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ENDP - Q2 2018 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 2Q18 total enterprise revenue of approx. $715m, GAAP operating income of $55m and GAAP diluted loss per share from continuing operations of $0.23. Expects 2018 revenues to be $2.75-2.85b and adjusted EPS from continuing operations to be $2.50-2.60.

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Nina Goworek

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International Second Quarter 2018 Financial Results Conference Call. (Operator Instructions)

As a reminder, this conference call may be recorded. I would now like to turn the conference over to Nina Goworek, Senior Director, Investor Relations. Please go ahead.

Nina Goworek

Thank you, George. Good morning, and thank you for joining us to discuss our second quarter 2018 financial results. Joining me on today's call are Paul Campanelli, President and CEO of Endo; and Blaise Coleman, Executive Vice President and CFO.

We have prepared a slide presentation to accompany today's webcast and that presentation as well as other materials are posted online in the Investors section at endo.com.

I would like to remind you that any forward-looking statements made by the management are covered under the U.S. Private Securities Litigation Reform Act of 1995 and the applicable Canadian securities laws, and are subject to the changes, risks and uncertainties described in today's press release and in our U.S. and Canadian securities filings.

In addition, during the course of this call, we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used by other companies. Investors

are encouraged to review Endo's current report on Form 8-K furnished with the SEC today for Endo's reasons for including those non-GAAP financial measures in today's 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, unless otherwise noted therein. I would now like to turn the call over to Paul.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Thank you, Nina. Good morning, and thank you for joining us for today's call. I hope you've had a chance to review the company's earnings release issued earlier this morning.

Let's turn our attention to the second quarter 2018 earnings presentation. Beginning on Slide 2. Here's a brief agenda for today's call.

Moving to Slide 3. Endo is extremely pleased to report another strong quarter of adjusted operating results. Revenues for XIAFLEX and our Sterile Injectables segment continued their double-digit growth momentum. Our second quarter performance also reflects adjusted gross margin expansion, driven primarily by favorable product mix as we continue to focus our efforts on driving growth in higher margin areas of our business. In addition, we continue to deliver increased efficiencies across our business, contributing to both our adjusted gross margin and adjusted EBITDA margin expansion in the second quarter of 2018. Based on these results, we are very happy to report that we are raising our full year revenue, adjusted EBITDA and adjusted diluted EPS financial guidance. Blaise will walk you through our updated financial guidance in greater detail later in our presentation.

Moving to Slide 4. You'll see a snapshot of our segment revenues for the second quarter. From a total enterprise perspective, the quarter's performance versus the same period last year was primarily attributable to the loss of exclusivity of ezetimibe, the annualization of 2017 competitive entries, product discontinuations in the U.S. Generic Pharmaceuticals segment, the divestitures of Litha and Somar, and our voluntary market withdrawal of OPANA ER. These factors were partly offset by continued strong growth in our U.S. Branded Sterile Injectables segment, as well as our continued growth in a specialty products portfolio of over U.S. Branded Specialty and Established Pharmaceuticals segment. That said, on sequential basis, total enterprise revenues increased 2% from $701 million in the first quarter of this year to approximately $715 million in the second quarter of this year.

Now moving to Slide 5. Our Branded Specialty portfolio continued to advance with growth of 9% year-over-year. This was largely driven by the significant growth of our XIAFLEX franchise, which grew 27% in the second quarter versus the second quarter of 2017. Sequentially, XIAFLEX also grew at a double-digit rate of 11% versus the first quarter of 2018. SUPPRELIN LA's second quarter sales were especially flat with first quarter of 2018. However, second quarter sales represented a decline versus prior year. This change is reflective of the second quarter 2017 SUPPRELIN LA sales, representing the highest quarter of sales ever partly driven by a favorable reserve true-up.

In addition, we have seen increased competition for new patient starts. We intend to increase our commercial initiatives through the year to support SUPPRELIN LA's highly differentiated product profile, with a long history of providing significant benefits to patients.

Branded Established Products were mainly impacted by the voluntary market withdrawal of OPANA ER, the discontinuation of SUMAVEL DosePro in this first quarter of 2018 engineered competition. That said, I'm extremely proud of what our branded commercial team has been able to achieve.

Our key product franchise, the XIAFLEX, grew an outstanding 27% year-over-year, fueled mainly by strong demand growth driven by our flawless execution and continued investment in our integrated commercial strategy. Based on robust June year-to-date XIAFLEX revenue growth, we now expect XIAFLEX full year revenue growth to be in the high teens percentage range versus our previous guidance of low to mid-teens growth.

Moving on to our CCH cellulite treatment development program. We were pleased with the recruitment of our 2 pivotal Phase III trials. Recruitment accelerated faster than expected, and we currently plan to share top line results from these trials in the fourth quarter of this year. This is a great accomplishment by our clinical development team and I couldn't be more proud.

