty obvious how you get that from the Qualitest business, but can you highlight what the sources of organic growth are for the rest of the businesses, growing the current products or some of the pipeline assets you have? Thanks.

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

Sure. In Qualitest, I think I made this comment in the first quarter as well, which is that this is a lumpy business and we do expect quarter to quarter variations. So this is very much in keeping with our expectations for the full year. We are very confident around the lower double-digit growth aspiration that we have for Qualitest for the year. This is not something that concerns us.

With respect to organic growth, as you pointed out, Qualitest is a big component of it. In AMS, the reason we highlighted the growth ex- our Women's Health business is to show that there is robust potential in our Men's Health business, our BPH business, as well as our international markets. So those are the markets that we expect to substantially contribute to organic growth. Again, going into 2014, as the market stabilizes we would expect Women's Health to hopefully join that category, as well. In Branded Pharma, we have the products that we have highlighted in the past. We have products like Fortesta Gel, Supprelin, Voltaren Gel, obviously subject to some of the discussions we have with Novartis. Those are all products that we expect to contribute to organic growth.

Beyond that, we obviously have our R&D portfolio. We're making good progress in preparing the REMS program for AVEED. And with that submission, we are hopeful that we can launch our brand in 2014. Similarly, with the good progress that we are making with BEMA Buprenorphine, assuming a successful Phase 3, which we will read out at the back end of this year or early 2014, that is a potential 2015 launch. So those are the types of things that are driving our organic growth prospects. In Qualitest, beyond the topics we've talked about, we do have a robust portfolio for the ANDAs that are already on file with the FDA. And as those get launched, those would also support organic growth.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay. Great. Thank you.

Operator

David Buck, Buckingham Research Group.

David Buck - *Buckingham Research Group - Analyst*

A couple of quick ones. First, for Qualitest, could you talk a little bit about what the trend has been in terms of gross margin profitability trend year-over-year or sequentially, and what effect is the cost savings likely to have on operating margin in that segment? Then for Alan, can you just talk about the level of Lidoderm sales and whether that reflects for the second quarter all the expected inventory reductions that you might see ahead of a loss of exclusivity, and similar situation for Opana ER? And then Rajiv, the two-year anniversary you commented on on the public health notices from the FDA. The expectation is that suits will decline after that. Can you walk through again the belief in why that might be, and whether there's any type of deadline we should be aware of? Thanks.

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

Sure. Let me first talk about the Qualitest question. If you look at our second quarter performance, our Qualitest gross margin is around 40%, a little bit under. But there is something that we continue to expect to increase over time. Part of the reason that we are making a substantial CapEx investment in Qualitest is, in fact, to improve manufacturing efficiencies. And our aspiration over time is to bring the gross margins into the mid-40s over the course of the next two to three years, and that will roll out over time.

With respect to the two-year anniversary of the FDA advisory, there is no firm deadline per se, but we do believe that plaintiffs will be less likely to file as more time passes. There has been a major push by plaintiffs' attorneys ahead of the end of the two-year anniversary, which I believe was mid-July. And as a result, we have this bolus of cases of both filed cases, as well as some that are served but not yet filed, which we are going to work through over the course of the back half of the year, and we are confident that the pace of new cases will decline after that period.

Alan Levin - *Endo Health Solutions Inc - CFO*

And then with regard to inventory levels for both Lidoderm and Opana ER, we ended the quarter at the lower end of our DSA agreed inventory levels, pretty consistent with where we were the second quarter of last year. I wouldn't expect that to change very much with regard to Opana, as we move forward into the third quarter. With respect to Lidoderm, we would expect some inventory reductions as we get closer to the launch by Actavis, presumably in mid-September. But it's a little early yet to see that reflected in actual levels.

David Buck - *Buckingham Research Group - Analyst*

Great.

