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Endologix, Inc. (ELGX)

Q1 2017 Earnings Call

CORPORATE PARTICIPANTS

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Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

OTHER PARTICIPANTS

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Chris Cooley
Analyst, Stephens, Inc.

Chris Pasquale
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Joanne Karen Wuensch
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Glenn John Novarro
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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Incorporated First Quarter 2017 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] And as a reminder, this conference call is being recorded. This conference call is also being broadcast live over the Internet at the Investor section of the company's website at www.endologix.com. And a replay of the call will be available on the company's website for one year.

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 material risks and uncertainties. For a discussion of risk factors, I encourage you to review the Endologix Annual Report on Form 10-K and subsequent reports also filed 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 4, 2017. 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 John McDermott, Endologix's Chief Executive Officer. Mr. McDermott.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon, everyone. Thank you for joining us for Endologix's first quarter 2017 earnings call. This afternoon, I'll provide a brief overview of our first quarter results and key business updates. I will then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our first quarter financial results and 2017 financial guidance in more detail. Then I'll open up the call to questions.

As an administrative note, we have posted our slide deck on our Investor Relations website and would point out that the only change in the deck is Slide 17, where we have provided our revenue guidance range for the second quarter.

Turning now to results, we're pleased with our accomplishments during the first quarter and our solid start to the year. Global revenue in the first quarter was $42.6 million, which represented an increase of 0.6% over the last year. During the quarter, we drove significant growth with Ovation and experienced softness in AFX2 due to the manufacturing issue and temporary CE Mark suspension. Nellix sales were lower due to the narrowed indication, but in line with our expectations.

Our U.S. revenue in the first quarter was $30.9 million an increase of 3.4% compared to the first quarter of 2016 as we continue to drive adoption of Ovation in our existing accounts. The strong Ovation growth was tempered by lower sales of AFX2 due to the manufacturing issue that has temporarily constrained our inventory. We're implementing additional testing and process improvements in the manufacturing lines for AFX2 and expect to return to a normal supply of AFX2 in the second half of the year.

I'd like to take this opportunity to thank our customers for their support and patience, while we work through this temporary issue and to reiterate our commitment to patient safety and innovation. Outside of the U.S., our first quarter revenue was $11.7 million, a 6.2% decrease from the first quarter of 2016. This decrease is a result of a narrowed Nellix IFU and a temporary AFX CE Mark suspension that was reinstated January 25th of this year. On a constant currency basis, our first quarter international revenues declined 3.9% year-over-year.

Now, turning to our product pipeline, I'd like to give you an update on our key programs. Later this month, we will meet with the FDA to review the Nellix two-year IDE results and also provide them with additional clinical evidence to demonstrate the effectiveness of the new IFU.

On June 3, Dr. Jeffery Carpenter will present the Nellix two-year IDE results at SVS. After his presentation, we will host an Investor Call to review the presentation in more detail.

Turning now to Nellix ChEVAS, there were several positive podium presentations last week at the Charing Cross meeting in London and we are on track to submit our designed RPA within the next couple of months. If everything goes according to plan, we could have CE mark for Nellix ChEVAS by the end of this year.

Regarding the ChEVAS IDE, we plan to confirm the requirements in timeline with the FDA this summer, but first want to make sure we have a common understanding of the past the PMA approval with Nellix and the new IFU.

On March 31, we began enrollment of our ELEVATE IDE study which is a 75 patient trial designed to demonstrate the efficacy of the Ovation Alto systems. We expect to complete enrollment by the end of this year, which sets us up for a potential FDA approval in early 2019. With also CE Mark, we are still exchanging information with our notified body in Europe, and don't yet have an updated approval timeline.

Another important milestone for Ovation will be the presentation of the LUCY clinical study results at SVS on May 31. LUCY is the first prospective multi-centered clinical study designed to evaluate the use of EVAR to treat it historically, underserved female population. We believe Ovation will enable physicians to treat female aneurysm patients more effectively and we report to sharing the results from this landmark clinical study with medical community at the end of this month.

With that, I'll now turn the call over to Vaseem to review the company's financial results and 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 first quarter of 2017 was $42.6 million, a 0.6% increase compared to $42.4 million in the first quarter of 2016. The U.S. revenue increased 3.4% to $30.9 million compared to $29.9 million a year ago. This represents a solid performance by the U.S. team despite the supply issues with AFX2. We saw a continued strong grant in the Ovation product line validating our investments in training and certification that we have made thus far. International revenue decreased 6.2% to $11.7 million on a reported basis with strong performance in Asia-Pac and Latin America.

