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Endologix, Inc. (ELGX)

Q1 2018 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix First 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. As a reminder, this conference call 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, and a webcast replay of the call will be available at the same time, approximately one hour after the end of the call.

Before we begin, I'd like to caution listeners that comments made by management during this conference call will include forward-looking statements within the meaning of the federal securities law. 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 visit 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, May 2, 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 like to turn the call over to Dan Lemaitre, Endologix Chairman of the Board. Thank you, sir. Please go ahead.

Daniel T. Lemaitre
Chairman, Endologix, Inc.

Thank you, Brenda, and good afternoon, everyone. As we begin our call, I would like to comment on the press release that was issued today after our earnings announcement. On behalf of the board of directors, I'm very pleased that after conducting an extensive search, we have made the decision to promote John Onopchenko to the role of Chief Executive Officer.

When we started this search, which vetted both internal and external candidates, we were looking for a CEO who have the ability to balance our operational, commercial and financial goals by also having significant manufacturing, clinical and regulatory experience. John not only hit the mark on all of these criteria, but also have the ability to hit the ground running, having been in our COO role for the past seven months and having earned the respect of our internal team during that time.

His experience building a large commercial operation at Johnson & Johnson as Chief Operating Officer and a board member of Volcano and as a medical device-ventured capitalist gives us confidence in his ability to lead Endologix on an exciting path forward.

On behalf of the entire board, I'd like to congratulate John and let everyone listening know how excited we are to have him leading the Endologix team. Separately, and on behalf of the board and the entire Endologix team, I would like to offer our sincere thanks to John McDermott for his remarkable contributions to the company and for making this a very smooth transition.

And now, I'd like to turn the call over to John Onopchenko.

John Onopchenko

Chief Executive Officer, Endologix, Inc.

Thank you, Dan, and good afternoon, everyone. I'm honored to be named the Chief Executive Officer of Endologix. Since joining the company in October of 2017 as the Chief Operating Officer, I've been deeply involved in the operations of the organization.

At that time, the company had recently experienced the AFX2 recall and a temporary suspension of our CE mark. That reality drove my focus over the last six months and led me to take a critical look into our quality systems, including how we design and develop products, our production and quality management review processes, along with our supplier management practices. The team has embraced my continuous improvement mandate, and I'm proud to say that we're upping our game on all fronts.

My second significant area of focus was understanding and improving how the company establishes cross-functional priorities, and then allocates resources in support of those priorities. We now have a tool and a process to ensure the right folks are working on the highest valued projects and our projects are prioritized appropriately.

Continuous improvement for quality, key support for regulatory submissions and hitting our operational and supply chain metrics each month are the highest value areas under my COO remit. It was significant and mission-critical work that required my undivided attention.

Shifting to today, I'm now on my first day of my tenure as CEO of diving into other areas of the business, and I'm confident in Endologix team and I'm excited about the bright future that this company has ahead of it.

As evidenced by our clinical study results, Endologix has an innovative portfolio of products to treat AAA, and I'm thrilled to be leading the company at this critical juncture. The nearly 20 years that I've spent at Johnson & Johnson and GE Healthcare, as well as the time I served as COO and Director of Volcano Corporation provided

me with an ideal environment in which to develop my senior leadership skills, as well as organizational attributes, while cultivating top-notch commercial teams and processes.

Additionally, over the course of my career, I've been privileged to have been a part of seven companies that have gone public as both an investor and a board member. Throughout that time, I gained invaluable operating and strategic experience, and I was able to help those companies grow. I interacted closely with top-notch executive teams and gained a deep understanding of investor expectations. In each of these situations, I successfully endeavored to create meaningful shareholder value along with the teams, and I look forward to doing the same going forward at Endologix.

Looking ahead at Endologix future, my goal is to continue to capitalize on the company's strengths and values, rebuild its credibility and reputation with our physicians and customers, and build a culture of accountability, with the ultimate goal of delivering value to our stakeholders around the globe. So I'd like to thank Dan and the board of directors for their confidence in me. I'm excited to get started.