Operator

Andrew Finkelstein, Susquehanna Financial Group.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks for taking the question. I was hoping you might be able to provide some color on where you stand with Opana. You talked about continuing to promote it, as long as that remains economically viable. Maybe if you could remind us what kind of resources you have on the product currently, where you stand with formulary positioning, and the gross to nets for the product, whether those are stable. And then more generally, remind us

of the commercial resources you have in place to support that brand and potentially the BEMA Buprenorphine product, if those data come out positively. Thanks.

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

Sure. With Opana, as I said in my comments, we continue to believe that abuse deterrent formulations are a very, very important part of the future of long-acting opioids, and we continue to support the brand. With Opana, we have not disclosed the number of sales representatives we have, but we have a robust specialty pain field force that supports that brand, as well as Voltaren Gel. And we will continue to do that as long as it remains economically viable, i.e., until we have multiple generics on the market and there is substantial share erosion. In terms of our observation so far, with a single generic on the market, it's actually been a pretty stable situation. We have not seen a lot of market share fluctuation over the course of the last few weeks and the last couple of months. It's been fairly stable. There's also been no major changes either in gross to net or formulary position. Obviously, that situation may or may not change, if and when additional generics come on the market.

The other thing that I would say is that we continue to be in very active dialogue with the FDA, and we are hopeful that we can find a path for eventual label change on the product. It will likely involve some additional clinical work on our part, which we are committed to doing in a timely fashion once that program is agreed with the FDA. And then finally, as I said in my comments, we have a very strong portfolio of intellectual property around Opana ER, and we intend to vigorously assert those against the generic filers.

Andrew Finkelstein - *Susquehanna Financial Group - Analyst*

Thanks. And then in terms of BEMA Buprenorphine, how do you assess what's needed to commercialize that, assuming it is successful in trials?

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

We are confident that with the current commercial footprint that we have that we ought to be able to fully support that brand. Obviously, there would be a need for some incremental variable advertising and promotion expense, which is what you would expect. But in terms of actual personnel, it is something that we believe we can manage within the context of our existing field organization. Obviously, the brand does better than we expect, we would look to support it with a bigger field effort.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

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

Operator

Chris Caponetti, Morgan Stanley.

Chris Caponetti - *Morgan Stanley - Analyst*

Thanks very much and congrats on the second quarter. I have two questions regarding financials and mesh. The first one is, your updated full-year guidance appears to imply second half earnings per share below consensus, at least at the midpoint of your range. I'm wondering what it is we're missing on the sell side, or are there any pushes and pulls just beyond the loss of exclusivity on Lidoderm and Opana? And second, in terms of mesh -- and my apologies if I missed this -- but would you please provide us with an update on the total number of filed cases? I think it was about 8,000 on the last call. And it would be helpful if you could help us understand the split between prolapse and incontinence cases. Thank you.

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

Sure. In terms of the second half performance, because as you can appreciate, there is quite a bit of uncertainty around how the second half will unfold. Part of that is Lidoderm. We have every expectation to see the Actavis launch come to fruition in mid-September. Obviously, it then remains to be seen how quickly the share erosion actually will happen and to what extent. Obviously, we have not been sitting still with Lidoderm in this intervening period. We've been working on various commercial strategies that could potentially mitigate the impact of generic erosion. So there is that answer. And then secondly, we have taken a view that there would be multiple generics on the market for Opana ER, which will result in substantial share erosion. Now obviously again, we are working on multiple levels to combat that, both in terms of working with the FDA, working on the commercial side with our customers, but also asserting our IP. So as all those things come to fruition, I think come third quarter, we'll obviously have a much better view as to how things are unfolding. But those are probably the two main assumptions that drive our view of the second half of the year.

In terms of mesh, we have, as of the end of July, filed cases totaling 13,500, which is obviously a substantial increment on the number that we had at the end of the first quarter. But again, this is not unexpected, because we did expect as we came up to the two year anniversary that we will see a big bolus of cases, and we expect this total number to potentially rise over the course of the next few months, but the pace of increase would certainly be much less from what we can see. In terms of the split between stress urinary incontinence and pelvic prolapse, in general it's a 60/40 split, plus or minus, 60% for stress urinary incontinence.