Our presence at recent and future aesthetic conferences provide a platform for us to credential the company in aesthetics and to showcase the encore Phase IIb data to key plastic surgeons and cosmetic dermatologists. In April, the encore Phase II data was presented to our hot topics, at the American Society for Aesthetic Plastic Surgery Annual Meeting. In June, the data was presented again at the Vegas Cosmetic Surgery Symposium, a premier aesthetic multispecialty meeting.

We look forward to communicating our Phase III top line results to you in the fourth quarter, while continuing our prelaunch efforts.

Turning to Slide 6. Our U.S. Branded-Sterile Injectables segment continues to deliver with sales growth of 21% in the second quarter of 2018 versus the second quarter of 2017. This growth was largely driven by ADRENALIN, with sales of $37 million in the quarter, a 93% increase versus the same period in 2017, as unapproved sources began to vacate the market in May 2017.

Adding to the strong growth was VASOSTRICT and other product. VASOSTRICT grew 11% year-over-year with quarterly sales of $106 million. While other Sterile Injectables grew 14% year-over-year, mainly driven by ephedrine sulfate in addition to glycoperelate, for which we are Somerset Therapeutics' exclusive distributor.

Adding to our portfolio, in late July, we launched ertapenem for injection, the authorized generic of Merck's INVANZ, which had IQVIA brand sales of approximately $390 million for the 12 months ending May 31, 2018.

Based on our strong year-to-date results and the launch of our ertapenem for injection, we now project full year U.S. Branded Sterile Injectables revenues to grow in the high teens percentage range. The continued strong performance of our Sterile Injectables business further validates our strategic decision to increase investments in this segment.

Further on Sterile Injectables. In the second quarter of 2018, Endo entered into an exclusive licensing agreement with Nevakar for the development of 5 differentiated 505(b)2 sterile injectable products in the U.S. and Canada. Nevakar will develop and bring these products through the regulatory process to seek FDA approval, and our U.S. brand of Sterile Injectables business intends to launch and commercialize these products upon approval.

We're also very excited to further enhance our Sterile Injectables portfolio with products that will benefit patients by providing new treatments in the hospital and the critical care environment. We expect that this deal, in addition to the previously announced Somerset Therapeutics acquisition will further bolster our U.S. Branded Sterile Injectables portfolio for today and in the future.

Speaking of Somerset Therapeutics, the acquisition remains on track to close by the end of 2018. We continue to be enthusiastic about the acquisition and we look forward to integrating Somerset and Wintac into the company. We've been very pleased with their continued regulatory execution. Since we announced the acquisition in April, Somerset has been able to attain 6 additional FDA approvals, demonstrating the near-to-medium term opportunities we previously discussed.

Now turning to our U.S. Generic Pharmaceuticals on Slide 7. The performance for the segment during the second quarter versus the same period in the prior year reflects the loss of exclusivity of ezetimibe, the annualization of 2017 competitive entries as well as previously announced product discontinuation, including the authorized generic of metoprolol.

First half performance was better than expected, primarily due to the shared first-to-market launch of memantine ER capsules as well as delayed competition on certain products, in which we enjoy limited or no competition.

More recently, on July 1, we were excited to launch colchicine tablets, the Authorized Generic of COLCRYS, which was the result of Paragraph IV settlement agreement. The launch is off to a great start. Now with regard to overall generic retail market conditions, we continue to be encouraged that the downward pressures we've experienced over the past few years appear to be stabilizing.

We've seen promising early signals and remain cautiously optimistic. We're excited about our pipeline, our product selection process and the progress we've made to date to reshape our portfolio for the future.

On Slide 8. Let's briefly discuss International Pharmaceuticals. As expected, our international performance reflects the divestiture of Litha and Somar in the second half of 2017. Second quarter international results include approximately $10 million of ex-U.S. XIAFLEX sales, which were originally expected in the third quarter. Paladin grew 6% year-over-year, which is better-than-expected due to better performance of our promoted business, particularly Monurol and XIAFLEX as well as delayed competition on certain products. We continue to be pleased with how we are building our product portfolio in Canada and our related business development activities. We have 2 Sterile Injectable product filings pending approval with Health Canada. In addition to the in-licensing of Envarsus XR, we recently announced a definitive agreement with Bioprojet to register, commercialize and distribute Pitolisant on the exclusive basis in Canada. This product complements Paladin's promoted specialty portfolio, and we expect, will provide us with additional growth pillars.

Turning to Slide 9. I've already touched on most of the scorecard numbers during our segment performance update.

To add to the U.S. Branded Sterile Injectables in U.S. Generic Pharmaceuticals segments collectively launch 6 new products today.

Once again, you'll see some of our key first-to-file, first-to-market opportunities for the second half of 2019 and beyond. We are proud of the many achievements to date and the steadfast focus of our employees to execute on all levels. Our industry is in the midst of some truly fundamental changes. The health care environment in Endo will undoubtedly look very different, several years from now, and we will execute on our strategy. I'm also so grateful to all of Endo's employees for the commitment and hard work.

