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ENDP - Q2 2014 Endo International PLC Earnings Conference Call

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OVERVIEW:

ENDP reported 2Q14 revenues of $719m and adjusted diluted EPS of $1.06. Expects full-year 2014 revenue to grow approx. 4-7% vs. full-year 2013 and adjusted diluted EPS to be $3.80-4.00.

CORPORATE PARTICIPANTS

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

Suky Upadhyay *Endo International PLC - CFO*

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Christopher Caponetti *Morgan Stanley - Analyst*

Gary Nachman *Goldman Sachs - Analyst*

Dana Flanders *JPMorgan - Analyst*

Corey Davis *Canaccord Genuity - Analyst*

Jim Dawson *Buckingham Research Group - Analyst*

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Michael Faerm *Wells Fargo Securities - Analyst*

Shibani Malhotra *Sterne, Agee & Leach - Analyst*

David Amsellem *Piper Jaffray - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q2 2014 Endo International PLC earnings conference call. My name is Steve and I'll be your operator for today.

(Operator Instructions)

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

Now I would like to hand the call over to Mr. Blaine Davis, Senior Vice President, Corporate Affairs.

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

Thanks, Steve. Good morning, everyone, and thanks very much for joining us to discuss our second-quarter financial results.

With me here in Dublin on today's call are Rajiv De Silva, President and CEO of Endo, and Suky Upadhyay, Chief Financial Officer. We have prepared a slide presentation to accompany today's webcast and that presentation is posted online in the Investor section at www.Endo.com.

I would like to remind you that any forward-looking statements by Management are covered under the Private Securities Litigation Reform Act of 1995 and Canadian Securities Legislation Act, 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 maybe different from non-GAAP financial measures used by other companies.

Investors are encouraged to review Endo's current report on Form 8-K filed with the SEC for Endo's reasons for including those non-GAAP financial measures in its earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial

measures is contained in our earnings press release issued prior to today's call. Our prepared remarks will begin by briefly discussing our second-quarter results and revised financial guidance.

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

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

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

On slide 2, you will see our agenda for today's call. We will start with a review of our recent accomplishments and follow that with the highlights of our strong second-quarter 2014 financial results.

Our positive year-to-date results have driven a raise to our 2014 full-year revenue and adjusted earnings per share expectations and will discuss the details of our revised financial guidance in just a few minutes. Following our prepared remarks, we look forward to taking your questions.

Moving on to slide 3, we have made substantial progress towards our priorities and achieving our goal to be a leading specialty healthcare Company. Let me quickly review some of the significant recent events. First, during the quarter we took several actions that we believe demonstrate a disciplined approach to capital allocation, highlighting our commitment to create shareholder value.

In June, we announced that we have entered into an agreement to acquire DAVA Pharmaceuticals, a privately held company specializing in marketed pre-launch and pipeline generic pharmaceuticals. DAVA is highly profitable and a very natural fit for our US Generics business.

In May, we announced the closing of our agreement to acquire the global rights to Sumavel DosePro. This product expands our portfolio of branded products in the treatment of pain and management of migraine. Our expectations for its growth will be supported by our current commercial team.

Last week, we announced the closing of our agreement to acquire Grupo Farmaceutico Somar. We believe this is an important step towards becoming a leading global specialty healthcare Company, as Somar establishes a platform for growth in key Latin American emerging markets.

I believe each of these transactions is an excellent example of how we would like to balance our M&A activities to support both near-term and long-term growth of our Business. We remain committed to actively pursuing additional business development and expect to execute additional deals in the second half of the year.

Second, our launch of the authorized generic version portion of LIDODERM in May has been highly successful. We believe that we can maximize the value of this franchise as we continue to manage loss of exclusivity of the brand.

Third, we are focused on the key organic drivers in all of our businesses. In US Branded Pharmaceuticals, we are encouraged by the early feedback from physicians and patients regarding Aveed. And in US Generics, we remain on track to deliver low double-digit organic growth in 2014, excluding the impact of Boca and the DAVA acquisitions. The strong organic growth from our Generics business is the result of solid demand trends driving volume and a dynamic pricing environment.

Fourth, in July, we announced positive results from our second BEMA buprenorphine phase 3 study. Following the announcement of those results, we had a pre-NDA discussion with the FDA, and based on that discussion, we believe that we are on track to file an NDA either later this year or in early 2015. And fifth, we are focused on meeting our financial targets and we have announced increases to our 2014 financial guidance for both revenues and adjusted diluted earnings per share.

