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EDITED TRANSCRIPT

ENDP - Q3 2014 Endo International PLC Earnings Call

EVENT DATE/TIME: NOVEMBER 05, 2014 / 2:00PM GMT

OVERVIEW:

Co. reported 3Q14 revenues of $764m and adjusted diluted EPS of $1.15. Expects 2014 revenue growth to be approx. 7-10% YoverY and adjusted EPS to be $4.10-4.25.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the third-quarter 2014 Endo International PLC earnings conference call. My name is Tahisha and I will be your operator for today.

(Operator Instructions)

As a reminder, this conference is being recorded for replay purposes. I would now like to turn the conference over to your host for today, Mr. Blaine Davis, Senior Vice President, Corporate Affairs. Please proceed.

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

Great, thank you very much. Good morning, everyone, and thanks very much for joining us to discuss our third-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 Litigation 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 the 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 8K 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.

In connection with the proposed Auxilium transaction discussed on this call, Endo and Auxilium may file one or more registration statements, prospectuses, proxy statements or other documents with the SEC. Investors and security holders of both Companies are urged to read those documents carefully in their entirety when they become available, as they will contain important information about the proposed transaction, including the names and interests of participants in any solicitation.

With that, I would now like to turn the call over to Rajiv.

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

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

On slide 3, you will see our agenda for today's call. We will start with the review of our accomplishments during the third quarter followed by a (technical difficulty) brief summary of our pending acquisition of Auxilium and end with the highlights of our strong third-quarter 2014 financial results. After our prepared remarks we look forward to taking your questions. Our positive year-to-date results have driven the third consecutive raise to our 2014 full-year revenue and adjusted EPS expectations. We will discuss the details of our revised financial guidance in just a few minutes.

Moving on to slide 4, we continue to make good progress in addressing our near-term strategic priorities that we believe will support our objective of becoming a leading global specialty healthcare Company.

First, our commitment to a disciplined approach to capital allocation was demonstrated by our recent deals. On October 9 we announced an agreement to acquire Auxilium Pharmaceuticals. I will focus on this transformative opportunity for Endo in the next few slides. But in short, we believe the combination will create a leading specialty healthcare Company with an expanded platform that will support long-term organic growth.

In July we announced the closing of our agreement to acquire Somar, which for Endo established a platform for growth in Latin America. And in August we announced the closing of our acquisition of DAVA Pharmaceuticals. DAVA is highly profitable and a very natural fit for our US generics business.

Second, we are focused on the organic growth drivers in all of our businesses. We continue to see strong performance from our branded portfolio, including double-digit prescription growth for Voltaren Gel.

Our US generics business also continues to deliver solid growth, led by our controlled substance portfolio. We are also very pleased by the performance of the Lidoderm authorized generic as well as our recent launch of the Fortesta authorized generic. Our Paladin Labs business launched two new products in Canada, Travelan and Veregen.

Third, we remain focused on supporting R&D opportunities that fit our development risk profile. In the US branded business we remain on track to file an NDA for BEMA Buprenorphine later this year or in early 2015.

We have completed our full-year objective for ANDA filings to support the growth of our US generics business. The 70 ANDAs we have on file with the FDA have a total market opportunity of approximately $15 billion based on IMS prescription sales data. That total increased significantly with this year's filings as we focus on higher-value opportunities.

In our AMS business we announced positive top-line data for the investigational TOPAS system. The results show that over a 12-month period 69% of women suffering from fecal incontinence who were implanted with the TOPAS system experienced at least a 50% reduction in weekly incontinence episodes, and experienced a durable consistent effect across the study period.

And fourth, we remain focused on meeting our financial targets. As I mentioned, we have announced increases to our 2014 financial guidance for both revenues and adjusted diluted earnings per share.

Moving to slide 5, I would like to briefly review our pending acquisition of Auxilium. We believe the combination will create a leading specialty healthcare Company with an expanded platform for future growth. Once closed, we expect the deal to be immediately accretive and to create significant value for shareholders of both Companies and deliver substantial long-term accretion. We believe this latter point is an important aspect for framing our long-term expectations for the combination.

We expect the deal will significantly enhance the revenue and earnings growth trajectory of our US branded business for both the near and long term. We expect Auxilium products to have a compounded annual revenue growth rate in the low double-digits over the next five years, with near-term revenue growth that is higher than the five-year average.

We expect to generate synergies of approximately $175 million on an annual run rate basis in the first 12 months following the close. This $175 million is inclusive of a $75 million operating expense reduction initiated by Auxilium in September 2014. The deal is anticipated to close sometime in the first half of 2015, pending customary regulatory reviews and an approval by Auxilium shareholders.

Moving on to slide 6, I would like to remind everybody of the strong strategic rationale for the deal. It forms the basis of why we are excited to bring Endo and Auxilium together. Once the transaction is completed, we will have multiple opportunities to leverage the strength of the combined Company in order to accelerate organic growth and maximize the value and long duration of Auxilium's products. Importantly, this transaction enables an even stronger Endo with enhanced financial flexibility, a proven M&A platform and an established corporate structure moving forward.

In summary, the acquisition of Auxilium is a transformative opportunity for Endo. We believe this transaction will create significant benefits for Endo and Auxilium shareholders, our patients, customers, and employees.