And now, I'd turn over the call to Vaseem to discuss the first quarter.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon, everyone. First of all, I'd like to join Dan and the entire Endologix team in congratulating John on his promotion. I've had the pleasure of working with John in his capacity as the Chief Operating Officer and have been impressed with the changes he has brought about, most notably his drive for accountability and a high sale [indiscernible] (07:33) ratio. It is a change that will take Endologix to the next level of success. Welcome, John, and I look forward to working closely with you over the years to come. I would also like to take this opportunity to thank John McDermott for his contribution and his leadership over the years.

Now, I would like to provide a brief overview of our first quarter key business updates. Then, I will review our first quarter financial results and our 2018 financial guidance. After that, we will open the call for questions.

As an administrative note, we have posted the updated slide deck on our Investor Relations website and will point out that the only changes in the deck are the slide 11, where we have provided our financial guidance, and the slide 12, which is the 2018 milestone slide.

I'd like to start with an update on the recently presented clinical data on our devices. Last week, we announced the results of a study which was presented by Dr. Marc Schermerhorn, Chief of Vascular Surgery at BIDMC, on the podium at the Late-Breaking Aortic Trials Session during the Charing Cross International Symposium. This retrospective, propensity-weighted study compares long-term survival for the Nellix EndoVascular Aneurysm Sealing System with traditional EVAR.

The study demonstrated a significantly higher three-year survival for EVAS patients. Those patients with larger aneurysms treated with EVAS had half the mortality at three years as compared to those treated with traditional EVAR systems. We believe these data validate EVAS as an important therapy for patients with abdominal aortic aneurysms and look forward to sharing this information with physicians where Nellix is approved and investigators in the United States.

During the quarter, we also announced the first results from ENCORE, a pooled, global analysis of several prospective clinical trials and registries studying polymer endovascular aneurysm repair, or polymer EVAR, using Ovation Abdominal Stent Graft Systems. The study encompasses nearly 1,300 patients, 160 centers and 339

investigators in the U.S., Europe and Latin America. The results of the analysis are extremely encouraging and provide a robust data set to support the continued adoption of Ovation and Alto in the future.

Now, a quick update on our product pipeline, beginning with Ovation Alto. In February, we completed patient enrollment in the ELEVATE IDE clinical study. This 75-patient study is evaluating the safety and effectiveness of the Alto Abdominal Stent Graft System for the repair of infrarenal abdominal aortic aneurysms. We are in the clinical study follow-up phase of the program and still plan to file regulatory submissions in the third quarter of 2018, positioning us for potential approval of the Alto device in both the U.S. and European markets in 2019.

Next, the EVAS2 confirmatory clinical study is designed to evaluate the revised IFU of our Nellix device together with our Gen2 system. The study is approved to enroll up to 90 patients with one-year follow-up data required for the pre-market approval application. We got off to a slower than expected start, having enrolled our first patient in March, but site activation and enrollment have picked up nicely since then. We also expect the EVAS mortality data that was announced last week at the Charing Cross Meeting to drive interest in the EVAS2 study. Based on anticipated enrollment, follow-up and typical regulatory review timelines, we continue to estimate the decision on our PMA by the end of 2020.

Turning now to ChEVAS, we are in discussions with the FDA regarding our IDE trial design and have also filed our design dossier for the ChEVAS CE mark for European approval. We expect to be able to provide a more complete update on the status and timing of each of these programs on our next earnings call in early August.

Now, moving on to our first quarter financial results, our total revenue for the first quarter 2018 was $42.3 million, a 0.8% decrease from $42.6 million in the first quarter of 2017. We saw a stronger than expected growth in our OUS markets with double-digit growth rates in AFX.

Ovation had another strong quarter with sequential and year-over-year growth in the U.S. U.S. revenue for the first quarter of 2018 decreased 4.9% to $29.4 million compared to $30.9 million a year ago, as the decline in our AFX business was partially offset by continued growth in our Ovation business. Our AFX business continue to be impacted by slower than expected sales recapture but the business is stabilizing. We also saw some cannibalization of our AFX business during the quarter due to a special incentive program to sell Ovation in the U.S. market.

First quarter international revenue increased 10.1% on a reported basis to $12.9 million compared to $11.7 million a year ago. On a constant currency basis, our first quarter 2018 international revenue increased 3.3%. As I already mentioned during the quarter, we saw strong growth in AFX in both Europe and CAPLA.