Moving on to slide 4, you will see that we had a strong second-quarter, reporting $719 million in revenues, up versus prior year, and $1.06 in adjusted diluted earnings per share. Suky will provide more details about the second-quarter results in just a few minutes.

Acquisitions clearly contribute to the year-over-year growth of our revenues and are directly aligned with the strategy that we have been executing over the past year. However, on the following slides, I will focus my comments on the organic growth drivers in each of our core businesses.

Moving to slide 5, Branded Pharmaceuticals delivered organic sales growth of 6% in second quarter 2014 compared to second quarter 2013. Our organic growth measures exclude sales from LIDODERM, OPANA ER, and royalties received from Actavis for the sale of its generic Lidocaine patches. It also excludes sales from Sumavel DosePro for comparison purposes.

We remain confident in our full-year expectations for low single-digit growth from our core products. We continue to invest behind our key growth drivers in this business, as we also explore opportunities to add additional products to our branded business through acquisition, partnerships, and/or licensing.

Moving to slide 6, our Generics business continued to deliver impressive results in the second quarter, with sales of $272 million, delivering 60% growth versus prior year. Growth in our Generics business this quarter benefited from the inclusion of Boca Pharmacal, as well as launch of the LIDODERM authorized generic.

Excluding these effects, sales grew 12% versus prior year, in line with our previously stated guidance in early 2014. The strong organic growth for US Generics continues to be led by its controlled substance business.

Moving to slide 7, we continue to see signs of progress within our AMS business. Year-to-date, total AMS sales have grown slightly, and by 3% when excluding Women's Health. Both of those measures have improved when compared to their 2013 performance. The turnaround at AMS is continuing to deliver results, while also delivering improving profitability and EBITDA contributions.

One final note regarding AMS, we are pleased with the progress that we are making in resolving the mesh litigation. We have made solid progress in finalizing the agreements that resolve the substantial majority of claims which we announced in April and we expect to complete that process in the near future.

Moving to slide 8, our International Pharmaceuticals business continues to perform well and is on track to meet our expectations. Recently, we announced the completion of our acquisition of Somar in Mexico. As a platform for growth, Somar provides Endo with a number of attractive opportunities.

It has a robust pipeline, which currently includes over 60 products expected to launch over the next three years. Through reciprocal regulatory agreements, Somar has the potential to further our expansion into Latin America markets, and its manufacturing capabilities have the potential to support an even broader sets of opportunities.

I would like to take this opportunity to welcome Norbert Oppitz to the leadership team at Endo. Norbert will join Endo as Regional President, Latin America, Africa and Export Markets. In this new role, he will have responsibility for Endo's business in Mexico, including Somar, as well as providing oversight for Endo's investment in Litha Healthcare, based in South Africa. Norbert brings a wealth of industry experience and will have a keen focus on expanding Endo's Latin American and emerging markets business by leveraging existing portfolio assets and advancing new business opportunities.

Paladin Labs continues to perform well, with solid growth in promoted prescription products and international brands. Paladin remains focused on driving growth with acquisition and in licensing of late-stage development projects and commercial stage projects.

Moving to slide 9, we continue to deploy capital on a number of fronts, with a focus on creating value for our shareholders. During the first half, we announced three significant transactions that resulted in us committing approximately $1 billion of cash and contingent payments. We were disciplined on price for each of the deals we executed and remain confident that each of the deals will meet or exceed our targeted returns.

As I stated earlier, deals are an important tenet of our growth and the pipeline of our opportunities we are currently evaluating remains robust. We will continue to be opportunistic in our approach to M&A and remain focused on small- to medium-sized deals, as we have announced so far this year. That being said, we also remain open to larger, more transformative opportunities that create value for our shareholders.

In June, we completed a high-yield offering that resulted in the placement of $750 million of senior notes at an interest rate of 5.375%. Lender interest in the offering was strong and we intent to use the proceeds primarily to fund our acquisition of DAVA Pharmaceuticals.

Moving to slide 10, we believe the acquisition of DAVA Pharmaceuticals is attractive for a number of reasons. It will add a high-margin generics portfolio to our US Generics business that we expect to drive immediate accretion following the expected close of this transaction this quarter. DAVA has a robust pipeline, including recent launches and approximately 20 ANDAs under FDA review.

We expect the DAVA pipeline to enhance the new product launches for our US Generics segment over the next few years, which will help support future organic growth. There is also a clear case for synergies and the potential for upside by leveraging our platform and commercial capabilities.