I would now like to shift and focus on Endo's strong third-quarter performance. Moving on to slide 8, you will see that we had a strong third quarter, reporting $764 million in revenues, up 16% versus prior year, and $1.15 in adjusted diluted earnings per share. Suky will provide more details about our third-quarter results in just a few minutes.

Acquisitions contribute to the year-over-year growth of our revenues and our full-year line with the strategy we have been executing over the past year. However, on the following slides, I will focus on the organic growth drivers in each of our core businesses that we believe demonstrate the underlying strength of our Company.

Moving to slide 9, US branded pharmaceuticals delivered organic sales growth of 11% in third-quarter 2014 compared to third-quarter 2013. Our organic growth measure excludes sales from Lidoderm, royalties received from Actavis for the sales of its generic lidocaine patches, and sales from Opana ER. It also excludes sales from Sumavel DosePro for comparison purposes.

The year-to-date performance gives us confidence in raising our full-year expectation for performance from our core products to mid single-digit growth. We continue to invest in organic growth drivers for branded pharmaceuticals. We are on track to file an NDA for BEMA Buprenorphine with the FDA.

Endo remains a leader in pain management, and we are excited about the potential for this product to further enhance our position in this space. We believe that, if approved, BEMA could provide patients with an innovative option in this area of significant unmet medical need.

Moving to slide 10, our US generics business continues to deliver impressive results in the third quarter, with sales of $319 million, delivering 74% growth versus prior year. Growth in our US generics business this quarter benefited from the additions of Boca Pharmacal and a partial quarter of

DAVA Pharmaceuticals. Sales of Lidoderm AG were a strong source of new growth as well. Excluding these effects, underlying sales grew 13% versus prior year.

The strong organic growth for US generics continues to be led by our controlled substance business. Hydrocodone and acetaminophen combination products performed well in the quarter. We also saw good growth across a broad set of other controlled substance products, including Endocet, oxycodone and our combination products that contain Butalbital, acetaminophen and caffeine.

Moving to slide 11, we continue to progress within our AMS business. Year to date AMS sales have grown by 2% when excluding women's health. We believe AMS is a premier business in the US urological device space and we remain focused on returning the business to growth while also delivering improved profitability and EBITDA contribution.

One final note regarding AMS. We are very pleased with the progress that we are making in resolving the mesh litigation. In September we reached massive settlement agreements with a number of the remaining leading plaintiffs' attorney firms, and accordingly, believe the Company has resolved substantially all of the known outstanding US claims against AMS.

Moving to slide 12, our international pharmaceuticals business continues to perform well and is on track to meet our expectations. Paladin's business development efforts are progressing well and that gives us confidence in the sustainability of Paladin's growth profile.

We are also progressing well in the integration of Somar in Mexico. Somar provides Endo with a number of attractive opportunities. It has a robust pipeline that can be used to further our expansion in Latin America and its manufacturing capabilities have the potential to support an even broader set of opportunities, including for our US generics business.

Finally, we recently initiated a process to acquire the outstanding shares for the Litha business in South Africa. We believe that having full operational control of that business would be of value as we evaluate our strategic growth options in this attractive emerging market.

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 us for today's presentation. We're very pleased with the operating performance Endo delivered in the third quarter. The quarter was marked by accelerated revenue growth driven in our core business and through strategic accretive M&A. In addition, disciplined resource allocation and a lean operating model led to net income growth above overall revenue growth on a year-to-date basis.

In addition, we continue to see solid underlying cash flow generation when you exclude one-time events and payments related to resolving the mesh liability. 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 14, and I will walk you through some of the financial details. Revenues increased 16% versus the third quarter of 2013. Last quarter we had a return to full company growth for the first time since early 2013, and that growth rate increased substantially this quarter.

Excluding the effects of the sales of branded Lidoderm and our AG, royalties on Lidoderm, sales of Opana ER, and acquisitions completed in 2014, underlying growth for the quarter was 9%. This is an important metric for the Company, as we expect to grow and deliver shareholder value from organic growth as well as M&A. We'll continue to remain keenly focused on creating future organic growth opportunities for our business.

Rajiv has covered revenues earlier in the presentation so I will move on to the rest of the P&L. Moving on to slide 15. As expected, gross margin declined in the quarter driven by a shift in business mix and lower royalty revenues. Despite our expected decline in overall gross margin for the year, we expect margins by segment to remain relatively stable.

Our operating expenses continue to track within our expectations. We achieved our objective of a $325 million reduction in our legacy business versus the 2012 baseline. We subsequently added strategic growth platforms, including Paladin, DAVA and Somar, which comprise about $500 million in annual pro forma revenue, and still improved adjusted operating expenses in the third quarter when compared to 2013.

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, which will drive our previously communicated tax rate to the low 20% range. 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, which ultimately results in improved margin on a year-to-date basis. Adjusted EPS of $1.15 is ahead of expectation as a result of stronger than expected operating performance.

Briefly, regarding the AMS litigation, on a reported basis our results include a pretax non-cash charge to increase the Company's mesh liability reserve to approximately $1.6 billion for all known, pending, and estimated future US claims. As noted earlier, the change in the accrual for product liability claims is primarily attributable to massive settlement agreements that the Company's AMS subsidiary reached in September to resolve substantially all the remaining known US claims against AMS. For additional details on our third-quarter 2014 financial results, please review today's earnings press release.