Now let me turn the call over to Blaise to further discuss the company's second quarter financial performance. Blaise?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Thank you, Paul, and good morning, everyone. First on Slide 10, you will see a snapshot of the second quarter GAAP and non-GAAP financial results. Paul covered company's segment revenues earlier, so I will not review that again.

On a GAAP basis, we had a diluted loss per share of $0.23 from continuing operations in the quarter versus a loss of $3.12 in the second quarter of 2017. GAAP operating income in second quarter 2018 was $55 million compared to GAAP operating loss of $587 million during the same period in 2017. This was primarily due to lower pretax noncash asset impairment charges. On an adjusted basis, second quarter results were stronger. Adjusted operating income of $322 million and adjusted diluted earnings per share from continuing operations of $0.76 exceeded our expectations for the quarter and reflects significantly improved gross margin versus prior year. The approximate 1000 basis point improvement in adjusted gross margin in second quarter 2018 versus the same period last year, was primarily due to favorable business mix, driven by revenue growth in Sterile Injectables and Branded Specialty Products, and benefits from our ongoing cost efficiency initiatives.

In addition, our adjusted gross margin reflects an approximately $8 million benefit, related to our contract termination.

Turning to Slide 11. Based on our better-than-expected first half 2018 performance, driven by both higher revenue and adjusted gross margin, we are raising full year financial guidance. We are raising our revenue expectation from our initial guidance of $2.6 billion to $2.8 billion, and now expect 2018 revenues to be $2.75 billion to $2.85 billion. We're also raising our adjusted EBITDA and adjusted earnings per share from continuing operations guidance, and now expect them to be $1.27 billion to $1.33 billion and $2.50 to $2.60 respectively.

Please note that we're also updating our adjusted gross margin and adjusted operating expense assumptions. We now anticipate our second half 2018 adjusted operating expenses to be at a similar level to first half 2018. This higher-than-previously-planned full year 2018 spend reflects our previously stated capital allocation priorities to fully invest in our core areas of growth.

In this context, the majority of the higher spend will be in both selling and marketing and R&D initiatives. The selling and marketing increase reflects continued strong investments in XIAFLEX to further fuel our growth momentum. In terms of R&D investment, we'll be funding a number of additional promising development projects across of our portfolio, to further enhance our go-forward pipeline.

In addition to investments in selling and marketing and R&D initiatives, we are also anticipating higher-than-previously-expected legal spend driven by ongoing litigation matters. In terms of second half 2018 adjusted P&L phasing, assuming the midpoint of our updated financial guidance range, we expect third and fourth quarter revenue and adjusted EBITDA to be fairly balanced.

Lastly, in terms of projected cash flow on Slide 12. We had $129 million in cash flow prior to debt payment in the first half of 2018, and now expect use of cash, prior to debt payment, for full year 2018 to be in the range of approximately $265 million to $205 million. The change primarily reflects higher adjusted EBITDA, favorable source of cash from changes in working capital and a shift of non-mesh legal payments to 2019.

We ended the first half of 2018 with approximately $1.1 billion of unrestricted cash, and at second quarter-end, our net debt to adjusted EBITDA leverage ratio was approximately 5.2x. Now let me turn it back over to Paul. Paul?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Thank you, Blaise. I continue to be extremely proud of our team and what we have achieved to date. The results of our actions over the last couple of years validate our believe that we have the right people in place that are helping turn Endo around.

Despite circumstances that could have easily distracted us, we had remain focused on our actions, we can control, and we will continue to do so. We are very excited and await the results of our Phase III trials for cellulite over the coming months.

In closing, I would like to thank Steve Mock, my friend and Endo's former Senior Vice President of Investor Relations and Corporate Affairs for his leadership, expertise and commitment to the organization. Since his retirement, we've been searching for the right candidate to lead these functions.

That said, I am pleased to announce the appointment of Laure Park into this role. Laure brings with her a significant business and strategic experience along with an outstanding leadership and communication style that will be great benefit for Endo and lead us us into the future. Nina Goworek will continue with the main point of contact for investors, while Heather Zoumas Lubeski will continue to be the main point of contact for our media coverage. I would like to thank Nina and Heather for their continuous contributions and professionalism during this interim period.

Now let me turn the call back over to Nina, to manage our question-and-answer period. Nina?

Nina Goworek

Thank you, Paul. (Operator Instructions)

QUESTIONS AND ANSWERS

Operator

And our first question comes from the line of Liav Abraham from Citi.