Just a reminder that our comps at the product level continue to be skewed due to the CE mark issue in Europe that resulted in favorable mix for Ovation in the first quarter a year ago and AFX distributor order pushes into the second quarter of 2017. We will see the impact of those shifts in ordering materialize as tougher comps in our second quarter 2018 results.

Our first quarter gross margins came in as expected at 67%, which is 20 basis points lower than last year. We saw pressure on our standard margin driven by a geographic mix due to growth in our OUS business and some investments we are making on the operations side. We were able to partially offset these negative impacts with favorable AFX to absorption-related variances driven by the inventory build last year. These variances will not be recurring.

We have already restructured our Irvine operations to reflect lower AFX volumes in 2018, but expect to see gross margin headwinds for the rest of the year due to anticipated lower volumes in Irvine and our initiatives to reduce global inventories to improve our cash performance.

During the quarter, we continued to manage our operating expenses, which decreased from 6.6% to $41.4 million in the first quarter of 2018, from $44.3 million in the first quarter of 2017. Looking more closely at our first quarter operating expenses, marketing and sales expenses were down 16.1%, research and development expenses decreased 0.6%, and clinical and regulatory expenses decreased 6.9% year-over-year. Offsetting those was a 16.9% increase in our G&A expenses driven by costs related to our CEO search and ongoing litigation expenses.

Net loss for the first quarter of 2018 was $19.8 million or $0.24 per share, compared to a net loss of $21.3 million or $0.26 per share a year ago. Adjusted net loss totaled $12.9 million, compared to an adjusted net loss of $15.3 million for the first quarter of 2017. Endologix reported a negative adjusted EBITDA of $7.8 million for the first quarter of 2018, compared to a negative adjusted EBITDA of $9.8 million for the first quarter 2017.

Moving to the balance sheet, our total cash, cash equivalents, restricted cash were $50.1 million as of March 31, 2018, compared to $60.6 million as of December 31, 2017. Our cash burn for the quarter was approximately $10.5 million, which we are very pleased with.

Since we don't have an immediate need for cash, we put negotiations with respect to the refinancing of our credit facility on hold, as we felt it was important to have input from our new CEO regarding the capital structure of the business. As a result, we have deferred the closing on the facility and now, with John's appointment, we expect to reengage with our lenders on the ABL.

Turning to guidance, we are reaffirming our previously stated revenue guidance range of $170 million to $180 million, representing a decrease of 1% to 6% compared to 2017. We continue to anticipate our full-year 2018 GAAP loss per share in the range of $0.89 to $0.95 per share.

I'd like to note that we will no longer be providing quarterly guidance. This decision shouldn't be viewed as a sign of decreased visibility or a lack of clarity. We provided quarterly guidance at the beginning of 2017 due to the disruption caused by the temporary loss of CE mark for AFX, combined with the ship hold on AFX in the U.S. market. With those disruptions now behind us, we've made the decision to no longer provide quarterly guidance in order to take a longer term focus on the business, both strategically and financially.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Our first question is coming from the line of Joanne Wuensch with BMO. Please go ahead with your question.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yes, hi. This is Matt Henriksson in for Joanne. John, welcome aboard, and quite a first day to be put into line of fire during an earnings call. My first question is kind of, broadly speaking, how do you kind of see your first 100 days with Endologix as CEO? What are kind of the first steps that you want to take? What are the main focuses that you want to put on an emphasis on?

John Onopchenko
Chief Executive Officer, Endologix, Inc.

A

Well, thank you for the welcome, Matt, and I appreciate the empathy. I want to critically focus on the parts of the business that I've not been as intimately involved with due to the design of how we have structured the organization. So I plan to take a significant amount of time immersing myself in the commercial side of the business, getting a detailed appreciation for our people and processes that support demand, prediction and sales execution, seeing our customer interactions, fully appreciating our level of training, the competitive actions that our folks witness daily, the tools we produce to advance our plans on the ground. So my plans include getting into the field and personally meeting with our commercial teams and our customers as part of my formal top to bottom review.