Moving to slide 16, 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.

First, consistent with our past approach, we do not include M&A transactions that have not closed. Given our better than expected performance in the quarter, we are increasing our revenue range by approximately $20 million.

Our revenue guidance range now projects revenue growth of approximately 7% to 10% versus full-year 2013. In the backdrop of loss of exclusivity on Lidoderm and Opana ER, this growth reflects our commitment to prudent capital deployment and organic growth.

Our new guidance range for 2014 revenues implies fourth-quarter revenue growth that moderates slightly. We have a number of strong sequential growth drivers over the remainder of the year, however as Rajiv mentioned earlier, our fourth-quarter revenues in US generics will be tempered by our recent decision to follow market dynamics and adjust prices within the controlled substances portfolio.

As a result, we expect to increase our rebate reserves in fourth quarter. We believe this decision will deliver significant value and enhance the growth trajectory of our US generics business in 2015 and beyond. We are also raising the top end of our adjusted EPS guidance range by $0.05 and tightening the range by raising the bottom end by $0.10. Adjusted EPS is now expected to be $4.10 to $4.25.

Our updated guidance incorporates other additional changes that I will highlight briefly. We are tightening our range for adjusted gross margin while maintaining the midpoint of 64%. We continue to project a mid to high single-digit decline in operating expenses versus the prior year, even with the addition of operating expenses from Paladin, Somar, and DAVA. We expect expenses to be slightly higher in the fourth quarter versus the third quarter due to the timing of certain marketing and selling expenses, as well as higher R&D expenses related to the progression of our pipeline.

Moving on, interest expense is expected to be about $220 million for full-year 2014. We now anticipate our full-year adjusted effective tax rate to be approximately 23%, which was the bottom end of our prior guidance range. As a reminder, we expect to maintain a low 20% tax rate over the midterm, but that rate can fluctuate modestly due to discrete timing events in any given quarter.

Overall, we had a strong third quarter and continue to deliver the proof points of our ability to execute against a strategy. To summarize, we have a strong revenue growth and are achieving that by completing value-accreting M&A, driving organic growth and optimizing our current brands. 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're focused on building a leading global specialty healthcare Company that has robust organic growth opportunities. In addition, 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 am encouraged by our progress to date.

And now, let me turn it back to Rajiv to close out. Rajiv?

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

Thank you, Suky. Before we start the question-and-answer session, I would like to close with a few brief thoughts. As we reinforce on slide 17, we continue to believe that this is an exciting time at Endo, as we transform the Company into a leading global specialty healthcare Company. We restructured and implemented the lean operating model which supports our belief that we can be better managers of assets.

The increased financial flexibility provides Endo with the opportunity to invest in two paths to support growth going forward. The first path is financially disciplined value-creating M&A, and we have established a strong track record in that regard. The second path is investment in organic growth drivers, which can be seen by the strong operating performance delivered in the quarter across each of our business units.

Our operating model has allowed us to produce the strong financial results that we share today. We continue to remain focused on meeting or exceeding the financial performance expectations that we have set.

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*

Thank you, Rajiv. This concludes our prepared remarks. We would now like to open the line to take your questions. In the interest of time, if you could limit your initial questions to allow us to get in as many as possible within the hour, we'd greatly appreciate it. Operator, if we can go ahead to the first question, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question will come from the line of Marc Goodman from UBS.

Marc Goodman - *UBS - Analyst*

In the generics business can you give us a sense what the gross margin was in the quarter? And can you give us a sense of the pipeline over the next 12 months? How many new products should we be expecting to launch in 2015?

And then, Rajiv, any update on Voltaren Gel? Any new thoughts on how we should be thinking about it? Thanks.

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

Sure. Let me talk about the new product pipeline and Voltaren Gel, and Suky will talk about the gross margins in generics.

So our new product pipeline, and as you know we have referenced our 70 ANDAs. We expect those 70 ANDAs to launch over the course of the next three to four years. So we do expect a reasonable number of launches in the next year. We have not disclosed exactly how many, but if you take the 70 and you know that roughly covers a four-year period, you ought to be able to expect a proportional number of launches over the course of the next 12 to 18 months.

Marc Goodman - *UBS - Analyst*

Can you give us any sense? Are there any significant ones that could come? Significant meaning $25 million, $30 million products.

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

Marc, the answer to that is probably. But I think as you know from our portfolio, we have a broad range of diverse products.

Many of them are older products where there is not a whole lot of active competition from other large generic manufacturers. So it is actually a little difficult to predict up-front what is going to be big and what is not going to be big.

But we certainly know as a portfolio, several of these products are going to be meaningful, in other words, will certainly be in excess of the $25 million number you put out there. So I would say we certainly expect one or more products to be in that category, but it is difficult to predict up front exactly which ones those are going to be.

Then to answer your question on Voltaren Gel, we continue to have a very constructive dialogue with Novartis. We've had good volume growth on the product. There's some channel mix dynamics this quarter, but from a long-term basis we continue to be very encouraged by the product.