Liav Abraham - *Citigroup Inc, Research Division - Director*

Just a couple of questions. Paul, firstly on XIAFLEX, can you go into little bit more detail on some of the drivers behind the strength? I know you've updated your guidance for the full year on this product. To what -- what's behind this? What returns are you seeing from the DTC campaign or anything else that you've seen that's affecting the positive growth of this product? And then secondly, I know you're not giving 2019 guidance, but any comments you can make on the potential for EBITDA growth in 2019 versus 2018, given some of the positive dynamics you see in the business, XIAFLEX, the injectable franchise, the contribution of Somerset, could we see growth -- EBITDA growth in 2019 versus 2018? Any thoughts would be helpful?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes, thank you, Liav. I appreciate the question. I'll start with the EBITDA. So I think it's still early in the process, so we're going to have to ask you and folks to be patient in that regard. There is still a degree of uncertainties in the Generic environment, while we feel good about a recent cautiously optimistic statement that we're talking about. There is -- there's still a degree of products that we need to watch very carefully. So it's going to be early on the EBITDA side. So for XIAFLEX, I think what we've talked about is how we've invested in a consumer activation program. We've put a lot of resources behind that and I think we've talked about how we've narrowed the focus, dating back about 18 months into our Specialty business and that's one of the main reasons we had, we had moved away from the pain segment. So I think being highly focused, focusing on consumer activation and then we want to continue, frankly, to put resources into this area and I think it still remains an area for some modest growth. And keeping in mind that this product for the indication or for Dupuytren's has been in market for probably about 8 years now, and maybe Peyronie's is just a little bit later than that. But maybe like in some specific areas, when we look at Peyronie's disease and we see the PD is up around 26% year-over-year. I think what excites us is when you talk a little bit about that particular indication, we like to always mention that. About 55% of all the Peyronie's patients that receive XIAFLEX, you've got to go back and look at Peyronie's specifically, 2% of those patients are diagnosed and 2% are treated. So I think at the end of the day, we feel pretty good about sort of statistics about being able to grow in Peyronie's. XIAFLEX captures an essence, 55% of those patients treated. So that's an area that I think will remain an area of focus. And similarly, in Dupuytren's, while it was up 6% year-over-year, we also see where we want to continue to invest in Dupuytren's and we think that's going to be a growth area and ultimately, XIAFLEX captures around 26% of treated patient. So these are still small percentages that we think we can grow, and we're going to continue to invest in our consumer activation program.

Operator

And our next question comes on the line of Ami Fadia from Leerink.

Ami Fadia - *Leerink Partners LLC, Research Division - Director of Specialty Pharmaceuticals & Generics and Senior Analyst of Specialty Pharmaceuticals*

Could you talk a little bit about the in-licensing transaction that Nevakar announced this morning? How does that evolve your thinking with respect to potential new product launches into '19 and '20? And separately, just on ADRENALIN, what's driving growth there, if you could elaborate on some of the drivers? And thirdly, just -- what's your latest thinking with respect to pricing and market potential for the cellulite indication?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure, okay. So we'll start with Nevakar. We always like to start out with our focus -- and so we have to be laser focused on debt paydown, so there was a modest investment in this development deal. I would call it more of a near-term type of opportunity. And I would say, it's probably a -- we are hoping that we would see some benefit in late 2020. I think what's special about this particular opportunity, as we mention it, it's 5 products, it's -- there is specifically -- in 505(b)(2) area, that's an area that we like. But we've got to go back to the company itself, and Nevakar and the people that run that company and we've got a past relationship with the Nevakar team -- that it was formerly known as InnoPharma, and the CEO is Navneet Puri. Ultimately, we've had a lot of success with this particularly team, back when we acquired our Rochester facility. And some of the products that we're very proud of that they brought us, included dexmedetomidine and ethacrynic acid, just to name a few. So we're kind of going back to people that we've had successful history on. We want to bring differentiated products into the critical-care's arena and it's always nice to really be focused on known entities.

Getting into the ADRENALIN question, I think really -- in our prepared remarks, specifically, the growth of ADRENALIN is really coming because of the benefit of having the unapproved sources off of the markets in 2017. So we feel good about our share, but I think you're getting the benefit, ultimately, of the unapproved sources of the market for a full year. And then, help me out on the pricing question again, if you could remind me on XIAFLEX...

Blaise Coleman - *Endo International plc - Executive VP & CFO*

CCH.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

CCH?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes.

Ami Fadia - *Leerink Partners LLC, Research Division - Director of Specialty Pharmaceuticals & Generics and Senior Analyst of Specialty Pharmaceuticals*

Yes, CCH's pricing strategy.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes, so I think right now -- I mean, I think what we're not doing is giving specific pricing. I think it's obviously very early in the process. What we're doing is, obviously, evaluating different use on how we will go about it. And frankly, it's something that we would not be disclosing until very close to our launch, but what we can do is talk about the market in itself. And what we would like to remind people that the category of cellulite does affect around 85% to 90% postpubertal women, and I think that's a -- obviously, a large population that we're starting with. Then we also like to remind everybody that the U.S. aesthetic market is about $15 billion market and it continues to grow, but specifically in an injectable aesthetic, that market's around $3.5 billion and it's growing at a rate of around 7%. So I think those are some of the facts. I think it's also probably important talk a little bit about the excitement that we're getting from the key opinion leaders, and frankly, these key opinion leaders are really looking for innovation in bringing something new into this space. So there's been a lot of excitement, specifically with physicians that we're meeting with. And then probably lastly, the last point that we like to put on the table as we credential ourselves as an aesthetics company, we're going out and we're making ourselves known at conferences that -- specifically at ASDF, which is the American Society for Dermatologic Surgery, they actually released the [survey] recently on body contouring. Body contouring is an area in which cellulite is going to be classified. That's up 300% over 5 years. So while we're not getting specific at the pricing and we're not going to, but we can say is that we're incredibly excited about the market, the market potential and the key opinion leaders are very excited about what we're doing.