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

Suky Upadhyay - *Endo International PLC - CFO*

Thanks, Rajiv, and good morning to those joining for today's presentation. We are very pleased with the operating performance we delivered in the second quarter and we expect our positive trend to continue through the second half of the year. As a result of this strong performance, we are raising our 2014 financial guidance for revenues and earnings per share.

Let's move on to slide 12 and I'll walk you through some of the financial details. Revenues increased versus the second quarter of 2013. This marks a return to full Company growth for the first time in four quarters and we expect year-over-year growth for the remaining quarters of 2014.

Through prudent deployment of capital, operating a lean model, and pursuing organic growth, we were able to more than offset the year-over-year decline related to branded LIDODERM and OPANA ER. Excluding the effects of branded LIDODERM and our AG, royalties from Actavis, OPANA, and acquisitions completed in 2014, underlying growth for the quarter was 7%.

Those details provide a clear picture of the organic growth in our Business today that is being supplemented with M&A. In going forward, we will remain keenly focused on creating future organic growth opportunities for our Business. Rajiv covered revenues earlier in the presentation, so I'll move on to the rest of the P&L.

Moving to slide 13, as expected, gross margin declined in the quarter, driven by a shift in business mix and lower royalty revenues. We expect margins by segment to remain relatively stable through the rest of the year.

Our underlying operating expenses continue to track to our overall cost reduction targets of a $325 million reduction in our legacy business versus the 2012 baseline. That is reflective of the 12% reduction this quarter in year-on-year adjusted operating expenses, a 19% reduction on a year-to-date basis.

In addition to our positive operating expense performance, we have an improving tax rate as a result of the Paladin transaction and remain on track to realize our annualized post-tax synergies. We continue to expect these improvements in our cost structure and overall tax rate to lead to full-year adjusted net income growth at a rate that is faster than our expected revenue growth.

Adjusted EPS of $1.06 is ahead of expectations and is a result of stronger than expected operating performance. On a year-over-year basis, adjusted EPS declined, primarily as a result of a higher share count. The issuance of shares for the former owners of Paladin Labs within the quarter, as well as the dilution related to our convertible notes, drove a decrease in EPS.

Briefly, regarding the AMS mesh litigation, as expected we had an increase from the first quarter in the number of cases filed by approximately 1,500 to a total of 25,000 cases filed. In addition, during the second quarter, we entered into a settlement agreement covering approximately 1,700 additional claims that adds to the substantial majority of claims under agreement.

The total of claims that we have now resolved is approximately 21,700. In terms of the liability, these updates result in approximately $30 million increase to our reserve. For additional details on our second-quarter 2014 financial results, please review today's earnings press release.

Moving to slide 14, let me make a few comments on our full-year guidance. I won't spend time going through all the items, but will highlight a few key considerations.

Consistent with last quarter, we do not include M&A transactions that have not closed. We are excited about the opportunity to close DAVA this quarter, but we have not included the accretion from this acquisition into our guidance.

As we committed earlier in the year, we have taken advantage of market opportunities to repurchase approximately 280 million, or nearly 75% in face value, of our convertible notes and related warrants through the second quarter. This substantially reduces the overall dilutive effects of these instruments in 2014 and beyond.

Given our better-than-expected performance in the quarter, and the close of multiple transactions, we are increasing the top end of our revenue range by $160 million. Our revenue guidance range now projects revenue growth of the approximately 4% to 7% versus full-year 2013. In the backdrop of the loss of exclusivity on LIDODERM and OPANA, this reflects our commitment to prudent capital deployment and organic growth.

We are also raising the top end of our adjusted EPS guidance range by $0.15. With the first half completed, we have greater certainty in the full year and we have also narrowed both the revenue and EPS guidance ranges. Adjusted EPS is now expected to be $3.80 to $4.

One additional comment to consider for the EPS guidance relates to our recent placement of $750 million of senior notes. We have factored in the incremental interest expense into our guidance. Excluding that effect, our operating performance would have supported a $0.25 raise to full-year 2014 adjusted diluted earnings per share.

Our updated guidance incorporates other changes that I will highlight briefly. We now expect a high single-digit decline in adjusted operating expenses versus the prior year. While we have achieved our underlying expense reduction of $325 million versus a 2012 baseline, projected year-over-year expense declines will be slightly lower due to the addition of operating expenses related to closed transactions.

