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# Endologix, Inc. (ELGX)

Q3 2018 Earnings Call

## CORPORATE PARTICIPANTS

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*Chief Medical Officer, Endologix, Inc.*

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## MANAGEMENT DISCUSSION SECTION

**Operator:** Greetings, and welcome to the Endologix Third Quarter 2018 Earnings Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference is being recorded.

This conference call is also being broadcast live over the Internet at the Investors section of the company's website at [www.endologix.com](http://www.endologix.com), and the webcast replay of the call will be available at the same site approximately one hour after the end of the call.

Before we begin, I would like to caution listeners that comments made by management during this conference call will include forward-looking statements within the meaning of federal securities laws. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the company's actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

For a discussion of risk factors, I encourage you to review the Endologix Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2018 and subsequent reports as filed by the company with the Securities and Exchange Commission. Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, November 1, 2018. Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances after the date of this call.

With that said, I'd now like to turn the call over to John Onopchenko, Endologix's Chief Executive Officer. Mr. Onopchenko?

## John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

Thank you, operator, and good afternoon, everyone. Welcome to our Third Quarter Conference Call. Today I'll provide a brief overview of our third quarter results, discuss the progress we continue to make toward executing our new business strategy which we revealed on our second quarter call and then discussed further during our investor meeting in early October. I will then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our third quarter financial results and 2018 financial guidance in more detail. After that we'll open the call for questions. As a reminder, we have posted a supplemental slide deck on our Investor Relations website directly below the Webcast link.

Many of you attended our recent investor meeting where we outlined our new business strategy and defined the steps we have taken to improve our execution, deliver profitable growth and restore credibility with customers and stakeholders. We remain focused on the leadership and process-related changes that enable consistent, strong and scalable execution in achieving our plan. I am pleased with our early progress toward realizing these goals and I believe that our third quarter performance is another encouraging sign that we are taking the right steps in the right direction.

I want to reiterate my strong belief that our well-differentiated EVAR and EVAS product portfolio, coupled with an expanding body of clinical evidence, remains compelling and continues to save lives.

With that, I'll turn to our quarterly highlights. Our total revenue for the third quarter was \$34.8 million. While this number represented a \$24.4 million year-over-year decrease, it was slightly above the high-end of our preannounced range of \$34.3 million to \$34.7 million. The strongest contributions to our top line came from AFX sales in the U.S. and Latin American markets as well as Ovation sales in U.S. and Europe.

During the third quarter, we completed the restructuring of our commercial team in the U.S. and our European operations. We are taking the necessary steps to retain our top performers, including the implementation of a tiered, results-based structure and performance management system. We have begun to establish territory-specific plans against targets, consistent with our strategy to stabilize, then grow AFX2 and Novation and subsequently grow sales in higher-volume centers.

We are delighted to see companywide engagement in our strategic reset. Our gross margins improved 180 basis points to 65.1%, while our operating expenses, excluding a restructuring charge, decreased 7.1% year-over-year. Our operating expense in the quarter was \$35.6 million, excluding the restructuring charge. These results are tightly aligned with our 2018 guidance. Finally, earlier this week, we consummated a registered underwritten public offering of \$20 million of our shares of common stock, which gives us more flexibility to pursue our strategic and financial goals, while also allowing us to pay off the remaining 2018 senior notes. Vaseem will discuss your financial results and the impact of this equity offering later in more detail.

While we recognize that there is still a lot of work ahead, Endologix delivered against our targets in the third quarter. Making and meeting commitments consistently defines improved execution. Improved execution leads to credibility and trust. Furthermore, based on our current level of sales and operating expenses, we are managing our financial covenants effectively and we believe improved execution is sustainable.

Now I'd like to give you an update on our products and clinical programs, including the recent FDA notice regarding our AFX product line. As we disclosed at our investor meeting on October 2, we received an update from the FDA regarding our Field Safety Notice, now known also as a voluntary recall of the AFX product line due

to Type III endoleaks with AFX Strata. To briefly recap this timeline of events, in December 2016, we issued a Field Safety Notice that was a voluntary recall of the AFX Strata product line in response to Type III endoleaks. As we continued to collaborate with the FDA, in July of 2018, we issued a Field Safety Notice that included guidance on re-intervention instructions. The FDA later classified this FSN as a Class I recall, which we addressed at our investors meeting, as well as in our October 5 press release, both of which coincided with the FDA's published remarks, which included product-specific codes involved in the recall. On October 15th, the FDA issued its second announcement that was intended to use nontechnical language in informing the public about this recall.