Operator

And our next question comes from the line of Greg Gilbert from Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Couple for Blaise. First, can you talk a little bit about how gross margin can bounce around in the back half? I know you have an influx of some AGs, but talk about how gross margin could bump around if you work on VASOSTRICT. Can we look at the second quarter level a sort of a pure demand-based level, such that we can apply the price increase to that to get sort of the ongoing run rate of that product? And lastly for Paul, back to Nevakar, can you help us better understand the types of products other than calling them 505(b)2's, we know they're injectable -- or we think they're injectables and they're B 2's, but how differentiated are they? Will then be detailed to docs, are they just clever tweaks? Increasingly competitive and an intensive care environment. So it begs the question on how differentiated these things need to be to justify the deal?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure, great. I'll take that first one.

Blaise Coleman - *Endo International plc - Executive VP & CFO*

And Greg, could you repeat your second question, we missed that. Sorry, the middle question there?

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Yes, on VASOSTRICT. So second quarter sales level demands such that we can apply the price increases?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes, and so we start with that one. What we saw was -- if you remember, we anticipated seeing a step down in Q2 sales, which we did. But the level of buying was sort of equal to demand, so that's a good assumption as you move forward. Just in terms of you thinking about the second half, and you think about gross margin, you just need to start with the top line, which is where we do anticipate and have factored into our guidance some additional competition on some of our key generic products that currently have either no or limited competition. And so as that starts to play out and also as you mentioned, some of the revenue that we're going to see in the second half that's helping with the increasing guidance is related to the authorized generics, which naturally have a much lower margin than the rest of our portfolio. So as you look at the full year guidance and sort of apply second half, you will see a step down in gross margin, mainly due to the mix of what's happening from a revenue standpoint.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

And then on the Nevakar question, Greg, I think it's -- the starting point is, we are going to distribute that portfolio from Nevakar with our existing branded Sterile team. So it's with the resources that we already have in place. Then with respect to like that we speak to it as being differentiated, it's really -- it's in the critical care's section of the hospital, ultimately, if there's a presentation that is not available and there could be either a preservative issue or a stability issue or a different type of presentation, that's pretty much of what we're talking about here. There is a need for it, and it's an area that we really want to expand in terms of our own internal development capabilities.

Operator

And our next question comes from the line of Randall Stanick (sic) [Randall Stanicky] from RBC Capital Markets.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

Paul, you've now referenced cautious optimism in the last several quarters and clearly, the results you're putting up are better and certainly better than some of your peers, particularly this morning. What do you specifically need to see to move off of cautious optimism, and get a little bit more comfortable that we're at the bottom or even improving? And then the adjunct to that is, are we yet seeing specific instances amongst the consortium buyers, where we're seeing scrambling for supply, given some of the pruning? Or do we still need to see the industry continue to contract or prune further?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes, thanks, Randall. It's a great question in terms of the use of the word cautiously optimistic. I mean we're halfway through the year, right? So I'd like to state I'm -- I still got it -- I still got halfway to go. So not to avoid the question, I think what's happened here is, I mean, I'll speak specifically for Par, right? And we made some tough decisions, more than 18 months ago and I think those decisions are showing some durability with the

existing Par portfolio. So while maybe some of my competitors are having some struggles but I think perhaps we were first movers when it came down to the portfolio. In essence, yes, I made the statement that there is really not much more that we're able to provide to the consortiums given where pricing levels went. And I think that's where we are. So let us see where the second half of 2018 lead us to, but I think we really took all the measures in place to make that portfolio as durable as possible. And then maybe Randall, maybe you can just remind me of the second question you had?

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

Yes, I mean, just very simply, one of the, I think, rebound points is when the industry has pruned enough product that we're down to enough competitors that we're seeing the consortiums think twice about price negotiations and look for security and supply. And so the question is, has the industry overall pruned enough? And have we shrunk enough to the point where we're looking at more stability and pricing power?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes, so it's another great question. I'm not sure that we're exactly there, when you look at it from an industry standpoint. So I think there's a little -- I think there is a ways to go. I think the way we are looking at it -- so you have these 3 consortiums and they all represent about 1/3 of the market. You have almost equal sharing, you have basically price parity. The issues that you're going to see coming out of this on a go-forward basis is probably the obvious. Where companies that are making tough decisions on prox because of price, then you have -- you got this dynamic of capacity and if you lose that, an account, you're not losing just a customer, you're losing a 1/3 of the volume. These are decisions that generic manufacturers have to be thinking about. That's what we were doing back a year ago, and you see the joining of the consortium. So -- you've got this pricing dynamic, but the fact of the matter is, you've got to be a willing to walk away from a customer. When you're doing that, you're making a statement on capacity, you're not turning a button and switching it back on. You, in essence, at least in Par's lens, are willing to walk away an not come back on certain types of products. That's where we are. I think that's where some of our competitors are heading right now.