Moving on to interest expense, with our recent placement of $750 million of senior notes, we now expect interest expense to be approximately $220 million. We have improved the range of our adjusted effective tax rate and now expect a full-year rate between 23% and 24%. This narrowing reflects the increased confidence that there is a lower risk of discrete items pushing us toward the higher end of the prior range.

Overall, we had a strong second quarter, and continue to deliver the proof points of our ability to execute against the strategy. To summarize, we believe that we have turned the corner on revenues and have begun to grow the top line through M&A, driving organic growth, and optimizing LIDODERM.

We are improving net income margins through operating expense discipline and a more efficient tax structure. We continue to enhance our balance sheet flexibility and are delivering on financial expectations, including an increase for both revenues and adjusted earnings per share.

We are focused on building a leading global specialty healthcare Company that has organic growth opportunities and a strong balance sheet to support our strategic objectives. We believe we have the right operating model, in tandem with sufficient balance sheet flexibility, to support M&A and other growth initiatives into the future.

I'm encouraged by our progress and now let me turn it back over to Rajiv to close out

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

Thank you, Suky.

Moving on to slide 15, in closing, I would like to focus on three or four priorities for 2014. Let me start with our objective to meet our financial targets.

We had a very strong second quarter and we exceeded our expectations, both for revenues, as well as adjusted diluted earnings per share. While Endo Management still has much to achieve in 2014, in pursuit of this objective, our strong operating performance in the second quarter builds on our momentum and supports the raise to our top- and bottom-line guidance.

Second, we had an objective to complete at least two to three near-term accretive, value-creating transactions. We achieved that in the first half alone and are now focused on beating that measure. Given the number of opportunities ahead of us, we expect to complete additional deals during the second half of 2014.

Third, we believe in the value of growth from a development pipeline. Our US Branded business received excellent news on BEMA buprenorphine offering program in the first half, with a pair of positive results in phase 3 studies. We have bolstered the pipeline for our international business through the acquisition of Somar and we expect to add approximately 20 ANDAs, for a total of approximately 70 ANDAs in our US Generics business when we close the DAVA transaction.

In conclusion, it is an exciting time at Endo, as we transform the Company into a leading global specialty healthcare Company.

And that concludes our prepared remarks. Let me now turn the call back over to Blaine to manage our question-and-answer period. Blaine?

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

Thanks, Rajiv. This concludes our prepared remarks. We would now like to open the line to take your questions. So operator, if we can go ahead and go to the first question, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Christopher Caponetti, Morgan Stanley.

Christopher Caponetti - *Morgan Stanley - Analyst*

Congratulations on the fabulous quarter. I have two questions for you guys. First on Generics, can you talk about how margins are progressing in that business. I know you disclose it in the Q, but I was hoping to get a bit of a preview. And then finally, on the potential for additional LIDODERM generics, what's in 2014 guidance? Thank you.

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

Thank you, Chris. Let me take the LIDODERM question and I will have Suky answer the question on the Generics margins. For LIDODERM, we have continue to expect another genetic competitor coming to come into the market in 2014.

That expectation has been delayed a couple of times. And from our standpoint, we still continue to expect another generic, but probably not towards the back end of the year, so that is included in our guidance. So with that, let me turn the other question over to Suky.

Suky Upadhyay - *Endo International PLC - CFO*

We were really happy with the second-quarter performance in our Qualitest business. It's continued a positive trend on our overall margin profile, specifically in gross margins. We're now hovering around the mid-40%s.

It's primarily driven by some of the capital improvements we've been talking about over the last year that are starting to come to fruition and starting to actually reduce some of our cost of goods. In addition, we've seen some opportunistic price opportunities in our pain segment, which is also contributing. So again, really happy where things have gone, and we expect that margin profile to be somewhat stable through the rest of the year.

Christopher Caponetti - *Morgan Stanley - Analyst*

Great. Thanks very much.

Operator

Gary Nachman.

Gary Nachman - *Goldman Sachs - Analyst*

Hi, good morning. A couple of questions. First, on DAVA, could you give us a sense of how accretive that could be when it closes. And then a little bit on the Methotrexate pricing and the dynamics in that market? And then Suky, could you update us on where you think your financial capacity is to do deals after you factored all the different sources and uses of cash throughout the year?

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

Thank you, Gary. Let me talk about DAVA for a minute and then Suky can comment on your other questions. Consistent with how we've delivered all of our acquisitions, we are not going to talk about the potential level of accretion until the transaction is closed. What I can tell you is that the review process for that transaction with FTC is progressing very well and we expect to close sometime this quarter and potentially in the very near term.