I would like to take a moment to address this announcement as it requires a detailed understanding of the words the FDA consistently uses in describing Field Safety Notices and recalls. First, our FSN of July 20 was a corrective action that was classified by the FDA as a Class 1 recall. However, the term recall is not synonymous with product removal in all cases. In this case, no commercially available product was subject to be removed. AFX Strata, the principal subject of the recall, is completely off the market. The product was last sold in the latter half of 2016 and it was last manufactured in 2014. Also, we know that all of our AFX Strata product was removed from the global inventory in the first half of 2017.

With regard to our current commercially available AFX products and their comparative performance, the DuraPly material used in our current AFX2 devices is now supported by four-year data based on complaint trends that encompasses nearly 1,000 patients and demonstrates excellent contemporary clinical performance of the AFX2 system and a meaningful difference to Strata.

These data are further corroborated by our LEOPARD study, a study directly comparing AFX DuraPly, AFX2 with contemporary competitive endografts and the comparative independent assessment of contemporary endograft performance found in VQI. We have educated our field representatives on the recently released four-year competitive dataset and have also distributed a customer letter through our commercial team to ensure we've conveyed a consistent, data-backed, well-understood message surrounding this most recent FDA posting. We stand behind our AFX data derived from multiple sources that show AFX DuraPly has a meaningfully lower IIIb endoleak complaint rate versus AFX Strata. And that AFX DuraPly has now been implanted long enough for endoleaks to have occurred. We remain confident in the competitiveness of AFX II and the resulting forecast for Q4.

Now, I'll provide a brief update on Ovation and Nellix. With regard to Ovation, we continue to target high-volume centers, which we view as our greatest opportunity for growth. We anticipate launching Alto in both the U.S. and Europe in 2019 and are convinced that the long-term outcomes using our unique patient-specific sealing capability offer meaningful and durable advantages over traditional EVAR. We have plans to advance these claims in a direct comparative study.

Regarding Nellix, as we highlighted during our investor meeting, enrollment for the EVAS II trial is a priority for the organization. We are pleased to report an increase in the number of activated sites. We remain on track to complete enrollment by the third quarter of 2019, which we anticipate will translate to FDA approval in 2021. Lastly, we have an ongoing collaborative dialogue with the FDA over the trial design for the ChEVAS IDE study. This is an entirely new therapy where trial design needs very careful consideration and we continue to predict that we would be able to enroll the first patients in this study in the first half of 2019.

We believe strongly that AFX2, Ovation, Alto, Nellix, ChEVAS and the next-generation EVAS platform effectively spans today's EVAR needs with the future of endovascular aortic repair, driven by evidence-based advantages. Traditional EVAR has reached the limits of its potential and we believe our portfolio offers the only set of differentiated solutions that address the unmet needs that have persisted over 30 years of EVAR.

And now I'd like to turn the call over to Vaseem to discuss the third quarter financial results and provide you with details on our updated guidance. Vaseem?

## Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

Thank you, John, and good afternoon everyone. As John already mentioned, our total revenue for the third quarter of 2018 decreased 24.4% year-over-year to \$34.8 million compared to \$46 million in the third quarter of 2017.

U.S. revenue for the third quarter of 2018 decreased 16.8% to \$25.7 million compared to \$30.9 million a year ago. The decline was driven by the impact of the Field Safety Notices and also the changes we made to reflect the lower costs to serve on the commercial side of our U.S. business. As [ph] messaged said (13:30) at the investor meeting, the impact of both of these actions was slightly better than expected during the quarter.

International revenue decreased 40.1% on a reported basis to \$9.1 million, compared to \$15.1 million a year ago. On a constant currency basis, our third quarter 2018 international revenue decreased 39.6% year-over-year. The biggest impact was in Europe where the restructuring changes resulted in a commercial head count reduction of approximately 40%. We also saw revenue reductions of approximately \$2 million versus our prior guidance due to us exiting some smaller markets around the globe, as we'll share with you at the investor meeting.