Chris Caponetti - *Morgan Stanley - Analyst*

Thanks very much.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

Can we go to the next question, please?

Operator

Michael Schmidt, Leerink Swann.

Michael Schmidt - *Leerink Swann & Company - Analyst*

Good morning. Thanks for taking my question. My question was on business development. I was wondering since you've been talking about the tax rate earlier, does managing the tax rate play a factor in your acquisition strategy? You already have a small European footprint. Is that something that you could leverage to manage the tax rate more efficiently? Thank you.

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

Thank you, Michael. What I would say is that our business deal open strategy in the business we are open to looking at can go forward, regardless of our view on tax rate. So it's not a factor that is a big driver of our strategy. Obviously over time, we believe it will be in the best interest of our shareholders for us to try to find a way to move to a more efficient tax structure. Obviously, with our AMS business, as you pointed out, we do have a manufacturing capability in Ireland, which provides -- acts as a starting point of a tax strategy for that business. And we are actively evaluating other potential structures for us, as we do acquisitions, to hopefully over time move to a more efficient structure.

Alan Levin - *Endo Health Solutions Inc - CFO*

That being said, I would add that historically our acquisitions have carried some tax attributes with them, whether they are net operating losses or step-ups in tax bases that have allowed us to leverage down the statutory rate in the US. And I would expect that on a going forward basis, future acquisitions would carry some of that, as well.

Michael Schmidt - *Leerink Swann & Company - Analyst*

Great. Thank you.

Operator

Tim Lugo, William Blair.

Tim Lugo - *William Blair & Company - Analyst*

Thanks for taking the question. Can you talk about the enrollment trends for the BEMA Buprenorphine trials? I believe originally the opioid experienced trial was to report out prior to the naive trial, but now it looks like both will report out in 2014?

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

Obviously, this is a product where we are conducting the program in conjunction with our partner. So there is limited detail that I can give you, in deference to BDSI. What I would say is that the enrollment remains on track, and there is a possibility that one of the trials may read out in 2013, but to be prudent, we are assuming that both will certainly be read out by early 2014. But more trials are on track.

Tim Lugo - *William Blair & Company - Analyst*

Thank you.

Operator

Elliot Wilbur, Needham & Company.

Serge Belanger - *Needham & Company - Analyst*

Good morning. This is Serge Belanger for Elliot. Just a quick question on Qualitest. Can you provide any insight on the constitution of your current pipeline there? You mentioned there was 40 ANDAs in total, but how many of these are potential first-to-market or first to file? And how many are high barrier to entry opportunities?

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

Sure. I think I would make a distinction between our historical ANDA portfolio that we inherited when we bought Qualitest and the new ANDAs we are filing. For competitive reasons, we are not going to talk about specific ANDAs. But the historical ANDAs, in general, would mirror our current product portfolio mix of controlled substances, but also some typical solid oral dosage form generics, as well. Historically, this is not a business that invested much in first-to-file ANDAs, so that is not our expectation in the very near term. But obviously, our strategy has shifted as we've brought

in new R&D capabilities to bear. We have a new pilot facility that we've just installed in Huntsville, and those new ANDAs will obviously have a different profile. But again, for competitive reasons, we can't talk about exactly what those are.

Serge Belanger - *Needham & Company - Analyst*

Thank you.

Operator

Tim Chiang, CRT Capital Group.

Tim Chiang - *CRT Capital Group - Analyst*

Hello. Thanks. I have a question for Rajiv and a question for Alan. Rajiv, I think you had made some comments about the amount of share you might be able to retain in Lidoderm. Was it around 50%, even with two generics? And then Alan, how much of the cost savings would you say is attributed to HealthTronics' divestiture? I think you had commented in a prior call that HealthTronics does make up part of the $325 million in cost synergies by next year.