In terms of Methotrexate, this is a product that has been a mainstay of the DAVA portfolio of the last few years, but our expectation is that there are multiple competitors in the market now and it will continue to diminish in terms of its relative proportion of the DAVA portfolio. Some of the newer products that have been launched from the DAVA portfolio will take on a more prominent role and as further -- and as also launched within the DAVA portfolio, over time, we expect that the contribution of Methotrexate the will come down. In the near term, we have seen fairly stable pricing in the market, though there is obviously some give-and-take on market share, as different competitors come back into the market.

Suky Upadhyay - *Endo International PLC - CFO*

Hi Gary. Regarding your question on financial capacity, I'll just fast-forward to the end of the year, just to keep it clean, and assume that the DAVA transaction is closed. By the end of year, we expect be somewhere about $0.75 billion of cash on the balance sheet and somewhere in the low 3s from a leverage ratio perspective and as we've talked about before, we're comfortable getting up to that 4 times.

So if you add both of those components together, that puts you at right about $2 billion, maybe slightly below. But again, that's a relatively conservative estimate, because again, that doesn't assume the EBITDA contribution of any assets that we would acquire with that financial capacity. Hopefully that gives you a little context around that.

Gary Nachman - *Goldman Sachs - Analyst*

Yes, that's great. If I could just squeeze another one very quickly. Rajiv, now you're close to settling almost all the mesh cases, so just latest thinking on potential for divesting that business, if you think there's actually interest out there and if that's something that you started exploring? Thanks.

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

Thank you, Gary. Look, I would say our thinking on AMS has not really changed very much since we last talked about it on the call last time. We continue to be impressed with the level of turnaround that the team at AMS is effecting in the business. We have substantially improved the margins of the business, we expect to be in organic growth with the business, and as you pointed out, we've also really turned the corner in terms of putting a real framework around the mesh liability.

Certainly from our perspective and external perspective, AMS is the platform in neurology, so it is a very attractive asset. That being said, we as a Company have not taken a decision as to the need to take a view on divesting the asset and we continue to enjoy the improvements that we see in the business. That being said, you've known that we always act in the best interest of our shareholders and will evaluate opportunities as they come our way.

Gary Nachman - *Goldman Sachs - Analyst*

Okay. Thanks a lot.

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

That's, Gary. Can we go to the next question please?

Operator

Annabel Samimy, Stifel.

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

We can go to the next question.

Operator

Chris Schott, JPMorgan.

Dana Flanders - *JPMorgan - Analyst*

Hi, thanks, is actually Dana Flanders on for Chris. Just two questions on business development. First, could you maybe talk about your desire to balance growth versus what are financially very attractive deals? Is this a function of just finding the right asset that is available at the right time or is this you're simply looking at deals from a more pure IRR perspective?

Then secondly, I know the sweet spot for deals you've mentioned in the past is in that $500 million range. What is your appetite right now for something sizable, so maybe several billion dollars worth for transaction and is that something that you consider in the near term? Thanks.

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

Thank you, Dana. In terms of our criteria for transactions, they've always remained pretty consistent, and there are four things we look for in our transaction. One is near-term accretion, so we like to do deals that are accretive within the first 12 months.

We like to do transactions where we think there is -- we're going to return well in excess of our cost of capital, which typically remains a return in the mid-teens. We also look for things that have a reasonably finite cash payback period.

Those are all the financial criteria but we also want to ensure that from a portfolio perspective, if you look back on all the transactions we've done at any given time, that they had been collectively accretive to organic growth. So to answer question, we do transactions from time to time that may appear to have a financial benefit that's near-term, but if you take a look at the portfolio transactions we've done, you will find that we are doing things that are accretive to organic growth over at least the medium term.

In terms of your question around the size of transactions, we've been pretty consistent with our statements and our actions in saying that our sweet spot are transactions in the $250 million to $500 million range. But I have also been clear that we always act in the best interest of our shareholders, so if there is a larger transaction that comes our way, that is a significant multiple of the small to medium size, we would certainly look at it and we have the capacity and the capability to do larger transactions if we choose to.

Dana Flanders - *JPMorgan - Analyst*

Great, thank you.

Operator

Corey Davis, Canaccord.

Corey Davis - *Canaccord Genuity - Analyst*

Thanks very much. Two questions. With all of the political rhetoric heating up on tax inversions, I'm curious to your thoughts on that. There is even some talk beyond inversions about amending the ability to use inter-company debt and loans there.