Gross margin for the quarter expanded 180 basis points to 65.1% compared to 63.3% in the third quarter of 2017. This improvement was primarily driven by a smaller inventory obsolescence charge, offset by some negative manufacturing variances. We continued to manage costs in concert with declining volumes by adjusting our direct labor and managing our inventory.

Our net inventory was down as we continued to push for better turns and lower cash consumption. Total operating expenses for the quarter were \$38.5 million, flat from \$38.5 million a year ago and included a previously discussed restructuring charge of \$2.9 million. Excluding this one-time charge, our operating expenses were \$35.6 million during the quarter, representing a 7.1% year-over-year decrease. This cost performance in the third quarter post-restructuring gives us confidence that we can deliver on our OpEx guidance for the next year.

The restructuring is almost complete and we don't expect any bid charges in the fourth quarter. This was a very important deliverable in our efforts to lower our cash consumption and represents a significant source of non-dilutive cash of approximately \$20 million to \$30 million in 2019.

Looking more closely at the third quarter operating expenses, marketing and sales expenses were down 20.7%. This decrease was attributable directly to our lower cost-to-serve actions and lowering our discretionary spend. Our research and development expenses decreased by 4.6% year-over-year. Offsetting these decreases was a 24% increase in our general and administrative spend, driven by the Deerfield refinancing and ongoing litigation expenses.

Our clinical and regulatory expenses remained almost flat year-over-year, reflecting continued investments in building clinical evidence in support of how we compete and anticipated new product introductions. Net loss for the third quarter of 2018 was \$10.1 million or \$0.12 per share compared to a net loss of \$14.3 million or \$0.17 per share a year ago. The net loss includes a \$5 million favorable change due to fair market valuation of our Nellix contingent consideration and a \$8.3 million favorable change in our derivative liability related to the Deerfield credit facility.

Adjusted net loss totaled \$13 million compared to an adjusted net loss of \$9.3 million for the third quarter of 2017. Adjusted EBITDA totaled a loss of \$9.3 million for the third quarter of 2018 compared to adjusted EBITDA loss of \$4.3 million for the third quarter of 2017.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were \$42.2 million as of September 30, 2018 compared to \$37.6 million as of June 30, 2018. As of September 30, 2018, we had a \$10 million outstanding on the Deerfield revolver. Excluding the impact of the revolver and a \$1.8 million raise on our ATM, our cash burn for the quarter was approximately \$8 million. Our cash burn also included a one-time payment of \$2.4 million in legal settlement costs incurred from a patent dispute with LifePort which was settled in 2016.

We expect a slightly higher burn rate in the fourth quarter due to the semi-annual interest payment on our convertible debt and an extra payroll cycle. Putting all of this together, our operating expenses and cash burn in the third quarter are both within the target ranges that we provided during our investor meeting and we will remain disciplined as we advance through the fourth quarter and into 2019.

Finally, I like to briefly address our recent equity raise. Earlier this week, we consummated a registered underwritten public offering of \$20 million of our shares of common stock with a 30-day option to purchase up to an additional \$3 million of our shares of common stock. We intend to use the net proceeds from this offering to redeem all of our \$18.3 million, 2.25% convertible senior notes due in December 2018 and any remaining proceeds to be used for working capital and general corporate purposes.

We started the process to address our balance sheet back in the second quarter by filing the equity shelf and subsequently converted \$40.5 million of our 2020 convertible debt into a non-dilutive term loan with Deerfield. We will pay off the remaining \$18.3 million outstanding 2018 converts in December and the completed restructuring significantly lowers our cash burn going into 2019.

Turning to guidance, we are reiterating the revenue guidance that we provided at our investor meeting in October. We continue to execute towards our 2018 revenue in the range of \$150 million to \$155 million. As John mentioned, we did see some transitory impact in our case creation numbers following the October 15 FDA recall notice, but are confident that with our performance in October and the updated LEOPARD data that would be presented at VEITH, we can hit our Q4 revenue guidance.

We now expect 2018 GAAP loss per share to be in the range of \$0.87 to \$0.91 compared to the previous range of \$1.12 to \$1.04 compared to the previous range of \$1.12 to \$1.04. These loss per share numbers contemplate the impact of restructuring charges in the second half of the fiscal year and include a total year OpEx number of \$160 million, but exclude the impact of any future changes and fair value of the contingent consideration or derivative liabilities.