Our European markets faired as expected. We were thrilled to see our Ovation business continued to gain traction in Europe during the quarter growing double digits year-over-year. On a constant currency basis, first quarter of 2017 international revenue decreased 3.9%. Our first quarter gross margin expanded 120 basis points to 67.2% compared to 66% in the first quarter of 2016. Adjusting the Q1 2016 gross margins to 71.1% to account for the purchase price related adjustment of $2.2 million inventory step-up our margins declined 390 basis points year-over-year. This decrease which is already reflected in our guidance was driven primarily by lower absorption due to lower production volume in Q1 2017.

Looking forward, we are on track to deliver our gross margins of 64% as indicated on our earnings call last quarter.

As we continue to successfully manage our cost and drive synergy commitments, our operating expenses decreased significantly year-over-year. Our total operating expense were $44.3 million in the first quarter of 2017, compared to $66.3 million in the first quarter of 2016. First quarter 2016, operating expenses included $12.1 million of expenses related to the TriVascular merger and $4.7 million of litigation settlement costs. Excluding these items, operating expenses in the first quarter of 2017 were $5.5 million, lower than the prior year period, a decline of 11% driven primarily by cost synergies related to the TriVascular merger.

Looking more closely at our operating expenses, marketing and sales expenses were down 7.2%. G&A decreased 10.8%, research and development expenses decreased 29.5%, and clinical and regulatory expenses were relatively unchanged year-over-year. This is a reflection of our synergy were completed to date, and the results of cost actions and spending controls we have implemented.

On R&D specifically, the reductions are a results of synergy projects and the timing of project expenses. We continue to invest in our key projects and our long-term product roadmap and we'll see a higher R&D run rate for the remainder of the year.

Our net loss for the first quarter of 2017 was $21.3 million or $0.26 per share compared to a net loss of $47.7 million or $0.62 per share a year ago. Adjusted net loss totaled $15.3 million, compared to an adjusted net loss of $19.3 million for the first quarter of 2016. We reported a negative adjusted EBITDA of $9.8 million for the first quarter of 2017, compared to a negative adjusted EBITDA of $14.1 million for the first quarter of 2016.

Moving to the balance sheet, our cash, cash equivalents, restricted cash and marketable securities were $36 million as of March 31, 2017, compared to $49.1 million as of December 31, 2016. As a reminder on April 4, we entered into an agreement with Deerfield Management a leading healthcare investment organization to provide us

with up to $170 million in funding to a $120 million six-year secured term loan and a $50 million three-year secured asset based revolving line of credit.

We have so far retired $68 million of the $86 million outstanding 2018 notes. We will use the remaining net proceeds from the term loan, for working capital and general corporate purposes and any additional redemptions of the 2018 notes payable.

Now turning onto guidance. For 2017, we had reconfirmed our previously issued revenue guidance and continue to anticipate 2017 revenue to be in the range of $193 million to $200 million representing reported growth of 0% to 4% and a constant currency of 2% to 5% growth compared to 2016.

For the full year 2017, we now anticipate GAAP loss per share of $0.83 to $0.89 per share, a revision from our prior guidance of GAAP loss per share of $0.70 to $0.76 per share. This revised guidance has been updated primarily to reflect the increased interest expense and debt extinguishment charges related to the recently announced credit agreement with Deerfield.

This range does not reflect, or this range does reflect the already captured and ongoing synergies from the merger, which positions us to reaffirm our full year 2017 operating expenses, in the range of $170 million to $175 million.

While we did better than expected in the first quarter and our confident in our full year guidance, we expect second quarter revenue in the range of $47 million to $48 million. This is lower than the $50 million target we communicated previously primarily due to AFX2 product availability in the current quarter.

Based on our first quarter experience, we are confident that the demand for AFX2 and Endologix's products is strong, but it will take another quarter to build and test enough AFX2 large diameter devices to satisfy demand. The impact of this will be felt primarily in the U.S. market where we had already transitioned to AFX2 early last year.