So even in the scenario, which is a long shot, but that something gets passed this year or in the near term, then could you articulate what, if any, impact that may have on your business and ability to do deals, as well as your current financials?

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

Thanks, Corey. Good to have you back. In terms of the regulatory environment, as you said there's a lot of rhetoric on this topic, in our belief is that ultimately the thing that will resolve this current conundrum is comprehensive US tax reform. We continue to believe that, that is a very complex matter and will likely take time to implement.

But back your question, in terms of potential implications for us. Obviously, for us, we closed our transaction several months ago, so we are very confident in our inversion. In terms of how we think about creating value with our current domicile and going to a Paladin transaction, there were multiple. One is Paladin was strategic even without the inversion, which is that it gave us a substantial start to our ex-US presence.

And then from a domicile standpoint, our Irish domicile gives us multiple points of benefit. One is that it allows us to be much more flexible in terms of how we can deploy capital and move capital around the globe. There is, as you pointed out, the benefit of US inter-company debt, and there is also the benefit of being able to buy assets into Ireland itself or through other domiciles into Ireland, so we are exploring creating value through all of these mechanisms.

So the inter-company debt mechanism is not something that we are solely reliant on. It certainly is an element, but what I would say is this whole inter-company debt concept is not what one that's unique to inverted companies, it's one that most global companies use, so this will have far-reaching impacts on lots of companies, not just us.

And so from a longer-term perspective, we don't worry too much about it. But certainly, if there were any changes, there may be some adjustments to our near-term tax rate expectations, but those things continue to be in my mind something that's likely to take more -- a long period of time to implement.

Corey Davis - *Canaccord Genuity - Analyst*

Great. Thanks, Rajiv. Then the second question on BEMA buprenorphine, I've always thought that molecule itself was underappreciated in the pain community. So thoughts on the potential for that without getting into specific guidance, which I know you won't give, and what's left to do in between now and filing the NDA? Anything unusual or is it just usual [book and feather] stuff?

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

Yes, we continue to be optimistic and encouraged by the progress of the BEMA program. As you saw, our latest phase 3 trial results were very strong. We had a very positive pre-NDA discussion with FDA.

As we all of these things, you can never count anything in the bag until the product is approved, of course, but we are encouraged with that discussion. There are a few items that we do need to clarify before we can file the product, but I would not classify those as being out of the ordinary. And we are on track to file the product, hopefully, towards the back end of this year, if not early 2015, so from a timing perspective, we are on track for how we thought about it.

From a potential standpoint, you're right, this molecule could have some substantial promise in the treatment of pain. There will be an unmet need for a molecule like this when it comes to market. We continue to believe is this will be Schedule 3 product, if it were to be approved, which also creates some unique characteristics around it in a broader pain market place that's changing. So without getting into the specifics about what our beliefs around peak sales will be, we do believe that this will be a substantial product and we look forward to working with the FDA to approve the product and ultimately launching it.

Corey Davis - *Canaccord Genuity - Analyst*

Great. Thanks, everyone.

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

Thank, Corey.

Operator

David Buck, Buckingham Research Group.

Jim Dawson - *Buckingham Research Group - Analyst*

Jim Dawson for David Buck. Great quarter. Can you talk about the run rate, what would it be annualized for the international business, including the closed transactions?

Suky Upadhyay - *Endo International PLC - CFO*

Sorry, the run rate of the international business after we close the transactions?

Jim Dawson - *Buckingham Research Group - Analyst*

Yes, exactly?

Suky Upadhyay - *Endo International PLC - CFO*

The best way to think about that, from the quarter, you can get, is that the international business is generally about $70 million of top line within the quarter, so you could look at that with low single-digit growth for the full year. Then the way I think about it is to superimpose Somar on there.

We haven't given specific guidance about Somar, but as part of the transaction, we did quote that I believe last year on the trailing 12 months, it was about $100 million of top line. So that can most likely give you the pieces to patch together how we think about the rest of the year.

Jim Dawson - *Buckingham Research Group - Analyst*

Okay, thanks. And then on Generic pricing, how sustainable and what was the level in the quarter? It seemed controlled release pricing is particularly strong?

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

If you look at the growth of our Generics business on a year-over-year basis, much our growth is driven by volume, not by price. This is a highly dynamic market. It is also one where we have a very, very fragmented portfolio.

One an average, most molecules actually have price declines, not price increases, but there are certain specific situations and market opportunities which we take advantage of, as do our competitors. These are sometimes short-lived, but -- and they mostly serve to offset the declines that we have in other products. So net-net for us, as we look into the future, our clear focus is on the launch of new ANDAs and volume growth.