Furthermore, in 2019, we continue to expect revenue of at least \$140 million, while operating expenses are anticipated to be in the range of \$130 million to \$140 million. Overall, we are pleased with our financial performance during the third quarter and as John mentioned, we still have more ground to cover, but it's the process and the leadership changes that gives us the confidence that these results are sustainable and they reinforce our beliefs that we have taken a step in the right direction towards achieving our financial targets for the remainder of the fiscal year and beyond. We will continue to focus on making Endologix profitable and to be a company that is rewarded for evidence-based innovation and growth.

With that, we will now open the call for questions. Operator?

## QUESTION AND ANSWER SECTION

**Operator:** Thank you. We will now begin the question-and-answer session. [Operator Instructions]

Our first question today will come from Mathew Blackman of Stifel. Please go ahead.

**Mathew Justin Blackman**

*Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Good afternoon, everyone, and thanks for taking my questions.

**John Onopchenko**

*Chief Executive Officer & Director, Endologix, Inc.*

A

Hey, Matt.

**Mathew Justin Blackman**

*Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Hey. To start, at the Analyst Day, you referenced I think a U.S. sales force footprint of 61 reps and 31 clinical specialists. So any update on sales force stability? And is there a point in time when you'll feel less anxious about the risk of above-norm sales force attrition rates?

**John Onopchenko**

*Chief Executive Officer & Director, Endologix, Inc.*

A

We are holding to those values, Matt. And as we go through and complete 2018 and probably through the first quarter of 2019 is when we would expect to feel a lot more comfortable that any attrition is behind us.

**Mathew Justin Blackman**

*Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Okay. And I'm not sure if Dr. Thompson is there, maybe John, you can handle this if he's not. But I was just curious as I reflected back on the 2Q call, if there's been any impact from the Ovation polymer leak issue you highlighted?

**John Onopchenko**

*Chief Executive Officer & Director, Endologix, Inc.*

A

Matt is here. So, I'll turn it over to Matt.

**Matthew Thompson**

*Chief Medical Officer, Endologix, Inc.*

A

Hey, Matt. So, in terms of the polymer leak, the thing that we're getting most from the field is that we're getting credit for being transparent, putting out these rights and reaffirming our IFU. And we've had a good successful training of the sales force with regard to making sure that the procedure is being done on IFU. And actually if we look at our clinical complaint data coming in, we've seen an almost instantaneous downturn in the number of complaints that we're getting. In terms of revenue on Ovation, then John obviously you may want to talk about that.

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Yeah. And I think, Matt, we talked about the revenue side. It's too early to call, but at least in the third quarter results that we saw, it was better than expected disruption as a result of the FSN. So, we're monitoring here how Q4 plays out and we'll give you an update at JPMorgan on how both AFX and Ovation did that will have four months of experience.

Mathew Justin Blackman

*Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Okay. That's great. Thanks. I'll hop back in queue.

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Thanks, Matt.

**Operator:** Our next question will come from Chris Pasquale of Guggenheim. Please go ahead.

Chris Hartstein

*Analyst, Guggenheim Securities LLC*

Q

Hi, this is Chris Hartstein in for Chris Pasquale. Thanks for taking my question. On Europe, this geography came in a little light of what we were expecting. Following the NICE draft guideline, have you seen other European countries change the way they practice or is there anything else in that region that you'd like to highlight? Thanks.

Matthew Thompson

*Chief Medical Officer, Endologix, Inc.*

A

Hey, it's Matt Thompson. So just in terms of the clinical aspects of that, we just need to remember that the NICE guidelines of draft, they won't be published now, I don't think in full guidance four months until December. The thing that I just think everyone needs to be aware of is that that's very much a UK issue. The European Society of Vascular Surgery is just about or just has published their abdominal aortic aneurysm guidelines and they are very different tonight in terms of recommending Endovascular Aneurysm Repair as an integral part of patient choice and that really mirrors what we see with the Society of Vascular Surgery guidelines as well.