Operator

And our next question comes from the line of Dana Flanders from Goldman Sachs.

Dana Carver Flanders - *Goldman Sachs Group Inc., Research Division - Research Analyst*

My first is, can you just touch on the outlook for ADRENALIN into the second half in 2019? I think you had a competitor on the 1 ml, I'm just curious if guidance reflects competition on the 30 ml or if you think that's a possibility? And then my second, just quick follow-up is, CCH obviously would benefit from being one of the first -- or the first noninvasive injectable product on the market for cellulite. How do you think about just the need to build market awareness and education and what steps are you taking on that front? I know we're still a ways out from launch, but just curious how you're thinking about that?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

So, great. Thank you. Starting with maybe the CCH question on market awareness. I think one starting point is that we brought talent into the organization, right? So we're planning for success. We've got Pat Barry leading us in the Branded Specialty division, we've recruited talent to help guide us on the marketing site. We're incredibly excited about that prospect. It's something that we've invested a lot of time in, so we've got people in place and bringing more people in place. And then it goes back to a little bit what I was talking about in getting ourselves credentialed out there. And clearly, there is a need for innovation. So we're out at the conference, we've got our name out there, awareness is going on and that's really the starting point. It's going to be an evolution as we await for the top line results in November and heading towards submission, but I think from a marketing standpoint, we're putting all the systems and procedures in place that you would expect us to be doing from an awareness standpoint. On ADRENALIN, we're not going to provide any specific guidance on 2019. What I can tell you is where we are today and then you can take that and view it how you would do a normal course. While there has been an approval on the 1 ml, there has not been a launch on the 1 ml. The company

that has the approval has an ampule. There is already an ampule on the 1 ml in the market. So there's a company called Belcher, they have an ampule. There is another pending, which has not launched and keeping in mind, there is an Orange Book patent on the 1 ml. So I think there's more to come in that regard. From market standpoint, I would tell you that the 1 ml represents about 20% of our market, keeping in mind that we have a more desirable vial in place. So I think that's where we are on the 1 ml. Regarding the 30 ml, that's still subject to Orange Book patents. Anybody that wanting to get into that, and nobody's filed yet, we have not been noticed by anybody that you need to file a Paragraph IV with respect to the 30 ml ADRENALIN. We are in litigation with Hospira on the 1 ml already. They filed on our existing Orange Book patents. What we are pleased to announce is that Judge Fallon dismissed a summary judgment plea by Hospira. That to me would indicate that we are moving towards a 30-month stay. So I think that's -- hopefully that clarifies the ADRENALIN question.

Operator

And our next question comes from the line of David Buck from B.Riley FBR.

David George Buck - *B. Riley FBR, Inc., Research Division - Analyst*

One for the Nevakar and Somerset in-licensings, maybe for Paul. How should we think about this in terms of added infrastructure, if at all, in 2019 and R&D spend or where these companies essentially spending now, sort of ahead of acquisition? And one for Blaise. Can you talk a little bit about whether there is still further benefit that you're expecting to see from culling your products and the transition out of Alabama, with some of the legacy generics? And finally for Paul, just the products on the Sterile Injectables going forward, do you see those being products that have patentability and sometimes exclusivity other than just some tweaks from preservative-free et cetera?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure, Dave, just for clarification, when you're talking about the patents, are you talking about specifically to for Nevakar, or in general to sound clear?

David George Buck - *B. Riley FBR, Inc., Research Division - Analyst*

Oh, well, just in general. So I mean, do expect to see that type of protection from Nevakar or Somerset and your own business?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes. Okay, so fair. So maybe just to differentiate a little bit. So as we have said, regarding Somerset deal, that was the starting point for Somerset. And if you look at the portfolio, the product that they gotten recently approved on and launched, those are product that are existing in the market. So they are off-patent, you're not going to see intellectual property with that portfolio of products in development, at least not to start. We'll build intellectual property as we move forward, but these are still really healthy margin products, we're really excited about that. The question -- we're not getting too deep into R&D spend for the future, but again on Somerset, they are injectables. You don't have to deal with bioequivalency, you don't have that expense. And so I'm anticipating -- I am not anticipating additional R&D spend with respect to Somerset. So we'll handle that with what we have. We're not going to go too deep further beyond on our R&D for 2019. Then with Nevakar, I think what you're going to -- what we're hoping to do with 505(b)(2)s where we can. Some products in essence and we always try to -- we'll just try to pursue this, when applicable, we like to go for intellectual property, as we did with VASOSTRICT and ADRENALIN, products of those nature. And I'm hoping, and anticipating that some of the Nevakar opportunity will fall into that category. And then I'll pass over to Blaise.