Jim Dawson - *Buckingham Research Group - Analyst*

Okay, thanks. And then finally, any update on the future [of labeling] moves for OPANA ER and the current expectations for Voltaren Gel competition? Thanks.

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

Sure. In terms of OPANA ER, there are no changes. We, and as we've talked in the past, we are in the courts actively, defending rigorously our patents. We are also in the process of conducting a [hints o flation] study, which was done at the request of the Agency, that is on track. We expect to have the ability to hopefully file the results of the study sometime towards the end of this year or in 2015.

We also continue to actively promote the product, to remind physicians to prescribe Opana ER. Our status in none of the major compendia have changed. So it is basically a situation where the status is no different than we've talked about in the past and we continue to see a situation where we do lose share to the generic, but not substantial, but the overall molecule has grown. So net-net from a volume basis, we remain fairly flattish.

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

Can we go to the next question please?

Operator

Tim Lugo, William Blair & Company.

Tim Lugo - *William Blair & Company - Analyst*

Thanks for taking the question and congratulations on the quarter. Following up on previous comments on BEMA buprenorphine, can you just update us on what your current sales force looks for Branded products, given the generic competition in the space in the past year? And maybe just your appetite for investing in a Branded launch, given your current strategic focus?

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

We have not disclosed our number representatives, but we have three sales teams in our Branded business in the US. One is a pain team and it is a substantially sized pain team, sufficient to cover all key targets. We also have a urology field force that is similarly sized, and then we have a smaller field force that focuses on our pediatric endocrinology portfolio.

The great thing for us with BEMA buprenorphine is that this is a market that we know very well. We know the target audience extremely well and we will not need to add additional sales representatives to launch this product.

Realistically, we are talking about advertising and promotion dollars, which can be very focused. So we are ready to take on the launch of this brand and we believe that, given our capabilities in this segment, that we can do a very good job without substantial new investments.

Tim Lugo - *William Blair & Company - Analyst*

Understood. And will there be any ex-US plans for BEMA buprenorphine?

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

There will be. We do have worldwide rights, but we have been really focused on getting the US approval through and we are in the process of figuring out how we want to manage the ex-US opportunity?

Tim Lugo - *William Blair & Company - Analyst*

Thanks for that.

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

Can we go to the next question please?

Operator

Elliot Wilbur, Needham & Company.

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

We can go to the next one, please.

Operator

Michael Faerm, Wells Fargo.

Michael Faerm - *Wells Fargo Securities - Analyst*

Good morning. Thanks for taking the question. After the recent series of deals and with BEMA buprenorphine coming, my question is around potential for future synergy, with future deals. How much capacity do you have left in the infrastructure, and particularly sales and marketing? Another way to say it would be how many more products do you have room for before you need to add incremental capacity?

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

I would say that we have a substantial capacity from a Company-wide standpoint to absorb other acquisitions. Obviously, the answer is a little different for different businesses. In the generics business, our commercial capability is such that we can very easily layer on multiple other acquisitions without having any increase in the commercial expenses.

From an R&D standpoint, obviously it would be a function of which ANDAs we expect to be viable for any companies that we by. And then our G&A costs are robust and we can take on a substantially increased load with our existing cost.

For our Branded business, we don't take a traditional monolithic view of being field forces being aligned, specifically with therapeutic areas. We tend to be able to have -- deploy very flexibly around opportunities that exist, so we do still have capacity in the field force. But that being said, if we find a great new opportunity, the fact that we may need to take on a new field force or build on our existing force will not stop us from taking on an opportunity like that.

Michael Faerm - *Wells Fargo Securities - Analyst*

Great and one follow-up, if I may, and with the overlapping calls today, I'm not sure if this was asked already, but with the strength seen in Generics this quarter, could you comment on some of the major drivers there and the extent to which you see them as being sustainable?

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

We have been very pleased with the performance of Qualitest, and if you look back over the last five years, this is I believe, one of the very few top 10 generic companies that have shown double-digit growth over that period of time. And there are three major components to our Business.

One is our control substance, our capability which is essentially the driver of our success. It is an area where we have deep expertise, and obviously, it's a complex area where there is oversight by not only the FDA, but also the DEA from a quota perspective.

We also have a liquids capability that has been a good one. And also then, we have a very, very broad portfolio of older brands, in many cases where we are one of a few competitors. All these things have helped our growth. And obviously from a very near-term perspective, Qualitest is also benefiting from the launch of the authorized generic of LIDODERM.