Chris Hartstein

*Analyst, Guggenheim Securities LLC*

Q

Okay. Thank you. And at your Analyst Meeting, you shared that you intend to initiate a pair of head-to-head studies, hoping to prove superior performance for Alto versus traditional EVAR and another one, hoping to show potential mortality benefit with EVAS versus EVAR. Have you decided on a trial design yet, any details you can share there would be helpful? Thanks.

Matthew Thompson

*Chief Medical Officer, Endologix, Inc.*

A

Yeah. It's Matt again. So I'm afraid I have to defer to the answer that I gave at the Investor Day. Obviously, we're looking to introduce Alto in 2019; that's going to be a big boost for us product-wise. But in terms of trial design, we've not worked through the power calculations yet the differences in the endpoint. So, I think to share anything at the moment would be premature.

**Operator:** Our next question today will come from Steven Lichtman of Oppenheimer. Please go ahead. And Mr. Lichtman, your line is open. You may be muted on your end.

Jia Min

*Equity Research Associate, Oppenheimer & Co.*

Q

Yes. Sorry. Hi. This is Jia on for Steve. First question is on Ovation. At Analyst Day, you indicated your Ovation market share in high-volume centers is around low single digits. Just trying to get a sense of what your Ovation market share looks like in your existing high-volume accounts.

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

We have talked about that consistently in the past that Ovation in the high-volume centers in the – is below entitlement and in the low single digits. And that's the biggest opportunity for us as we think about the future. So we expect to raise that from the current levels to a higher number in 2019 and beyond.

Jia Min

*Equity Research Associate, Oppenheimer & Co.*

Q

Okay. So and then on AFX stabilization, since that product is – you've mentioned in the past that it is an ideal fit for low-volume users, now that you are increasingly focused on high-volume accounts, how does that impact your goal of AFX to stabilization in the U.S.? Thanks.

John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

A

Yeah. It's a very good question and one worth spending a bit of time on. It's important to recognize that we intend to serve every one of our customers, low-volume or high-volume customers. Our go-to market approach, given the reset, is one where we want to purposely begin to use our clinical specialists more frequently as the professionals that will be responsible for primary case coverage in our base business, which we have shown is predominantly in these lower-volume centers. With that, it creates capacity for our aortic account managers to spend increasingly more time at these high-volume centers in order to gain the necessary traction to secure a more competitive share position in those accounts.

**Operator:** Our next question will come from Joanne Wuensch of BMO Capital Markets. Please go ahead.

Matthew Henriksson

*Analyst, BMO Capital Markets (United States)*

Q

Yes, hi. This is Matt Henriksson in for Joanne. The first question kind of piggybacking off Chris's question on Europe, that \$9 million rate, is that appropriate run rate to think about through over the next three quarters as you anniversary this sales restructuring?

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Yeah. So Matt, if you remember, we had specifically talked about that as a line item in the reset where we said for the second half of the year, we would see a \$4 million impact on the heels of exiting some of the smaller, non-scalable markets. So what you saw in the third quarter numbers as we talked about at the Investor Day meeting,

the impact was about \$2 million. We continue to see another \$2 million impact here in the fourth quarter. So on an annualized basis, we expect the impact to be about \$8 million, as a matter of fact, just exiting those countries and then hoping to spend some time in energy on what's left in our footprint, especially a few direct markets and then mostly indirect markets where we might see a little bit of a mix change from – on ASPs as we adjust from full price to transfer prices. So, again the annualized impact of what we saw as a matter of the reset for next year is going to be about \$8 million.

Matthew Henriksson

*Analyst, BMO Capital Markets (United States)*

Q

Okay. That's helpful. And then my follow-up is related to your cash burn. You have \$40 million now give or take, you have an \$8 million cash burn. You have some lower interest expense, things like that. But walk us through how the cash burn improves between now and 2020 when you expect to be cash flow-breakeven?

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Yeah. So, we can – at a high level, listen, the elements of reducing the cash burn are what we have laid out in the past, right. So, our OpEx, as you saw in the third quarter, I think we had a terrific finish on cost. We expect, excluding any unusuals or the one-time items to end at about \$35 million or so for the fourth quarter because I gave you the total year guidance on OpEx now at \$160 million.