It's also important that I get to know you folks, so please plan on seeing me and getting to know me. I also want to understand the supporting practices that we've established on the commercial side and as they've transferred kind of into supply chain and the rest of the operations' organization. I also need to spend more time with our folks in clinical development and in regulatory affairs and medical affairs, again, by design and under my prior remit. So, that's what the first 100 days looks like.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay, great. That's helpful. And then, just to follow-up with that, Vaseem, I understand that you guys are no longer providing quarterly guidance. But is there any commentary on the cadence for the rest of the year regards to kind of how it was in prior years? And thank you very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Appreciate it. No, Matt, that's a great question here. Listen, I think, as you saw, first quarter we came in slightly better than the consensus and we came in towards the high end of the range, and that's the first quarter that we've had with really no big disruptions, if you will, either internal or external. So, there's really no timing issues on deals, on channel. But the good news here is that Ovation continues to grow nicely and the AFX business is stabilizing. So again, it's the first quarter here in the year and we want to really get some more experience under our belt with the second quarter and get a sense on the total here.

So at this point, we feel very confident about the $170 million to $180 million range that we have out there, but obviously, we have a new CEO and John is going to take a look at the business to his point on the commercial side of the house where he has not been engaged in, and we'll come back to you guys with any changes. So at this point, I feel great about the quarter that we had and we just got to be focused on the rest of the year to deliver our commitments.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay, great. Thank you very much.

Operator: Our next question is coming from the line of Matt O'Brien with Piper Jaffray. Please go ahead with the questions.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Hi, guys. This is Kevin Farshchi on for Matt today. Thanks for taking the questions, and welcome, John. Looking forward to working with you.

John Onopchenko
Chief Executive Officer, Endologix, Inc.

A

Thanks, Kevin.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

My first question is on the U.S. specifically, definitely much better than we expected. Was just wondering any kind of account-specific color you can provide on what AFX was doing with the slower recapture and Ovation adoption. Was it those special incentives for Ovation that you mentioned on the call or is it something more that's resonating with clinicians right now sort of at the account level?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So Kevin, I think as I mentioned earlier, we did have a good quarter in the U.S. And again, in the past, we have talked about messaging to The Street on whether the business is stable or it's stabilizing. And I'd say I'd characterize the U.S. business as stabilizing. AFX was down in the first quarter but we did actually have a pretty good growth on the Ovation product line. And I think to your comment, we have messaged to some of the prior earning call that we actually had a special incentive program this quarter for our guys to start to focus more on Ovation, and we saw some cannibalization. So at this point, I'd say while Ovation did a pretty good job, it was not able to offset the declines in AFX and that it's something that we got to continue to monitor here as we go into the second quarter.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Okay. Thanks so much. And then, just one other one, if I could sneak it in here, you mentioned the cash position. It looked a lot stronger in the quarter. I'm curious, if we can, to hear some of the early thoughts on the position at the moment. And then, is this a similar burn rate we can expect to kind of for the rest of the year?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So, we've actually – we have been focusing a lot on cash. And if you remember, we have said that we focused the last couple of years on non-operating expenses and have done a great job bringing them down from $228 million on a combined basis pre-merger to the $162 million that we delivered last year. And as we kind of think about that, we are looking at every opportunity we have to improve our cash performance. And when you look at what we were doing on an average all of last year, we were in that $10 million to $12 million range. And when you look at the first quarter cash performance, we have $50.1 million in the bank. The burn rate was about $10.5 million, and that $10.5 million actually included a payment to Deerfield for the term loan which was about $2 million. So, you adjust that for that on a year-over-year basis.

Listen, I think we have made some very good improvements on cash. We'll continue to focus on and we have plans right now to reduce our inventories around the globe. So, we expect us to be in that $8 million to $10 million burn rate for the remainder of the year. So, we feel very good about our cash position where we are and with the plans to refinance our ABL, we feel we'll have enough liquidity to run the business comfortably.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Thanks, Vaseem. That's really helpful.

Operator: Okay. Our next question is coming from the line of Matthew Blackman with Stifel. Please go ahead with your questions.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Good afternoon, everyone, and congratulations, John.

John Onopchenko
Chief Executive Officer, Endologix, Inc.