From our perspective, we continue to believe that the aspirational target that we've talked about in the past, which is high single-digit organic growth in this business, is entirely possible, because we do have a pretty robust portfolio of ANDAs that we have now in place, legacy Qualitest from Boca, as well as from DAVA. We also have now recently invested in an R&D capability for the business that is continuing to generate new ANDAs. So overall, we are very opportunistic about the outlook for this business.

Michael Faerm - *Wells Fargo Securities - Analyst*

Thank you.

Operator

Shibani Malhotra, Sterne, Agee.

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

Thank you. Hi guys and congrats on the great quarter. Just a couple of questions. The first, Rajiv, we were just on the Teva call and they talked about pain being a major focus for them as a therapeutic area.

I have always considered Endo one of the leading experts in pain, so can you talk about your current views on that franchise? You've diversified away from this a lot, but is this something that you are still focus on?

And then second, and I hope this has not been asked already, but when we think of future acquisitions, can you talk about how you're thinking about US versus outside the US and specialty versus generics going forward? Thanks.

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

Hi, Shibani. In terms of your first question, we absolute are committed to the pain space, both in our Generics business, as well as in the Branded business. Obviously, with the latest results of the BEMA buprenorphine program, we now have a possibility of a new product with substantial patent life well into the late 2020s, with substantial potential.

So we are very excited about it. We will continue to invest in BEMA buprenorphine, as well as in defending Opana, as well as continuing to promote Voltaren Gel, while that promotional agreement last. And as you saw, we also continue to enhance our portfolio with small acquisitions.

We bought Sumavel, which also is a good fit, into the pain portfolios, as well. So absolutely, we do continue to find that to be an important segment. That being said, we've also been clear that we are pretty agnostic in terms of therapeutic area when it comes to acquisitions and future targets, so that will not be our only area of focus in terms of looking for acquisitions.

On your second question, about how we think about opportunities in the Branded business, Generics, as well as outside the US, what I would say is that we will continue to want to invest in all three areas. We will certainly want to expand our emerging presence around the two foundations we currently have, in South Africa, as well as in Mexico. Latin America is likely our area of greatest focus.

Then we also want to balance our opportunities between Branded in the US, as well as Generics. Obviously, if [you heard druthers], we would love to do more things in the US branded space, but ultimately, we are driven by opportunities ahead of us and our ability to find the right transaction at the right time. So as long as transactions meet our major criteria, we will do things in all three of these areas, but over the longer term, we'd want to be able to look back and say that we've been able to capture opportunities in all three.

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

Okay, great, thank you.

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

Thanks, Shibani.

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

If we can go ahead and go to the last question that we have, that would be great.

Operator

David Amsellem, Piper Jaffray.

David Amsellem - *Piper Jaffray - Analyst*

Thanks, just a couple. I want to come back to DAVA. Can you, if you can, call out any specific opportunities from that ANDA pipeline and also how many of these are Paragraph IIIs or IVs, where you can launch product at market formation?

And then the second question, I just wanted to get your general thoughts on aggressive pricing actions that we've seen in the [phase], both on the Brand and Generic side. And do you believe that there are opportunities to take price significantly going forward in your commercial portfolio? Thanks.

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

Thank you, David. In terms of the DAVA portfolio, for obvious competitive reasons, we are not going to talk about any of the specific ANDAs that are currently in the pipeline. What I would say, though, is that these are mostly Paragraph III ANDAs, not Paragraph IV, but DAVA, historically, has

been able to find niche opportunities that create above market type of growth niches and we do expect to have several of those type of opportunities in their pipeline.

In terms of your question on pricing, I'll go back to what I said a few minutes ago in answering a similar question, which is that as with any generic business, at the outset of the year we expect pricing declines [on] price increases, but there are opportunities price increases that may present themselves. Those usually either have to do with comparative action or supply issues in the marketplace.

Given the broad portfolio opportunities -- sorry, products that we have -- those opportunities do come our way from time to time. But as we think about the longer term, our growth strategy is not dependant on pricing.

Essentially our growth strategy is around the ANDA pipeline, making sure that those are approved on time, and ultimately, things that drive volume growth. Again, based on our historical experience, we believe that aspiring to high single-digit growth in our Qualitest business is entirely achievable.

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

Thanks. I just want to take the opportunity to thank everybody for joining us today to discuss second-quarter results. Jonathan Neely and myself will be available for any follow-up questions that you may have. Thanks so much.