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

Let me actually answer both questions, and Alan can add. With respect to Lidoderm, with one generic, we would expect to retain 30% of net sales, and with two generics, we expect to retain 20% of net sales. But again, this is all subject to things that will happen over the course of the next month or two. And we will obviously be the wiser, shortly.

With respect to HealthTronics, just to clarify, our $325 million reduction included some reductions that we are taking within the HealthTronics business, but it is a very small proportion of that $325 million. The reductions have already been taken, and so we remain very confident around the $325 million, regardless of whether HealthTronics is sold in the short term or not. Alan, you want to add to that?

Alan Levin - *Endo Health Solutions Inc - CFO*

I'd say that's quite correct. And we've made some very good progress in implementing the cost reductions that are a part of this plan, and so we're tracking very nicely against our $150 million year-over-year reduction this year, which in turn will lead to the $325 million reduction in 2014.

Tim Chiang - *CRT Capital Group - Analyst*

Okay. Great. Thanks.

Operator

Ken Cacciatore, Cowen and Company.

Ken Cacciatore - *Cowen and Company - Analyst*

Thanks, guys. Just a real quick question on the vaginal mesh. It was my understanding that you had a tentative settlement this quarter. I was wondering if you could give us a sense of the amounts in the tentative settlement and then the number of cases that that tentative settlement encapsulated. Thank you.

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

So this was a tentative settlement that we actually announced in our first quarter results, when we did the first quarter results. The total settlement is $54.5 million. And that settlement has been finalized; but obviously, the plaintiffs' attorneys now need to go through a process of getting approval from the individual litigants. And we have not disclosed the number of cases, and that's subject to a confidentiality agreement between us and the plaintiffs' attorneys.

Ken Cacciatore - *Cowen and Company - Analyst*

Okay. So we'll never know how many cases that encapsulates?

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

That is correct.

Ken Cacciatore - *Cowen and Company - Analyst*

Okay. Thank you very much.

Operator

Irina Rivkind, Cantor Fitzgerald.

Irina Rivkind - *Cantor Fitzgerald - Analyst*

Thanks for taking the questions. I just wanted to explore the cost savings a little bit. For the approximate $70 million remaining in this year, does that assume that you're going to cut additional Opana promotion and that is where the $70 million is going to come from? And if the Opana generic situation doesn't turn out as badly as you're expecting and you choose to retain that promotional presence, is there a chance that you're not going to cut as much out of expense? Thank you.

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

In terms of the remainder of the year, so we have taken all of our cost reductions in the US, when it comes to headcount savings, already. And those were announced to employees on June 5. But if you look at our year-to-date results, there's only a small fraction of those reductions that actually incorporated into the first half results, as you can imagine, because you only have about a month or so of those reductions in the first half results. So those will have a run rate benefit over the course of the second half of this year. So in other words, we don't need to make any further personnel reductions in order to make our cost savings target.

For the reasons I've said before, we remain confident in the promotion of Opana ER. The same field organization promotes Voltaren Gel, and we expect the same field organization to promote BEMA Buprenorphine. And obviously, we are also actively looking for BD opportunities to incorporate

into the field organization, as well. So obviously time will tell, but we are confident as we get into 2014 that we will have multiple products for that field force to promote.

Alan Levin - *Endo Health Solutions Inc - CFO*

The other thing that I would add is the cost savings themselves are fairly broad-based across all of our operating segments, as well as the staff functions for the company, and were sized with an understanding as to the range of outcomes with respect to Opana.

Blaine Davis - *Endo Health Solutions Inc - SVP, Corporate Affairs*

Great. And at this time, there's no more questions in the queue, so we'll go ahead and wrap the call with that. So if you have any additional questions, Jonathan Neely and myself will be available this afternoon. Again, thank you very much for joining us today.

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

Thank you.

Operator

Ladies and gentlemen, this concludes your presentation. You may now disconnect and have a good day.