A

Hey, Matt.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

John, I'll spare you questions on this conference call but maybe not so much in upcoming calls. Vaseem, maybe to start with you, just maybe talk about the sales force. And is the sales force stable? Are all the territories filled? I know we talked heading into this one Q that there may be some disruption related to CEO search. Did any of that materialize? Any sort of overarching comments on the sales force would be appreciated. And I have a couple of follow-ups.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So Matt, as we have said that we have factored a certain amount of turnover in our guidance that we had put out there. And it's probably the one watch out that we are continuing to monitor. We saw some attrition in Q1, like we said in the last call, not unusual, normal course of business; and that position continues. But it's something that we got to monitor. And when we talked about the guidance range of $170 million to $180 million, the $170 million was kind of aligned with the thinking that we would have a very stable sales force. And right now, we do

have a few open positions, primarily in the Texas region and a couple of places where we have had some turnover, but nothing at this point to worry about. But it is something that we got to monitor and make sure that ahead of the Alto launch that we have the right commercial footprint, so that when we get the approval for Alto in the U.S., we can actually push the growth curve for the business. And that's a pretty big source of growth for us in 2019.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.
Q

Okay. That makes sense. And then, another one for you, Vaseem. I may have missed the commentary in your prepared remarks about gross margins, but they clearly outperformed at least our projections. How sustainable is this level of gross margin? What were some of the drivers? I think you had called out geographic mix, but just want to be clear on what's going on with the gross margin line. I guess, I'll get my last out. I don't know if Dr. Thompson is there or if anyone can comment...

John Onopchenko
Chief Executive Officer, Endologix, Inc.
A

Yeah, he's right here.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.
Q

Good afternoon, Dr. Thompson.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Hey, Matt.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.
Q

The follow-up question for you would be just on the – I think I heard you – I don't want to confirm I heard Vaseem mention that you filed the ChEVAS CE mark. Did I hear that correctly? Number one.

And if that is the case, just sort of reflecting back on sort of the regulatory process for Alto, is there a risk similar to what we saw with Alto that the body may come back to you and ask for more data or should we look at the signal of a filing as a sort of a level of comfort of what you need to submit and what they're willing to accept? That's all I have. Thanks so much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Thanks, Matt. I'll maybe deal with the clinical questions first, then get you back to gross margins with Vaseem. Yes, you're right. So we filed the design dossier with GMED to look for CE mark on ChEVAS, and that's under review at the moment and we expect to have more news in a few months' time.

In terms of Alto, at the moment, we're still planning on filing the design dossier as described. And we have a level of confidence around the fact that GMED are unlikely to – NSAI, rather, unlikely to want any more information that we'll be submitting to the FDA.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. That makes sense. And, Vaseem, on gross margins?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah, sure. Listen, we ended the quarter at 67% gross margin. Its 20 basis points lower than last year. And when you strip out some of the unusuals, if you will, the operational performance on gross margin was at about 64%, Matt. And the big unusual that we had or the favorability that we saw this quarter came from, if you remember when we had the big AFX inventory issue last year, we had a pretty significant build of inventory. And that build gave us better absorption and, as a result, better manufacturing variances that are running through the P&L here in first quarter and will probably run through the P&L a little bit in the second quarter. But we think that the total year guidance at about – or not that we haven't given a guidance, but we think the mid-60s is a good place to be for the year and we should start to see that come down in the second quarter, third quarter and fourth quarter.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. Thank you so much.

John Onopchenko
Chief Executive Officer, Endologix, Inc.

A

Thanks, Matt.

Operator: Thank you. [Operator Instructions] Our next question comes from the line of Jason Mills with Canaccord. Please go ahead with your questions.

David Rescott
Analyst, Canaccord Genuity, Inc.

Q

Hey, it's Dave Rescott on for Jason Mills. Can you guys hear me all right?

John Onopchenko
Chief Executive Officer, Endologix, Inc.

A

Hey, Dave.

David Rescott
Analyst, Canaccord Genuity, Inc.

Q

Hey. Quickly, first, I guess on the ENCORE study and the data that came out from Charing Cross, can you talk maybe a little bit about how reps – or how you kind of see the conversations changing or what kind of the data is being presented as far as using that data to drive sales and as far as what kind of feedback you've been hearing from physicians on this?