So when you run rate that out next year, you clearly see the non-dilutive cash aspect of us going down about \$20 million to \$25 million just as a result of lower spend. Second, we also see the impact of the changes that we're making on some of the top line and driving more productivity in the U.S. And as we give you more guidance on the top line for 2019 at JPMorgan and then the changes that we have based on the interest expense with the deal with Deerfield and now having raised another \$20 million, it all together kind of lends us to believe that we have a very high confidence to get to this \$5 million cash burn number for next year.

Now, obviously there will be seasonality in that, Matt, where you might see the first half typically come in slightly higher of the \$5 million, but we do expect on an average to be at a \$20 million cash burn for total year next year.

Matthew Henriksson

*Analyst, BMO Capital Markets (United States)*

Q

Great. That's very helpful.

**Operator:** Our next question will come from Robert Marcus of JPMorgan. Please go ahead.

Q

Hey, guys. This is actually [ph] Han on for Robbie (31:47). I just had a quick question on Ovation Alto. I know you haven't given color on it before, but just directionally, when in 2019 should we really expect that to launch? And in the near term, what kind of benefits should we really see, what kind of – what's the shape of the launch as you obviously address existing Ovation customers and then ultimately go out to target new accounts at Alto?

Matthew Thompson

*Chief Medical Officer, Endologix, Inc.*

A

Hi, it's Matt again. So, from a sort of [ph] clin right (32:16) perspective, we're sticking really to what we said at the Investors Day is that we have full expectations that we will launch Alto in 2019 both in the U.S.A. and the EU. More color on that at the moment is probably not appropriate. In terms of boosts that we say, I mean I can talk from the physician perspective of it. We've got good excitement for people who are looking forward to launching Alto, they can all see the benefit of moving the sealing wing up and increasing patient applicability. So you've got a good cadence of clinical excitement coming up surrounding this.

John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

A

Yeah, maybe just to dovetail to those remarks. As I mentioned during the investor event, planning is already underway with the commercial team to select really 20 to 30 centers in the next 12 to 18 months. There'll be – there are specific criteria to guide our selection, many of whom are existing Ovation customers. And then again, it gets back to a common belief that we will reach with these customers on EVAR outcomes. And I mentioned this during the Investor Day that I think it's worth reinforcing in that the four beliefs that we need to share are; one that going back to open surgical repair is not the answer given the divergence between EVAR outcomes and open surgical outcomes.

Two, that supporting the continuation of current EVAR outcomes has really reached its defensible peak. It's very difficult to defend the fact that after 20 years, EVAR has five times the increase in AAA-related mortality compared to open surgical repair. Three, that the evidence produced in the EVAR has to move from marketing studies to prospective randomized controlled trials with active contemporary stent graft comparators that ultimately separates the signal from the noise which has been persistent.

And then the last set of – if you think about EVAR RCTs, where EVAR1, DREAM, OVER, they were completed over 20 years ago. And then finally the fourth element that would commonly bind us is that we not only want to increase the clinical development rigor, but in concert, we want to expand to clinically meaningful claims. And if you remember the pyramid which you'll find in the supplemental deck that Matt reviewed during the investor event, sharing and trading differences on device design, the current basis for competing has to rise to ultimately making mortality-related benefits and ultimately all-cause mortality-related benefits if we're dutifully serving the patients who need this treatment.

Q

Got it. Thank you.

**Operator:** [Operator Instructions] Our next question will come from Matt O'Brien of Piper Jaffray. Please go ahead.

Kevin M. Farshchi

*Analyst, Piper Jaffray & Co.*

Q

Thanks, everyone. This is Kevin on for Matt today. I wanted to start and put a bit of a finer point on guidance as I think we learned a little bit more about the trends in Q3 today. I guess my question here is how much conservatism is baked into Q4 and how much of that guidance near-term is a function of the sales rep attrition versus the recapture of AFX? It seems to me like both of those headwinds were not as bad as we thought. So how do those trends progress in the near-term that gets you to that number for the quarter?