Absent the launch of a generic, we believe that we ought to be able to see continued promotion of Voltaren Gel going well into 2016. As we have talked about before, this is a product where a generic would need to do clinical trials. It is not a very straightforward product for a generic company to genericize, so we are cautiously optimistic that we will promote this into 2016. Suky, the gross margins?

Suky Upadhyay - *Endo International PLC - CFO*

Sure. Gross margins, Marc, in the quarter were in the mid to high 40%s. This is an improvement from the earlier part of the year.

We expect, on a full year, to average out to the mid 40%s. That improvement that we're seeing through the year is in part due to some opportunistic price throughout the year, but also due to some improvements in efficiencies and reduction in COGS.

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

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

Operator

Your next question will come from the line of Gary Nachman from Goldman Sachs.

Gary Nachman - *Goldman Sachs - Analyst*

Rajiv, also on the generics business, the 13% growth in the legacy piece that was mostly from controlled substances, how much was price versus volume? How much was from taking advantage of competitive situations versus new launches?

Give us a sense of dynamics there and elaborate on your pricing strategy going forward. Then on AMS, quickly, comment where you are in terms of considering strategic alternatives for that business. Thanks.

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

Sure, thanks, Gary. With respect to generics, we continue to enjoy very robust growth in our controlled substance business. And what we're seeing is a combination of price and volume. Probably a little bit less than half, about a third in price and third in volume in terms of what's driving the growth.

There have been some substantial volume growers. For example, if you take our hydrocodone-APAP combination, the 300 milligram, that's been a very successful product for us. We have about 65% market share in that category.

If you take the overall, our hydrocodone-APAP combinations, we have roughly around a 30% market share. So that's a robust volume that's helping us.

But certainly we have been opportunistic in terms of following market dynamics in the controlled substance space in terms of some price adjustments. From a longer term perspective, we continue to believe that the generics business is one where we ought not to be depending on price increases. Outside of controlled substances, there's continued downward pressure on an annual basis.

So if you take our strategic plan, it basically relies on opportunistic price increases to offset the natural decline in price that we see. Then it is basically mix and volume that we believe will drive growth into the future and that we've talked about, the high single-digit in terms of aspiration for growth in this business, in the US generics business in the medium term.

For AMS, the situation is as we have described in the past, which is that we continue to focus on really getting the business back to growth. We have seen some lumpiness this quarter, but net-net, the business is back in growth except for women's health, which continues to show a very sluggish market against a backdrop of the prolapse market in particular.

And as we disclosed in our last earnings call, since we entered into our mass settlement agreements around mesh, we certainly have seen an increase in the number of inbound inquiries that we get on AMS. It is a very attractive device platform in the urology space. As we would always do when we get inbound inquiries, those that we believe are serious and viable, we do take a look at and respond to, which is what we're doing.

But that being said, our Board of Directors has not taken a decision as to the future of the business yet. And I have also been clear in my commentary before, that from a long-term basis that we are likely not the best owners of this asset.

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

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

Operator

Your next question will come from the line of Shibani Malhotra from Sterne Agee.

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

Thanks for taking the question and congrats on a great quarter. A question on Auxilium, Rajiv. You talk about double-digit growth, but can you give us some more color into what you mean by double-digits? Is it 10%? Is it 30%? Also the components underlying your growth assumptions.

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

Sure. Shibani, when we talk about double-digit, we talk about from a medium- to longer-term perspective. So five-plus year horizon.

We certainly expect the front end of that certainly, or the next couple of years, to be substantially well into the double digits. We're not going to be more descriptive than that. But if you look at some of the underlying growth dynamics in Xiaflex and STENDRA, in particular, we expect that it will be very robust in the nearer term.

And in terms of -- I think the second part of your question was around what is the basis of our belief. And it basically goes back to our belief that Xiaflex has substantial potential, particularly in Peyronie's disease. But certainly there is more potential in Dupuytren's contracture as well, particularly now with the multi-cord label expansion.

And STENDRA, with its 15-minute onset indication, should make it a well-differentiated product among the PDE5's. So those are certainly things that give us encouragement in the longer-term outlook.

Certainly if you look at the third quarter results that Auxilium themselves have just announced, it supports this outlook. If you take Testim out of the picture, revenues grew in excess of 75%. So that gives us a lot of confidence as we think about how we have modeled this in our transaction.

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

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

Operator

Your next question will come from the line of Randall Stanicky from RBC Capital.

Randall Stanicky - *RBC Capital Markets - Analyst*

Thanks. Rajiv, I have a bigger-picture question for you. As you think about putting the Endo asset base together, how are you thinking about organic growth? What level of organic growth are you targeting, and what year in terms of getting there?

And then the second, or the follow-up to that would be, you spent a lot of time over the last year or two talking about deals in the $250 million to $500 million range. Obviously Auxilium was bigger than that. Does that deal profile in terms of size still hold? Or are you looking potentially to step up the size of opportunity? Thanks.

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

Thanks, Randall. So in terms of organic growth, what we've talked about in the past is that prior to the Auxilium transaction, we are essentially looking at longer-term growth in the low to mid single-digits. Basically that's a combination of a branded business that's likely growing in the low single-digits, a generics business that's growing in the high single-digits, an international business growing in the double-digits and AMS, which is in the mid single-digits.