In summary, we have made good progress with AFX2 over the past few months and are particularly pleased with the growth and adoption of Ovation globally. We are also encouraged by the excellent clinical outcomes with the new IFU for Nellix and we look forward to sharing the two year results at the SVS next month. We will continue to build on our first quarter accomplishments and grow the business sequentially in future quarters.

And now, I would like to turn the call back to the operator for Q&A. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you. We'll now be conducting a question-and-answer session. [Operator Instructions] Our first question comes from the line of Ravi Misra with Leerink Partners. Please proceed with your question.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Hi. Thank you for taking the question. Can you hear me?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hello, Ravi.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Hi, Vaseem, Hi, John. So just wanted to talk a little bit more about the 2Q guide down and the AFX supply issue. Can you just, is that – should we be thinking about that in the sense of basically you're putting the revenue into 3Q that was not going to be realized in 2Q or is there anything more to that? Then I have a question on the gross margin performance.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Well. Specifically what's changed slightly from our original expectation, it's just taken us a little longer than planned to implement the test and run them through the regulatory process, but we've made some great progress and feel very good about getting back online in the second half. So, I wouldn't necessarily think it's just going to shift into Q3. There is going to be some slight case loss in Q2, which is what we're adjusting for. That said, we still feel confident about hitting the full-year guidance of $193 million to $200 million, we think we can clearly make that up with anticipated growth in the second half.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Great, thanks. And then just on the gross margin performance, very, very stronger versus consensus. You are still reiterating full-year guidance. Can you maybe talk through about how we should be thinking about that for the remainder of the year, I mean that implies a pretty big step down I think versus consensus. I think you're originally saying that the 2Q number should be coming down with these testing issues that might be happening. I suspect there might be a little bit more. But can you please maybe help with the ramp?

And then just maybe one last one on Nellix and AFX actually rather. Can you just, you gave about a year ago just how many centers were performing those procedures at about 900 or so, can we just get an updated number on

that and how that may have changed over the last three to four months based on these disruptions in prices? Thank you.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.
A

Yes. Let me start with the last part of the question and I'll hand it over to Vaseem for the margins. You might recall also well that we communicated that we would stop providing kind of account level detail. So, I'm not going to give you any updated information on those former numbers. Those were also I think premerger, I'm not sure exactly that when the dating on that 900 some number, Ravi, but we don't really see account loss. I would say during the disruption we've just unfortunately been unable to supply some of the physicians with the AFX2 and we're trying hard to pivot them to AFX1 and Ovation. But we'll see a little bit of softness in Q2 and then expect to have that behind us and good growth in the second half.

So, with that, I'll turn it over to Vaseem for the margin question.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Sure. So, Ravi, just to level set here. Last year, the reported margins were 66%, we had that $2.2 million of inventory itself but that got us to about 71% on an operational basis. And right now we reported 67.2%, now there is a couple of things that are happening here. One is – it is stronger than expected and I think part of that is better mix because U.S. came in a lot of stronger than we expected. And second, the reason the guidance kind of lowers down as the sampling impact of $2 million that we have talked about has started to kind of kick in here in the second quarter and then kind of extend a little bit into Q3 and into Q3 that's primarily coming for some mix changes on AFX1 to AFX2, because we've had such a significant change in terms of supply chain. So, we are still on track between the 64% gross margin number and the Q1 number is just a little bit more strength on the heels of a strong U.S. number for AFX.

Ravi Misra
Analyst, Leerink Partners LLC
Q

Thanks for taking the questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

No problem.

Operator: Our next question comes from the line of Chris Cooley from Stephens. Please proceed with your question.

Chris Cooley
Analyst, Stephens, Inc.
Q

Good afternoon, John and Vaseem. Thanks for taking the questions. Can you hear me, okay?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.
A

Hey, Chris.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. Hey, Chris.

Chris Cooley
Analyst, Stephens, Inc.

Q

Super. If I could just start looking at the core EVAR portfolio at Charing Cross last week, there was a discussion about polymer-based devices in general having some potential incremental clinical utility. And you commented in your prepared remarks about Ovation being stronger in the quarterly period realize, you probably don't want to parse it out between AFX and Ovation, but just given some of the data that was presented in that discussion at Charing Cross last week and the strength you are seeing in that device. Does that alter in any way at all, how you think about the core EVAR portfolio, it's growth potential going forward once AFX2 is fully back up in terms of its availability. And I have just one quick follow-up.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, Chris. Cleary, the utilization of polymers offering some advantages that I think clinicians are just now starting to appreciate in particular this absence of aortic neck dilation, so without applying ongoing outward radial force to the neck, we're not seeing a kind of neck expansion that could see with other traditional devices. That together with a very low-profile of the Ovation device is gaining some momentum. And as our sales team gathers more and more experience and confidence, that's why we're seeing such good growth.