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes. So David, on your gross margin question, just in terms of our full year adjusted gross margin and the increase year-over-year, just to break that down about 2/3, and assuming in the point of our guidance, about 2/3 of that is due to favorable sales mix and then about 1/3 is going to be due to cost efficiencies. So if you look at our full year guidance, yes, we will have some additional benefit from the cost efficiencies in the second half of the year, when we think about it from a year-over-year perspective. And obviously, that's built into our guidance we provided today.

Operator

And our next question comes from the line of Annabel Samimy from Stifel.

Nicholas Carl Rubino - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

This is Nick Rubino on for Annabel Samimy. We just have one quick one, and just to dig a little more into XIAFLEX and cellulite. What's the average number of vials, and how will you start to look in terms of overall cost of the treatment?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

So I'll start, again, the cost or i.e. the price, we're not going to get into. That is something that we will provide as we get closer to launch. And I'll go back to my previous statement that we've provided color on the aesthetics market. Regarding the...

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Number of vials.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

The number of vials. 3?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

3.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

For cellulite?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

(inaudible)

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Well, I thought it was for XIAFLEX. (inaudible)

Why don't you clarify your question...

Blaise Coleman - *Endo International plc - Executive VP & CFO*

(inaudible) question on vials.

Nicholas Carl Rubino - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Sorry, what was that?

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Nick, can you question clarify your question on the vials? Sorry, we're trying to clarify what your question was.

Nicholas Carl Rubino - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Yes, I guess we're just wondering what the average number of vials, I guess, per patient would be in terms of over the course of their treatment.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

For cellulite, Peyronie's or Dupuytren's?

Nicholas Carl Rubino - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

For cellulite, please.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Okay. Yes, so the clinical trial of our protocol was 3, 3 treatments, 2 vials per treatment. So it's -- again, I'll simplify it, 2, 2 and 2 for total of about 6 vials, that's the clinical trial.

Operator

And our next question comes from the line of David Amsellem from Piper Jaffray.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

So I joined late, so you may have already addressed this, so I apologize if you did. So just quickly on ertapenem, on the AG. Can you just talk about your economics there? And how it compares to corporate margins? And then how the competitive landscape on that product's going to shake out the number of pending filings? And how you're thinking about competition emerging over the next 6 to 12 months? And then secondly, on the Somerset product, you cited a half a dozen approvals, I believe. So if you have any specifics on those approvals, the underlying sales opportunities there, that would also be helpful.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure. So on ertapenem, what we typically explain -- ertapenem -- keep in mind we are a distributor on behalf of Merck. So there are -- there have been standards in terms of what a surrogate AG would be. I would say this is a standard AG deal. So I think it's relatively known what that means

in the environment. So there is -- we're incredibly proud to be best distributor from working this particular product, but you should look at it as you would any standard straight AG deal. Regarding the market conditions, there is one generic approval, we're going to head-to-head with right now. While, I don't get too far ahead of the future, I think it's well known that there is probably about 3 A&Ds on file pending some approval process. So I think you should look at it in those terms. And then regarding Somerset terms, we have approvals but we haven't provided any financials. At this point in time, I think it's too early to go into the specifics. I think what we're saying is, this is the company that is -- has historically executing, they got commercial products already in the market and since the announcement back in April, these guys have not missed a beat. We're just incredibly excited, we're hoping the deal is going to close in the fourth quarter. At that point in time, we'll be able to provide a little bit more color.

Operator

And our next question comes from the line of Gary Nachman from Bank of Montreal.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

First, Blaise, what's your updated target for when you could get leverage, maybe down below 4x, can that happen potentially next year? And Paul, I know you said with Nevakar, you are conscious of investment, so are there a lot more Nevakar's out there, or Somerset's out there? And then just -- oh yes, just one more -- just on cellulite. How many patients are you enrolling? And the acceleration, was that just from demand? Or did you also add sites in the study?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

So on cellulite, it's a 2-by-420 patient study, we have 50 sites. The bottom line is that the enrollment went a little bit quicker than we anticipated. So that's the justification for the update. And Gary help me out on Somerset, what was the question?

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

I know you said with Nevakar, you are conscious of investment, given your leverage, obviously. So are there a lot more Nevakars out there, or (inaudible) deals out there. Then Blaise, when you think you could get leverage down meaningfully?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Yes, so I think the way when I look at the Somerset and Nevakars, I mean these -- the business development team here and they're always on the hunt for opportunity that maybe somebody else hasn't seen. These 2 particular injectable opportunities really are not new to us. I think this is something that we have followed for a series of years and I think we were able to execute at the right time. The question is, are there are a lot more out there? I mean, I think they evolve over time, it's probably the best way of looking at it. So if we take it very thoughtful and mindful approach and follow things. And whenever we can partner with someone that we've got a positive previous history, it makes a little bit easier. But frankly, we've got to be laser focused on our capital allocation and in our debt paydown. So they're going to be a lot of due diligence on a go-forward basis. I think what I'd like to maybe just make sure everybody understands is, with Somerset, there's going to be considerable integration and we're on the process of expecting favorable top line data for a cellulite. We have a lot of work to do, as we look at 2018 and 2019. So there's going to be a lot of focus on just that. So we're going to be very cautious about executing on other business development deals near term. There's enormous amount of integration that's going to be happening in 2019.