Now clearly what the Auxilium transaction is going to allow us to do, is to aspire to growing our branded business in the double-digits, ex Lidoderm, in the near term and certainly in the longer term. So our longer-term aspiration, as we do more transactions like Auxilium, is essentially to get to double-digit organic growth.

I think in terms of when that trajectory begins, and obviously it's a function of when we begin to see other generics of Lidoderm, which will essentially see the final bit of decline of Lidoderm. So it is good news-bad news that we've had Lidoderm this long.

We certainly continue to benefit from the cash flows we get from the business and we hope we'll continue for as long as we can. But certainly it makes it a little bit difficult to predict when the final dip from Lidoderm will be. So certainly as we look into 2016 and beyond, we would begin to think about that as the period where our organic growth aspirations will begin to materialize.

And in terms of deal size, we've always had a preference for the small- to mid-sized deals, which is in the $250 million to $500 million range. And we still like those kinds of deals.

We've also been clear that as we think about our business, that we're open to larger transactions if they're, in fact, transformational for us, which is what made Auxilium such a great fit. So as we look beyond Auxilium, certainly we continue to look at the small- to medium-sized transactions, but we are very open to the concept of doing larger transactions.

That being said, clearly our near-term priority is to get Auxilium closed and the company integrated. Because having a smooth transition here is very important to us.

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

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

Operator

Your next question will come from the line of Gregg Gilbert from Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks. Suky, I wanted you to flush out your comments a little more about those rebates you expect in 4Q. I assume that's rebates or penalties tied to raising price. Maybe you could talk about what sales base is affected there so that we can envision how much that sales base could go up going forward.

Then a more general generic question, for you, Rajiv. What would you like to do more of in the generic space, given the capabilities you have already? Thanks.

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

I'll have Suky start with the first part of your question.

Suky Upadhyay - *Endo International PLC - CFO*

Gregg, you're right, the additional rebates are reserves that we plan to take in the fourth quarter are related to shelf stock, inventory in our generics business, primarily in our controlled substances category. We're not specifically talking about what that level is or what the future benefit is, but we do believe it is a decision that ultimately will drive long-term shareholder value for us into 2015 and beyond. The one thing I would say around that is if you were to look at Q4 growth rates into, for generics, without this increase you would see a profile that is relatively similar to the underlying growth profile for Q3.

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

And in terms of your question about the future of generics, obviously we've been very pleased with the progress that we made with Qualitest in the controlled substance space, in our liquids, cough-cold space, as well as the diversity of all the products that we continue to support. That being said, I think what we'll always continue to look for are new platforms and new verticals for Qualitest.

Namely these would be areas where we would still be able to benefit from better competitive dynamics and better margin profiles. So areas like semi-solids, ophthalmics, and injectables continue to be areas of interest to us.

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

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

Operator

Your next question will come from the line of David Risinger from Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. So I just wanted to ask a couple more questions about pricing, please. First, could you discuss the competitive pricing environment for controlled substances, and whether that's changing currently? And then the second question is, with respect to the net pricing outlook for 2015, could you frame for us how we should think about total generics pricing next year? Thank you.

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

Thank you, David. In terms of pricing, obviously this is a sensitive area, so we don't talk too much about it, and I don't intend to discuss the specifics. But what I would say is that the controlled substance category is one that is regulated not only by FDA but also by the DEA. Both agencies have become more and more stringent in terms of their requirements.

We've also seen up-scheduling of the hydrocodones from Schedule III to Schedule II. All of these things make for a supply chain that is expensive to maintain.

And as we move the hydrocodones into category II, the complexity and the expense base around this business has also proportionally gone up. So I believe that what we have done with our pricing is responsible and in keeping with other market dynamics.

But what I would also say is looking forward, going back to the comments I made earlier, we are not relying on price increases for our strategic plan. If you look into 2015, obviously we have not given guidance yet. But if you think about the medium-term aspiration we put out there for the business, which is high single-digit growth, we expect the bulk of that to come from volume and mix as we launch our new ANDAs and not by net price.

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

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

Operator

Your next question will come from the line of David Amsellem from Piper Jaffray.

David Amsellem - *Piper Jaffray - Analyst*

Thanks, just a couple. On the testosterone franchise, can you give us a sense of how Fortesta fits in now that you'll be taking on Testim? Does it make sense to have two PDL products in the portfolio?

Then a question on OPANA ER. Your thoughts on competition, on the non-AB-rated generics. I believe Roxane and maybe one other player have approvals of their non-AB-rated products, but have yet to launch. Wanted to get your thoughts on potential for new entrants there. Thanks.

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

Sure. With respect to Fortesta and Testim, I think what I would remind you is that these are both products that are on the back end of their lifecycle, as evidenced by the fact that both Companies independently launched authorized generics of their own branded molecules. These are also different strengths of testosterone.

And also if you look at how Auxilium has chosen to commercialize the authorized generic, they used a partner to do that. So our expectation is that Fortesta AG is something that Qualitest will continue to commercialize.

Assuming we get the Auxilium transaction closed along the timeline that we expect, we would expect to continue the current commercial arrangements for that product. So as a result, we don't really see an issue with maintaining the commercial viability of both of those products.