So, I do think from the time we did the merger until today, we are getting more and more bullish about the Ovation platform and with Alto around the corner, it looks very promising. So it's encouraging, it's very encouraging.

Chris Cooley
Analyst, Stephens, Inc.

Q

Great. Thanks. And then maybe just as a quick follow-up. I realized this is still little bit early, but could you just provide us any, maybe in broad strokes the level of confidence or why your may not domestic regarding the Nellix? And it's potential to move forward even though you're going to have to essentially be doing a retrospective look at that two year data? And just any – maybe any color you can provide in terms of your discussions with the agency at this point? Thank you.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Sure. Well, we have ongoing dialog with FDA and are providing them with all of the main meeting materials in advance and of course we expect to get their feedback after they've had a chance to review those materials when we meet later this month. That said, as you've seen from the more recent presentations, the capital may occur look favorable for the new IFU, that together with analysis that we've performed now on the EVAS Global Registry continues to provide us with a lot of encouragement that the new IFU is effective.

So, we're not going to know until we get face to face with the agency here in a few weeks, but we like the way this is coming together and we'll just have to see if they agree that the two year data looks really good and we can proceed as planned.

Chris Cooley
Analyst, Stephens, Inc.

Q

Understood. Congratulations again on the good quarter.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, Chris.

Operator: Our next question comes from the line of Chris Pasquale from Guggenheim. Please proceed with your question.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. John, that FDA meeting is going to be a pretty important event for the company. How are you thinking about what public disclosure requirements there might be depending on the outcome and how you might communicate that to the Street?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. Our view is that if the timelines don't change, the anticipated timelines don't change we wouldn't necessarily have any kind of disclosure following that meeting. If we come out of that meeting and we feel like the expected timelines for the program is different than what's already expected then we would provide some kind of communication.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Absent any change than what we would do is provide some kind of an update on our June 3rd conference call, when we go through the Nellix two year data after SVS.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay. And you've planned to analyze some European Nellix data using the revised IFU to help validate the recut IDE dataset. Do you have those results at this point? Can you share anything about that analysis with us?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. What we have done is look at the patients from the EVAS Global Registry, so recall that the 300 patient study that we presented two year follow-up on at VEITHsymposium in November. So, we've been gathering CT images and site reported data and I have seen a very similar type of outcomes between the on and off IFU patients that we've been able to gather data on.

Recall that's kind of a post-market registry, it doesn't have the same kind of imaging rigor. So, for the images in the site reported events, we've been able to capture it, it looks very similar to what we see with the IDE, so that's one validation. Another is we've mentioned that we're working with a group of physicians in Holland, who are gathering up about 300 patients and applying the new IFU to their data retrospectively. We have not seen that data yet, that's an arm's length transaction. They've got the protocol, they are doing all of that analysis independently, so we expect to get that in June, we haven't seen that yet.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay. And then the last one for me. Can you just give us an update on where the sales force stands today? As all the back and forth over the last few months caused any increased turnover for you guys?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. The sales teams have been relatively stable. We have had a bit of turnover, but still remained below the industry averages and have a very good team on the ground.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Great. Thanks, John.

Operator: Our next question comes from the line Joanne Wuensch from BMO Capital Markets. Please proceed with you question.

Joanne Karen Wuensch
Analyst, BMO Capital Markets (United States)

Q

Hi. Thank you so much for taking the question. Can I circle back please to the reintroduction of AFX and the somewhat lower guidance for the second quarter. What exactly are the steps to get that back to sort of full throttle and which would increase our comfort level or confidence in the second half goals?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. So specifically Joanne, we were implementing some new testing methods on the line and just working through a regulatory process to get those implemented and then once that done we've already started to scale up the manufacturing. We just need this new testing methodology to be able to start releasing greater volumes of products. So we're through the root cause and all of those activities now we're just kind of in the later stages of the regulatory process, and hope to get that resolved here this quarter.