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Kevin, it's a great question and thanks for asking it because we want to make sure and I think we tried to do the same at the Investor Day and we've given you the same color here. We've had now the month of August and September and also for the fourth quarter, the October experience. And the biggest risk that we see here was the risk that Matt Blackman asked earlier about rep attrition and we're still not out of the woods. We have taken steps to make sure that we have retention packages and doing anything possible we can to get our teams settled. It's the single biggest risk that we see here; to throw confetti is too early in this point. So I don't think that we are very conservative here in our guidance. I think we've been very realistic. And I just hope that as you guys are thinking about Q4 and next year that you keep that in mind as you guys are putting out your models because for us, the range that we have put out there on the \$29 million to \$33 million is real, it's realistic and with a couple or maybe three good reps exiting, we could easily be at that \$29 million.

So – but at the same time, as we saw in the quarter, we have a shot at getting to the \$33 million or the high end of the guidance as well. So again, we are just being realistic here that while having the experience with the three months is positive, but there's still some wood to chop here and make sure that we continue to execute and drive the process capability that we've been talking about for better [indiscernible] (37:55) so, that's – it's too early. For 2019, we'll have a pretty good picture as we come to JPMorgan and give you a pre-announcement on the top line, but more importantly give you guidance which we would normally give out in the middle of February as we have done in years past.

John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

A

Let me just kind of reinforce a few points that Vaseem has made. First, with respect to retention, it is not in the form of everybody gets the same thing. What we have implemented is a tier-based performance plan that were formed by the historic results of any given aortic account manager. We have now four tiers of performers and those tiers, the first three of those tiers guarantee a pay-out as well as a retention incentive.

The last of those tiers does not. And we're going to provide incentive for over-performance, not incentive to simply stick around, and that is in fact at the heart of the matter here. It is a very deliberate tension between expecting improved productivity and performance, which our top performers consistently rise to the occasion for and showing frankly that our bottom performers, there is an opportunity to improve and there is an opportunity to gain obviously greater income as well as greater stability in their income as their performance improves. So I wanted to be clear about that. Secondly that since our U.S. restructuring, we have not experienced a regrettable loss commercially. But again, it is too soon to feel any sense of comfort or confidence that we may still be confronted with it. That's why we remain pretty pragmatic about this.

Kevin M. Farshchi

*Analyst, Piper Jaffray & Co.*

Q

Thank you, guys. That's extremely helpful. I think the only follow-up I would have there is just that it sounds as though the higher performers are more likely to stick around given that type of a structure and those folks are more important. Have you seen – have those folks been talking whatsoever on the competitive dynamics in the marketplace as you're moving into those high-volume centers that you're focused on? I know it's very early, but I guess I'm trying to think about next year as well, what can bring you above that floor that you've laid out with approval of your Alto product? Thank you so much.

John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

A

I would say across the board, as we lay out our plans for the balance of the year and through 2018, I would say to a person, whether it's a clinical specialist or an aortic account manager, they're excited about the prospects of taking our products and advancing them to even more valuable, higher-volume centers where more patients could be more successfully treated using our products. So I'm excited along with them about the prospects of our strategy and approach moving up market. I will reinforce the fact that this strategy is informed and guided by crawl, walk, run. It is not a one-shot, one-size-fits-all solution, it will be tailored initially to these 20 and 30 centers, something that balances our willingness to accept both financial and clinical risk in support of giving them a frictionless choice to start using our product more frequently.

Kevin M. Farshchi

*Analyst, Piper Jaffray & Co.*

Q

Perfect. Thank you so much.

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Thanks, Kevin.

**Operator:** And our last question today will come from Richard Newitter of Leerink Partners. Please go ahead.

Jaime L. Morgan

*Analyst, Leerink Partners LLC*

Q

Hi John. Hi, Vaseem. This is Jaime on for Rich.

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Hey, Jaime.

Jaime L. Morgan

*Analyst, Leerink Partners LLC*

Q

A quick question on gross margins...

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Yeah.

Jaime L. Morgan

*Analyst, Leerink Partners LLC*

Q

...you guys obviously came in better at least against our expectations. So I was just wondering kind of what your expectations are for the remainder of the year. I think at one point, you guys maybe had talked about 2 to 3 point headwind potentially to gross margins. Does that still kind of hold true for the balance of the year? And then looking into 2019, is it fair to still assume that gross margins could still see some pressure?

Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

A

Yeah, I think very consistent with what we have said in the past, Jaime, is that we do expect to finish the year in that 64% to 65% range and we had also talked about the impact of these unfavorable manufacturing variances that actually started to hit us here in the last month of September and we'll see a full quarter of those variances in the fourth quarter. So, we're not walking away from the previous guidance. So, I think we still expect to finish in that 64% to 65% range for the total year, I think is one.