With respect to OPANA ER, the situation is much as we have described in the past, which is that we continue to be encouraged by our market share retention. We are holding in excess of 60% of the molecule market share on the brand.

We have two active generics on the market, which are Impax and Actavis, but there's been no change in managed care formulary. As you outlined, Roxane has an approval for the brand of the product as well, but we have not seen a launch. We have not seen any other approvals, either.

So we continue to follow our strategy, which is we continue to assert our very robust patents in the courts. We continue to commercially support OPANA, which allows physicians to write OPANA ER in their prescriptions, which makes it very difficult for anyone to switch them.

And we continue our clinical trial program, which is to complete our insufflation study, as well as to collect the requisite epi-data to go back to the FDA in support of a possible label change. So the situation is no different than what we've discussed in the past, but we continue to be encouraged by it.

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

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

Operator

Your next question will come from the line of Chris Schott from JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Great, thanks very much. Just had a couple, here. Following up on the double-digit organic growth for Auxilium, is that a number you can achieve based on the existing portfolio? Or does that assume pipeline success in terms of new indications, et cetera?

And, again, similar question on the M&A hurdle rates for that deal. Is the base case assume the existing portfolio or, again, pipeline, is that just up side to the assumptions? I'm giving you that question, I was interested in terms of what you are baking in there.

The second question was on bus-dev and the focus on assets that are additive to organic growth. What is the appetite for further acquisitions in the generic space given on one end how strong your results have been this year? On the other hand, some of the longer-term growth visibility you get on the branded side, is generics still fitting in the M&A picture at this point? Thanks very much.

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

Thanks, Chris. So with respect to the Auxilium products, the simple answer to this is I think there is real potential in STENDRA and Xiaflex in Dupuytren's contracture and Peyronie's such that a double-digit growth profile should be maintained with the currently-launched and approved indications for these products. But we're also encouraged by the pipeline.

So certainly that should be additive to how we think about the longer-term viability of this platform. We're obviously not going to talk too much about exactly how we model this from an acquisition standpoint, but we tend to heavily risk-adjust pipeline assets when we do that. I'll leave it at that.

And maybe I'll ask Suky to talk about our hurdle rates and how we think about transactions. Then I'll come back and talk to you about generics and business development.

Suky Upadhyay - *Endo International PLC - CFO*

Sure, Rajiv, happy to do it. Beyond the strategic levers that we look for in any acquisition, there are pretty rigorous financial metrics that we look to. First of all, as we look to an IRR in the mid-teens. That's on the basis of cost of capital that's in the high single-digits.

Generally we look for pay-backs that are somewhere in the seven- to nine-year range. And of course we look for deals that are immediately or very near-term accretive, both on a cash as well as a GAAP basis. Ultimately that's an important metric because it ultimately expands our EBITDA base and provides us the opportunity to expand our M&A strategy.

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

And then to follow up on the question on generics. For us, clearly doing a meaningful transaction in the branded space was a priority, which is why Auxilium was such a good fit in terms of transaction value to us.

But once we look beyond Auxilium, clearly for us our US generics business has been a substantial growth driver. We think it's a very attractive asset and we intend to build upon it.

While I can't put a time frame on it, I think you will see continued M&A activity that supports the build-out of all three of our main pharmaceutical businesses, being generics, US branded, and international. Certainly, as we look from a comprehensive standpoint, we do expect a meaningful proportion of that to go towards branded products for the US. We certainly will see some M&A activity in generics as well.

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

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

Operator

Your next question will come from the line of Corey Davis from Canaccord.

Corey Davis - *Canaccord Genuity - Analyst*

Thanks. I would like to ask two, if I could. First, I'm not sure you are willing to do this, but if you are, give us some directional net profitability guidance for the AMS business.

So that in the event that you are able to sell it, we can gauge the dilution to EPS at some point when the sale occurs. But also not forgetting that you might be able to use the -- hopefully would be able to use the proceeds from that to buy something equally, if not more, accretive than what you would be losing in AMS.

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

Sure, Corey. We've historically answered this question, I have no issue answering it. Which is that we have EBIT margins in this business that's in the low 30%s or maybe their margin is a little bit higher than that. So it's a pretty good margin profile in the device space.

Corey Davis - *Canaccord Genuity - Analyst*

Okay. And then my second question would be, and you touched on this, but maybe elaborate a little bit more. What, if anything, do you think you can do better than Auxilium in terms of driving the growth of Xiaflex? Can you give us some sense of timing for the new indications in frozen shoulder and cellulite?

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

Sure. On the timing of any potential new indication, I'm not going to speculate on that because -- and obviously we are still two separate Companies. And we need to understand the deal as the time plans some more before we can have our own point of view on it.

But certainly as you know, in cellulite the Company completed the Phase II trials and are awaiting the start of the Phase III. In frozen shoulder, there is a Phase II trial that needs to be out sometime in early 2015, in terms of milestones we need to see before we can have a final deal open profile in mind.

And in terms of your first part of your question, so I think this is a case where the collective efforts of our two Companies together is going to be substantially more than what Auxilium could have done by themselves. And a couple of examples. I think when it comes to the urology arena, the combined Company will have several products that are in growth mode.