Joanne Karen Wuensch
Analyst, BMO Capital Markets (United States)

Q

But when you say regulatory process, is there a step for FDA approval?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. We're gaining concurrence from FDA on our new testing methodology.

Joanne Karen Wuensch
Analyst, BMO Capital Markets (United States)

Q

Okay. And is there – how should we – let me revert this – in addition to the data at SVS, I was about to say what else other than that data which seems silly, what other data should we be looking for this year maybe at these or other meetings that will sort of help us get a better feel for your pipeline? Thank you.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Sure. Well, so SVS will be the two year Nellix data, which I think will be helpful, in terms of understanding the effectiveness of the IFU then there will likely be some additional presentations over the remainder of the year. We haven't decided which meetings and who will the presenters be, which will show further validation, we expect with the registry as well as the Dutch dataset. I think you'll start hearing more and more about what seems to be an early trend in all-cause mortality benefit for Nellix.

So, we've got several hundred patients out now three years and we're starting to see what looks like a sustained trend in mortality benefit with Nellix over traditional EVAR devices. So, there will probably be some more presentations about that. As it relates to Ovation, we're very excited about the release of the initial LUCY data on May 31, at SVS, so that's going to be the first time. There has really been a critical evaluation of EVAR in between men and women. And so stay tuned for those results and then probably more Ovation clinical data presented at another meeting later in the fall. We probably won't have any LEOPARD clinical data yet for this year, but those are the highlights of the new clinical data and the pipeline for the rest of this year.

Joanne Karen Wuensch
Analyst, BMO Capital Markets (United States)

Q

Thank you so much.

Operator: Our next question comes from the line of Michael Weinstein from JP Morgan. Please proceed with your question.

Q

Hey guys, this is actually Andrew in for Mike. Thanks for taking the question.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hi, Andrew.

Q

Hey. I wanted to start off, there is a lot of moving pieces in the OUS business and I just wanted to go through some of them just to get some incremental color on some of the pushes and pulls, specifically in Europe. So, it

sounds like Ovation Alto is pushed out a bit, you had the reinstatement of AFX in January, so are you seeing any – can you just sort of quantify what the impact was in the quarter?

And John, you also said that Nellix was in line with your expectation, but how do we think about being in line and what it – how did Ovation performed out in the field to help offset some of these challenges.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So let me take the first part of it and then, I'll let John go on the Ovation piece. I think on the impact of the reinstatement, if you remember we got the approval in January 25, so we essentially lost a month of AFX units. And what's reflected into our guidance now as we had communicated about $1 million on our step up is coming from getting that one month back here in the second quarter. So it's about $1 million to put that into perspective.

Now, also remember that when we had given out the guidance and we had explained the step up from the $41 million as expected number for Q1 to Q2, we had talked about this AFX2 issue where we had said that $4 million of the step up from $41 million to $50 million was going to come from the seasonality of it, $2 million of it was going to be the carryover for the orders in Q4 and then $1 million on the CE mark. And then the last piece was this AFX2 impact $50 million. So, now, as John mentioned, all of these manufacturing changes that we are making and working through the regulatory process that has gotten pushed to later in the quarter in June. So, that's the reason we're walking down from $50 million to $47 million. But we feel very confident about Ovation, we had a solid quarter on Ovation in Q1 and then expect continued strength on that portfolio. And I'll let John comment on that.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, before I touch on Ovation, Andrew, just another piece of information. So, we talked about getting AFX2 approved in Japan, so that has happened, so that, that should have some positive impact for us in the second half as is just yesterday we actually received reimbursement approval in France for AFX2. So, after the summer holiday, we'll start with AFX2 in France.

So, AFX2 is actually teed up to have a very good second half of the year. And then for Ovation, honestly, we've seen growth globally, almost every market has – as the legacy Endologix team has gotten up to speed with the product, I think, almost without exception we've seen nice sequential growth. And I don't see any reason that that shouldn't continue. We're getting very good clinical outcomes acutely and there is a growing amount of long-term clinical evidence and it's got the broadest IFU of any infrarenal EVAR device.

So, it's a nice combination of sales team getting up to speed and a very well performing product. So, we're pretty bullish with the Ovation outlook and it looks like there is some good things happening with AFX2 in the second half and then I just add to that, go back to Nellix and say, with these results that will be presented at SVS in this continued trend toward a mortality benefit, we also think, we should be able to get some growth going in the second half from Nellix. So it's kind of a choppy first half, but we remain bullish on the guidance for the full year, based on those variables.