Second, the 2019 number will all depend on the mix of our U.S. and O.U.S. business and as we transition from some of the direct markets to indirect markets and quite frankly wind down some of the smaller, indirect markets, we'll have to look at that mix of the revenue and will that impact us on our margins. So I don't expect us to significantly erode margins in 2019. But we do expect to see some pressure just naturally because of the volumes that we're seeing and are also walking away from some significant portion of the business where we're walking out these smaller markets. So we'll give you more color on that when we give you the guidance, but at this point, with visibility on Q4 and the total year, we do expect to come in line with our previous estimates.

Jaime L. Morgan

*Analyst, Leerink Partners LLC*

Q

Okay, that's helpful. And then as my follow-up, on clinical data, can you just remind us, I guess, first what are kind of some of the more needle-moving data readouts that we should be expecting, either year-end or in 2019 and kind of how are you guys thinking about these specific data readouts? Is it more just give a sense of validation of your products and their effectiveness or do you guys really expect that some of these data readouts will be helping with the actual adoption pathway of these products?

Matthew Thompson

*Chief Medical Officer, Endologix, Inc.*

A

Hi, it's Matt. So, let me give you some color perhaps on each of the three products. So, with regard to AFX, you know that we've just been through some discussions with the FDA on the FSN and then the classification of the recall. So as we said before, we pretty carefully triangulate our data with AFX and our next big release will be the most recent data cut of the LEOPARD trial, which we'll be presenting at the VEITHsymposium later on this month. So that's billed as a one-year data cut, so all patients in both arms of the trial out of one year. But in reality, because we've been enrolling for several years, we'll have good and robust comparative data, directly between the AFX platform and the three competitive grants that are randomized against AFX in the LEOPARD trial and we'll have those data out for three years. Now obviously, I'm not in the position to tell you what's going to be in those data sets. But there was a data cut presented at the Society for Clinical Vascular Surgery in March of this year and I'm not expecting to show any very significant differences from the tone of that message. So that's what really gives us excellent assurance that when assessed in the round, the AFX platform is achieving comparative results to any other contemporaneous graft that's on the market.

And of course what that does do is it further validates the full-year combined data that we've now just released in the last week or so that shows there's a very meaningful difference between DuraPly grafts at four years and Strata grafts at four years on the AFX platform. So that's really where we're heading with AFX.

With the Ovation family of products, maybe just some color on two data releases then clearly you know that we have the 1,300 patient ENCORE data sets, where we're expecting the publication of the data that we presented on ENCORE earlier this year to be in the first half of 2019 and what that publication will show will be excellent performance out of five years of polymer sealing technology.

In addition to the overall long-haul platform then, as promised, we'll start to do subgroup analyses. And what you can expect to see in the first half of the year is a gender sub-analysis that we're planning to present around the LINC Symposium. And then at the Charing Cross Symposium, which is April/May this year, what we'd do is give you some color on the mechanism of action of Ovation and show some differential graft performance with relation to sort of the traditional contemporary trials. So, that's really what we've got with historic Ovation data. Clearly as we go towards launching Alto, next year, we'll also be releasing the first data cut of the IDE Alto trial. So that's really where we are with [indiscernible] (48:02) more conventional platforms with regard to Nellix, really the excitement is all around further investigation into the apparent signal that we see in the reduction in all-cause mortality with regard to Endovascular Aneurysm Sealing. We will have some further mechanistic data and causality data to present again in the first half of 2019 with regard to the Nellix platform. So that's kind of where we're at. Hope that helps.

Jaime L. Morgan

*Analyst, Leerink Partners LLC*



Thank you.

**Operator:** Ladies and gentlemen, this will conclude our question and answer session. I'd like to turn the conference back over to Mr. Onopchenko for closing remarks.

John Onopchenko

*Chief Executive Officer & Director, Endologix, Inc.*

Thank you very much, operator, and thank you everyone for joining the call. We look forward to updating you on our progress next quarter. Have a great evening. Thank you.

**Operator:** The conference has now concluded. Thank you for attending today's presentation. You may now disconnect your lines.

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