And then, maybe as far as looking at Ovation, AFX selling, I know kind of you mentioned that Ovation was kind of cannibalizing AFX sales. Have you kind of broken that out at all seeing or quantifying how much of the sales innovation has come from cannibalizing AFX. And if we think about the Ovation product, are a lot of the sales coming from existing AFX accounts or are they coming from new accounts opening? And then a follow-up as well.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So let me take some of the financial pieces, and then I'll hand it over to Matt to comment about the data and what's being talked about and how we are leveraging the data. Listen, first of all, the all-cause mortality data that was presented at Charing Cross, we feel that while it will not meaningfully change the Nellix business in Europe, it will at least provide a shot in the arm or put some base, if you will, into that business. And we have a message that when we did product line reporting at the end of the year, that we were expecting a flat Nellix business year-over-year, okay? So that's about Nellix.

On ENCORE, we have taken the data and we have operation license and we'll start to have those conversations. And it's aligned with the guidance range that we're talking about, which is the $170 million to $180 million. The $180 million reflects some pretty nice uplift because of the ENCORE data, and more importantly, just the growth of Ovation for us to make our number. So again, these are meaningful datasets that will help the commercial organizations but we don't expect it to really be a pretty big step up from where we are. And it's also dependent on how well it's received and our ability to really drive some change and some call points with the data.

But in terms of what the data was, I think I'll let Matt comment on where – how it's being used. The last point, I know you asked the question. Listen, we have not given product line details. And the best thing I can give you is that in the first quarter, we did see some cannibalization in the U.S. business with Ovation and AFX because we were, I think, [ph] gathering (32:11) our teams for Ovation. It's too early to kind of go back and start to do account level analysis and give you those details. And again, we have decided that we're not providing product line details. So, we'll give you more color on the direction on where it's going, but we clearly did see some cannibalization in Q1.

So Matt, I'll pass it to you.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hi, Dave. So in terms of the ENCORE data, so I think if you go to a lot of the international meetings that have been held in the last 6 to 12 months, then the big issue around EVAR is the long-term durability. So, the ENCORE data is very important for the Ovation platform. As you know, it has a different mechanism of action to the other endografts which are largely predicated on self-expanding metal frames covered with fabric, Ovation seals with a polymer ring in the neck. And there's always been questions around which one of those methodologies is likely to give you the most durable outcome.

So for me, I think the most important heads-up finding from the ENCORE database is the durability of the proximal seal resulting in very few Type I endoleak, so naturally a rate of aneurism-related mortality that would stand comparison with any previous studies.

So, I think that gives us a great deal of assurance around the durability of the platform with the EVAR studies we generally tended to see in nutrition in aneurysm-related mortality after three years. So, the fact that we still got 1% rate of aneurysm-related mortality out of five years actually is hugely reassuring for the platform. So that, in addition to the very low limb thrombosis right in the high applicability, and it gives us a very nice talk track for the durability of that platform going forward.

David Rescott
Analyst, Canaccord Genuity, Inc.

Q

All right. Thanks. Then, quickly, a one follow-up, just if we think about kind of the balance sheet cash flow statement kind of $8 million to $10 million a quarter, $50 million left in the balance sheet, is the breakeven where cash flow positive still what you're thinking about in the second half of 2019, s that still the guidance?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

That's still unchanged. And as we have said in the past, the big driver of that is going to be how well we are able to execute with Alto, the launch and the timing of that. And at this point, assuming that it launches on time in 2019 we just planned for, we feel comfortable with the second half breakeven on cash flow.

David Rescott
Analyst, Canaccord Genuity, Inc.

Q

Okay. And then, directionally, I know you kind of mentioned OpEx being more or less flat for the next year. Would we assume that the gross margins would be directionally up in 2019?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Again, the simple way to think about it is for every $5 million of top line impact, we see our gross margins expanding by a point.

David Rescott
Analyst, Canaccord Genuity, Inc.

Q

Great. Thanks. I'll hop back in queue.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. Welcome.

Operator: Thank you. We've reached the end of our question-and-answer session. I'd like to turn the floor back over to management for closing comments.

Daniel T. Lemaitre
Chairman, Endologix, Inc.

Okay. Thank you, Brenda, and thank you, everyone, for joining us on the call this afternoon and for your interest in Endologix. Have a good day.

Operator: Thank you. Ladies and gentlemen, this concludes today's teleconference. You may disconnect your lines at this time and thank you for your participation.