Q

Got it. Congrats on the approvals. When do you expect reimbursement on AFX2 in Japan?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Well, we're – we've got the approval now, we're just – we just need to build the inventory, get through our system and...

Q

Okay.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

They need enough, as I know, you're familiar in Japan, they need – they just want to make sure that, they've got plenty of stock before they launch. Our partner, Japan Lifeline has been very, very successful with first-generation AFX and we want to just make sure, we've got plenty of inventory for them to be even more successful with AFX2. So sometime in the second half.

Q

Got it. And then I just have two others, I just rail them off real quick. So in the U.S., what specifically drove the outperformance in the quarter? And then, just to dig into a question that was asked previously on sales rep turnover, is there any particular geography in which you're seeing higher levels versus others?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes. So the first part of your question, outperformance in the U.S. was really Ovation. It really was the key driver. And as I said, it's a combination of good outcomes. The reps are building confidence, doing a great job and there has just been a nice steady stream of positive clinical evidence to support the platform.

So we've also – the other thing that I didn't mention is, we've started Alto IDE and there is a growing awareness about the next-generation platform that's in the pipeline for Ovation, so I think, that's building some awareness as well. As it relates to sales force, no, no there hasn't been any geographic to just kind of here and there nothing I would say outside of the ordinary.

Q

Thank you.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

You're welcome.

Operator: Our next question comes from the line Mathew Blackman from Stifel. Please proceed with your question.

Matt Blackman

Q

Good afternoon, John, Vaseem.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Hey, Matt.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hey, Matt.

Matt Blackman

Q

Vaseem, I just want to go back to the guidance very quickly for the second quarter and make sure I've heard you correctly. So we should think of this provision not as a loss of AFX procedure demand, but purely a lack of supply or limited supply is that the right way to think about it?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. It's a limited supply, Matt, absolutely.

Matt Blackman

Q

Okay. And then John, for you, something you just go over the data you hope to submit to FDA for now, just a little bit more detail. And I wanted to start on the U.S. trial. if I look at the capital minor curves that the add risk numbers, the on-label populations about 131, if I'm reading it correctly. So are you going to be able to submit to FDA in that package at the end of June 130 patients on the new IFU label? Is that the right way to look at it? And then just a quick couple of follow-ups.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Well, we're going to submit Matt, on a full 333 patient data set, all of the patients that have gotten out two years. I don't know what that exact number is, I don't have those notes in front of me right now, but it will be all of the patients that we have about two years and then split between the two buckets. So, on the new IFU and all other patients that fall outside of the new IFU.

Matt Blackman

Q

Okay.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

In addition to that data we will be providing the analysis of the data that we've gathered from the EVAS Global Registry. We won't have the Dutch data for the May meeting, but we will have that available for the submission that goes in June, but we'll talk to them about the process that we're using with the Dutch data as another method to validate the IFU effectiveness.

Matt Blackman

Q

Okay. And then on the registry and the Dutch study, I think we're – all of us sitting here, we could come up with multiple reasons why FDA may not accept that as supplemental data. I'm just curious, I know it's a little bit tricky, can you give us some sort of preview of your argument as to why those datasets are important and should be looked at in the same lens as the U.S. IDE trial.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Well, they probably shouldn't, in fairness be viewed as in the same lens as the IDE trial because the IDE study has got very good imaging. So admittedly these are retrospective analysis, but the reason I think they are useful is that they're all being analyzed independently and they're coming out to the very similar conclusion. So if we saw these different datasets and they were all getting different answers, it would be much more confusing, but in fact these different datasets are all landing around the same place.

So, is it going to enough for FDA? Obviously we don't know that for sure, but it would appear to us that the work that's been done is confirming that the new IFU was effective and hopefully they will agree. I mean between the 333 patients, the global registry and the Dutch, you've got over 900 patients and we'll see if that – that's going to be enough.