In particular you have STENDRA, you have AVEED, and you have Xiaflex in Peyronie's. Having a broader sales force to be able to commercialize those is only going to help. These are areas where obviously Endo knows the customer base extraordinarily well.

When it comes to Dupuytren's contracture, it's an area where we've had a long heritage of calling on orthopedists, hand surgeons, and others who are very important prescribers for Xiaflex in Dupuytren's as part of our own pain efforts in the past, as well as currently. We also call on a broader set of prescribing physicians who are an important referral basis for Xiaflex as well, namely the specialties like rheumatologists.

Again, the combined Company ought to have resources that are broadly helpful. And in addition, we do have a heritage in buy and build, with products like SUPPRELIN. And certainly with the launch of AVEED, we've had to build up that capability even more in terms of the ability to service physicians' offices, reimbursement support, et cetera, which, again, is something that is very important to Xiaflex.

So I think this is, from all the examples, you can usually take away that there are multiple areas we think that we can collectively do better. Finally, from an R&D standpoint, in the context of a larger Company and a larger revenue base, we're going to be able to apply the resources that are required to maximize the value of the Xiaflex platform.

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

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

Operator

Your next question will come from the line of Jason Gerberry from Leerink Partners.

Jason Gerberry - *Leerink Swann - Analyst*

Thanks for taking the question. A couple on BEMA Buprenorphine, wondering with the potential rescheduling of the hydrocodone products, if you can comment on, your partner has at least commented that they see upside of their peak sales. Potential for this product. I'm curious if you guys have any updated thoughts there.

If you can frame maybe 2015 Lidoderm scenarios for us. I know you have a couple of settlements for a few companies that come in the first quarter 2015, although I don't see any tentative approvals yet. I'm curious if any of those settlements include AG provisions or if we don't see any approvals there, there could be potential up side of the 2015 numbers. Thanks.

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

On the BEMA question, we have not talked about peak sales potential, although our partner may have. But what I would say is that we continue to be optimistic about the product. We are getting prepared to file our NDA, which we're hopeful we can file before the end of the year or early in 2015.

Certainly our expectation is that this will be a Schedule III product when it is launched. Obviously this decision is not final, it is in the hands of the DEA and will only be finalized when the product is approved.

But certainly that's the case with the rescheduling of the hydrocodones. BEMA Buprenorphine will enjoy a pretty unique position in the spectrum of pain therapeutics, which would give it meaningful potential.

And going beyond that, it is certainly a new innovation in terms of treatment for moderate to severe pain. And so between the innovative nature of the product and the potential Schedule III classification of it, we are optimistic about the outlook for it.

I'm sorry, your Lidoderm question. With Lidoderm, there are, to our knowledge, three other filers. We've certainly talked about the potential for the next approval to be that from Mylan, and our expectation is we will see that sometime over the course of the next few months.

There are two other filers, TWi and Noven, who could file sometime in the first quarter of 2015. But to answer your specific question, there's no authorized generics partnerships included in those settlements. So if they do not have approvals, we would not expect to see them on the market.

Jason Gerberry - *Leerink Swann - Analyst*

Okay, thank you.

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

Can we go ahead and take the next question, please?

Operator

The next question will come from the line of Michael Faerm for Wells Fargo.

Michael Faerm - *Wells Fargo Securities - Analyst*

My question is about the generics business. Could you provide any color on the contribution of any of the new pieces that came into the business this year? Specifically DAVA, Boca and the Lidoderm authorized generic? And secondly, if you could provide any, even high-level, color on your views about the longer-term growth profile of DAVA, that would be helpful. Thank you.

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

Sure. Many of the new elements that have come into Qualitest are the ones that actually -- they're doing quite well, and we're quite pleased. So if you take the Lidoderm authorized generic, between the authorized generic and the brand, we continue to hold about 50% market share of the molecule, which we are very happy about.

And our authorized generic, if you take purely the generic portion of it, we have a 40% share of the generic market for lidocaine patches. So we are very pleased with how our Qualitest team has done with that.

If you would think about our Fortesta launch, the early results of that, we are beginning to convert share from molecules beyond the Fortesta brand, which is also an encouraging fact. I talked earlier in the call about the market share that we have on the hydrocodone-APAP 300 milligram combination, which is the product that we got from the acquisition of Boca. That's obviously a very important contributor for this year.

I would say that DAVA is off to a reasonable start. It's obviously too early to tell, we just completed that transaction. But we are holding reasonable share on methotrexate, which we've said is likely to decline over time.

Our early success in terms of performance on Doxycycline is also encouraging. Again, too early to tell. But I think all of these things are pointing in the right direction.

From a longer-term standpoint for DAVA, and I would go back to the comment I made on the last call, which is that this is a product that obviously brings us meaningful near-term accretion. Obviously historically the Company has been very dependent on methotrexate.

We do expect the methotrexate brand to decline over time, but we believe that there's a strong portfolio of other brands. I have talked about Doxycycline. Doxazosin is the other product that we got from DAVA. And this ANDA portfolio of about a dozen or so ANDAs that we got from that acquisition.