Blaise Coleman - *Endo International plc - Executive VP & CFO*

Yes, and then Gary, just in terms of your question on leverage, as we have stated our -- or should probably or one of us should probably -- if you get back to under 4x overtime. And yes, we've talked about, that's really going to come through a combination of ultimately through adjusted

EBITDA growth and net-debt reduction. But we do have a number of uncertainties in front of us, so at this given point in time, we haven't put any time frame on that, and we're not going to do that at this time either.

Operator

And our next question comes from the line of Louise Chen from Cantor Fitzgerald.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

I had a few here, so first question I had was on your cellulite product, do you expect price imparity between your medical indication and your aesthetic ones? And then secondly, if cellulite works as planning, you get it approved, will you bring on more aesthetic products to add to your portfolio? And then lastly, just back on the generic market environment, you did note some stabilization, just curious if you think that pricing will eventually improve or will stay the same for the foreseeable future? And what do you think is driving this stabilization?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure. So Louise,I'll start with Generics. In terms of pricing improvement, I mean, that's something that I don't see. I think it's understood with the consortiums and that's the challenge. What I'm saying is, when we see it stabilizing -- I think what we're saying is, is erosion is not worse than expected. And it's starting to flow into what I was referring to it as kind of the pre-2015 normal course. Now we don't provide guidance on erosion, but the way, I think you should be looking at it is that stabilization means it's not getting worse and I would leave it probably at that. Regarding, now back up, in terms of your question on adding more aesthetics products into the portfolio, the very first thing that we have to do, we just talked about delevering and being focused on debt paydown. That is the #1 priority. So again, our BD team is always going to go out there and look for an opportunity, we're going to have a database full of potential opportunities, whether it's aesthetics or injectables or even generic products. But in the case of aesthetics, let us pass the study, let us prove success, let us focus on debt paydown and then we can look at next steps for our aesthetics team that we're building. Regarding pricing on cellulite, we're not going to get into specific pricing with respect to in-market indication and in cellulite, I think that's something that, again, just we're asking everybody to be patient and as we get closer to launch, we can talk more about pricing.

Operator

And our next question comes from the line of Stephen Ragard from Mizuho.

Stephen Anthony Ragard - *Mizuho Securities USA LLC, Research Division - Research Associate of Americas Research*

So on the CCH program in cellulite, will you need to submit a separate BLA and if not, what regulatory pathway do you plan to pursue?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

So regarding that, our intention is to file a separate BLA, right? So I think that's going to ultimately be the focus of what we're -- that we're looking at. We -- what people need to understand -- I think we've communicated in the past that what we have done is, we have created a new presentation, right? And we talked a little bit about concentration being 1/10 of the concentration that's used in the already approved indications. You've got a new indication, you got a new concentration and you've got a new patient population and these are areas and reasons why we believe that we will be filing a separate BLA.

Operator

And our next question comes from the line of [Navan Pirian] from Citigroup.

Unidentified Analyst

My question is on litigation risk. Do you expect any near-term update on the litigation front and on opioids? Can we expect an update this quarter on the motions to business. I know that some motions have been fully briefed. Any update on that?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

I'm sorry, we're going to need you to repeat the question. Unfortunately, I just couldn't hear your question, I apologize.

Unidentified Analyst

On the -- if you have any near-term update on the litigation front, and any update on the motion to dismiss on the opioids front?

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Sure. So our starting point is we're never going to go into any great detail, we can't comment specifically on ongoing litigation. And I think this is going to be specific to opioids, that's where I assume your question really is headed. What we've communicated regarding opioids is that ultimately we are -- what we're saying, we still believe that we are, for the most part, at the early stages and what we've communicated is that last earnings call, we indicated that there was about 860 cases against Endo and it has increased to about 1300 cases, 3 months later. What we are telling people is that the judge has communicated that there's going to be 3 bellwether cases that are targeted for March. However, we have reason to believe that those 3 cases could be pushed back a little bit. So it's really (inaudible) and so that probably is as far as we can go specifically on opioid litigation. I would maybe make one further comment that over the next couple of months, I don't want to leave you with the impression that we're not doing, and if you're nothing is happening, I would say that there has been some dialogue with plaintiffs and state AG's. I would probably say, it's somewhat constructive, but I don't want anybody to believe that this thing is advancing. It's still at the very, very early stages, but for the fact, there has been dialogue and I'll leave it at that.

Operator

I show no further questions at this time. I would like to turn the call back over to Paul Campanelli, President and CEO, for closing remarks.

Paul V. Campanelli - *Endo International plc - President, CEO & Director*

Thank you. All I just really want to say is that we do in fact appreciate your continued interest in support of the company. We do look forward to providing you with updates as we move forward later in the year. And thank you all for joining us this morning.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone, have a great day.