Matt Blackman

Q

Okay. That makes sense. And then my last question. Is there any way to tease out, how much of this Ovation momentum has been let's call it de novo demand versus just back throwing for AFX procedures that you're missing because of supply?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, it's good question. We've looked at it pretty carefully Matt and the feedback from the field is that, the good bit of this growth has come from expansion in existing accounts, when we talk to, the folks on the ground it looks like there is real growth occurring in legacy AFX accounts beyond just backfill. And the nice thing about Ovation as we've talked about before and as you know already is that it's got a broader IFU. So, actually have the potential to get more cases in even existing accounts with the transition to Ovation, so it's encouraging.

Matt Blackman

Q

Okay. Thanks very much, guys. Congratulations on a good quarter.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, Matt.

Operator: Our next question comes from the line of Glenn Novarro with RBC Capital Markets. Please proceed with your question.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay. Hey, thanks guys for taking my question.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Hi, Glenn.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Hi. I wanted to go back to the graph you have in the deck, with – that's just preliminary two-year Nellix data, and this is data that you stated as of February 2, so we're going to get at SVS, more patients in the follow-up. So, my question is, is there any risk that the – with under the new IFU the freedom from endoleak and sack expansion and migration. Is there any risk that that number gets worse? And, so that's question one.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

I guess there is some risk although, Glenn, I guess what I'd do is point out to you that these data in this slide in our presentation, it's online right now, are very similar to what was presented back in November. So we had a limited number of patients at that time, and we're able to show differences that are very comparable. So, well, it's possible that the numbers will look slightly different heading into SVS, so wouldn't expect them to be materially different.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay. Good. Good, good. And then, Nellix in Europe under the new IFU, I know you've got away from talking about Nellix sales and so forth, but maybe can you qualitatively talk about what Nellix demand looks like in Europe under the IFU? And based on what you're seeing in terms of demand in Europe under the new IFU, are you still confident in the market opportunity for Nellix? And in terms of market opportunity, again I'm going back to your slide deck, and I think its Slide 13 where you talk about what you're seeing the market opportunity is for Nellix? Thanks.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. I would say, what we experienced in the first quarter was still some, what I'd call settling into the new IFU, and in particular of physicians, the early adopters of Nellix were very enthusiastic about using it outside of IFU to solve problems that they couldn't solve with other devices.

So, as physicians now are embracing the new IFU, and seeing the results, I think there is a – there's a keen interest in continuing to use Nellix even if it is for a smaller subset of patients. And as I said earlier, I think that

two-year data at SVS and the subsequent data that we'll present over the course of the year should enable us to build some momentum off this reset base of Nellix.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay, great. Thanks. Thank you for taking my questions.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

You bet.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, Glenn.

Operator: [Operator Instructions] Our next question is a follow-up question from the line of Ravi Misra from Leerink Partners. Please proceed with your question.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Hi, thank you for taking the follow-up. I just wanted to get a little bit more in-depth on that Nellix, ChEVAS opportunity in Europe especially given the patient stratification commentaries that you just answered in Glenn's question. Should we be thinking of kind of the initial rollout as addressing the – for a lack of better word, the lost cases in the – under the prior IFU or do you guys really see this as going enable to get even more incremental cases beyond that? And if so, how quickly do you think, that adoption could ramp? And also just one last one, ASP differences on ChEVAS, any differences that we should contemplate in our models versus Nellix?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, so ChEVAS will address the different patient population. It won't recapture the patients that fall out of IFU in the traditional segment, it will open up access to the complex market, which is important because that market has got the most unmet needs. So I think of ChEVAS is really opening up the complex market, which is that one-third of patients that really don't have very good EVAR alternatives today.

As for the ASPs, I think, you should for modeling purposes at this point just view them as similar to the infrarenal alert. There maybe, some pricing upside for us in the future, as we integrate a branch device into our portfolio, but out of the gate I would just use the same. And then in terms of adoption, we plan to go pretty slowly and methodically and just make sure that each individual physician has very positive experience and the patients are very, very well treated, so we'll go pretty slowly, I wouldn't expect any a real steep ramp but we are seeing signs that can be very durable, good procedure, great alternative to fenestrate it. So we think it's going to be a winner, but we just want to take our time and do it right and that will be the approach.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Thank you.

Operator: There are no further questions left in the queue. I'd like to hand the call back over to management for closing comments.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Okay. Well. Thank you, operator and thanks to everyone for joining us on the call this afternoon. We're pleased with our solid start to the year and look forward to updating you again on our next call which is scheduled for June 3. Have a great evening.

Operator: Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time. And have a wonderful day.