Over time we expect the business to essentially convert from methotrexate into these new brands. If we take a longer-term standpoint, we take a five-year view of this, we expect this to be a single-digit growing asset. Obviously there'll be some lumpiness year to year, depending on when we see the decline of methotrexate, but from a longer term standpoint we do expect to benefit from the ANDA pipeline that we got from this acquisition.

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

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

Operator

Your next question will come from the line of Annabel Samimy from Stifel.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Back to the generics business, it's obviously been growing at a pretty nice clip, in the low double-digits. Next quarter, we understand, there's going to be some pricing.

A little bit surprised about the high single-digit long-term guidance for the business, given the 70 ANDAs, the good growth from DAVA, and overall the strong margins of the business. So can you talk about what your biggest concerns are in the generic business that would keep the growth under its average growth that it's been? Thanks.

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

Annabel, the first point I would make is I think you probably know by now that we are prudent forecasters. We don't like to get ourselves too excited and we don't like to get others overly excited about things either.

But you are right, this is a business that has grown double-digits for the past five years. If you look at generic companies of this size and of this volume, we're one of the very few that have shown that kind of growth trajectory. Certainly there's a real chance that we can continue to do that.

But obviously we will now, going into next year, be at least a $1.1 billion, roughly, plus or minus, generic business. And then as we keep growing bigger, double-digit growth becomes more and more meaningful in terms of the absolute magnitude, the new sales you're adding, which is why we are being more cautious as we talk about the growth rate. But there really is nothing about the business that concerns us, and we are very encouraged by all the elements that we see.

And the one other comment I would make is certainly from a very near-term standpoint, keep in mind that at some point we will have competition for the hydrocodone-APAP 300 milligram combination. And we will also likely have other Lidoderm patches. As we analyze those effects going in, you can take that into account as well, when we think about growth in the business in the medium to longer term.

Annabel Samimy - *Stifel Nicolaus - Analyst*

Okay. And on the margins, the longer term margins for the business, do you expect stability around the 40% range?

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

Suky, do you want to answer that?

Annabel Samimy - *Stifel Nicolaus - Analyst*

For generics.

Suky Upadhyay - *Endo International PLC - CFO*

Yes, so as I said, this year we expect to be in the mid 40%s. And on our long-term aspirational average, we expect to be in the high 40%s, Annabel.

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

Great, thanks. In the interest of time, we will go ahead and take two more questions. So can we go to the next question, please?

Operator

Your next question will come from the line of Tim Lugo from William Blair.

Tim Lugo - *William Blair & Company - Analyst*

Thanks for taking my question. Maybe digging a bit more into the generics segment and hydrocodone-APAP. With the schedule move less than a month into it, have you seen any impact to the hydrocodone-APAP market? And how do you forecast that over the next year? Are you expecting eventually to see volume declines and maybe some price opportunity?

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

In terms of the rescheduling, I think it has gone relatively smoothly from what we can tell. We had expected some lumpiness going from third quarter to fourth quarter. Other than the rebates we talked about, there is really no lumpiness. I think it has been handled pretty well.

Certainly our expectation is that one of the reasons why these products are being up-scheduled is to maintain control over volume. So our expectation is that volumes in these categories will likely moderate and go down over time.

But at the same time, we believe that they will continue to be economically attractive, which is reflective of some of the price adjustments that we have made. Which is, again, in keeping how other major market participants have viewed this.

But as I said before we're not really projecting ongoing major price increases in these categories. Obviously if there are other market discontinuities that allow us to do that, we'll be opportunistic, but that is certainly not part of our strategic plan.

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

Great, thanks, Tim. Could we go ahead and go to the last question, please?

Operator

The last question will come from the line of Swati Kumar from Guggenheim.

Swati Kumar - *Guggenheim Securities - Analyst*

Most of my questions have been answered, but I wanted to ask a big-picture question. We like the Auxilium deal and the base business is clearly strong. What do you think some investors are missing?

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

We like the Auxilium transaction, too. I think you know, for the reasons that I outlined a bit earlier, we are in a position now to have an aspiration for our organic growth to go from the mid single-digits to double-digits for the Company.

We have the possibility to add a couple of real growth drivers, STENDRA and Xiaflex, to our portfolio. And in Xiaflex we see a longer-term platform. All of those things are additives to our Company.

We have talked about the underlying robustness of our US generics business and how, with our Endo portfolio, that could certainly be a meaningful contributor for the foreseeable future. We are beginning to see the resurgence in the AMS business and earlier signs of our international business are also great.

So I think it's all pointing in the right direction, and obviously there's not a lot of visibility that we can or will provide around our generics business and the pipeline. That's perhaps frustrating for some, but we are very encouraged by the growth that we are seeing.

So if we take a step back, and look at what we've been able to achieve, even looking at our third-quarter results, we are seeing growth, we are seeing margin expansion in all of our businesses. And in another quarter, very strong operating cash flows. So all of these things are positives, and we are very encouraged and look forward to 2015 and beyond.

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

Great, thanks. With that, we will wrap up the call for today. I just want to thank everybody for joining us. As people have follow-up questions, please feel free to contact myself or Jonathan Neely and the Investor Relations Group. Thanks so much for the time. Take care.

Operator

Ladies and gentlemen, that will conclude today's conference. Thank you for your participation. You may now disconnect. Have a great day.
