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ELGX - Q3 2016 Endologix Inc Earnings Call

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## PRESENTATION

### Operator

Greetings, and welcome to the Endologix Incorporated Third Quarter 2016 Earnings Conference Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. (Operator Instructions).

As a reminder, this conference is being recorded. I would now like to turn the conference over to your host, Zack Kubow of The Ruth Group. Thank you. Please begin.

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### Zack Kubow - The Ruth Group - IR

Thanks, Operator. And thanks, everyone, for participating in today's call. Joining me from the Company are John McDermott, Chief Executive Officer; and Vaseem Mahboob, Chief Financial Officer. This call is also being broadcast live over the internet at [www.endologix.com](http://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's Annual Report on Form 10-K and subsequent reports as 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, November 1, 2016. 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 would now like to turn the call over to John.

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**John McDermott** - Endologix Inc. - Chairman and CEO

Thanks, Zack. And good afternoon, everyone. And thank you for joining us today for Endologix's third quarter 2016 conference call. This afternoon I'll provide a brief overview of our third quarter results and key business updates. Then I'll turn the call over to our Chief Financial Officer, Vaseem Mahboob, for a review of our third quarter financial results, our 2016 guidance, and an update on our synergy plans in the TriVascular merger. After Vaseem, I'll come back on to provide an overview of our top priorities, and then we'll open up the call for questions.

Starting with the third quarter, global revenue was \$52.1 million, representing 10% pro forma constant currency growth, and the third consecutive quarter of good top-line results following the merger with TriVascular. These results are due to a successful merger integration, which is now mostly behind us, along with our broad and innovative product portfolio, supported by our high-caliber sales, clinical, marketing and medical affairs professionals.

In the US, revenue was \$36.3 million, representing pro forma growth of 9%. During the quarter, we continued to benefit from the launch of AFX2, which began in the second quarter. We also made excellent progress in the training and certification of our US sales team on Ovation, and now have over 80% of the team certified. This keeps us on track to have the entire US team certified on Ovation by the end of the year, which is particularly important given the very positive results from the Ovation LIFE study that we announced at VIVA a few weeks ago.

Highlights from this 250-patient multi-center study include a low 30-day major adverse event rate of 0.4%, which is the lowest ever reported in the history of endovascular aneurysm repair. No ruptures, no conversions or secondary interventions, a 99% freedom from type 1 endo leaks, and a 30-day EVAR hospitalization readmission rate of 1.6%, which compares to 8% from the American College of Surgeon's National Surgical Quality Improvement Program. These results are outstanding, and we think will help drive the adoption of Ovation in the US and other markets over the next year.

Outside of the US, our third quarter revenue was \$15.8 million, representing constant currency pro forma growth of 12%, which compares to international market growth of about 6%. During the quarter we also treated the first patients with the Ovation Alto System in New Zealand. This represents an important milestone toward bringing this next-generation version of Ovation to the market.

Ovation Alto has the potential to expand the addressable EVAR market by treating AAA patients with short and challenging aortic necks, which represent a meaningful segment of the underserved complex AAA market. When available, Ovation Alto is expected to provide the broadest indication of all infrarenal EVAR devices in the world.

On the clinical front, we recently completed enrollment in the ASCEND study, which is a physician-led trial on Nellix with branch stent grafts for the ChEVAS procedure. This study enrolled 187 patients, and the results will be presented at the VEITH meeting comparing ChEVAS to other treatments for complex aneurysms.

In addition, we remain on track to complete enrollment in the 225-patient LUCY study by the end of this year. LUCY is studying Ovation in patients with challenging aortic necks and small access vessels.

Our LEOPARD clinical study is also on track, and expected to enroll about 400 patients in the first quarter of 2017. It represents the first head-to-head clinical trial on EVAR comparing AFX against Gore, Medtronic, and Cook.

On a related note, we recently announced that Dr. Matt Thompson will be joining us as Chief Medical Officer in December. We're excited to have Dr. Thompson join the Endologix leadership team. As many of you know from attending various medical meetings, he is an international thought leader in vascular surgery and endovascular therapies. His deep experience treating a wide variety of aortic conditions will benefit our clinical programs, physician training initiatives, and product development activities.

In addition, Dr. Thompson is one of our most experienced Nellix users and clinical investigators, which will be valuable as we continue to advance EVAS in the global markets.

Regarding Nellix, we recently ran an updated data cut from the IDE clinical database, and noticed an increase in migration in aneurysm enlargement in some patients with 2-year follow-up. We've learned that migration with Nellix can occur in patients with small flow lumens and a lot of thrombus, because there isn't enough space to inject sufficient polymer to support the stents. Our solution is a simple update to the patient selection criteria that measures the ratio of an aneurysm diameter to the flow lumen, to ensure there's enough space for polymer.

To further minimize migration forces and address aneurysm enlargement, we're also reducing the aortic neck diameter indication from 32 millimeters down to 28 millimeters, and will now require a distal iliac seal zone of 10 millimeters, which is standard for EVAR.

When we examined the IDE data for patients that fit within this updated selection criteria, we see extremely positive safety and durability results out to 2 years, which gives us confidence that Nellix can be a leading device in the treatment of abdominal aortic aneurysms. Keep in mind that unlike other EVAR devices, Nellix has the potential to treat both traditional and complex aneurysms. So this refinement of indication only affects a subset of the traditional aneurysms that are easily treated with Ovation or AFX.

In terms of sales impact, we may see a little softening with Nellix as physicians adopt the new guidelines, but we still expect to achieve solid growth in the fourth quarter due to the depth of our overall product portfolio.

In terms of the US PMA, we achieved the clinical endpoints in the IDE and have shared the latest clinical data with FDA. We've also provided them with our updated patient selection criteria and have had positive discussions so far. The Nellix PMA approval timelines are unchanged, although we think a panel is more likely now, given the updated indications. We estimate the panel meeting will be in April or May, which would lead to a potential PMA approval in the third quarter of 2017.

With a Nellix gen-2 device, we hope to begin enrolling in the CAP around the end of this year, and will provide an estimated timeline at our investor meeting scheduled for November 17th at the VEITH meeting in New York. With that, I'll now turn the call over to Vaseem for his financial review. Vaseem?

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**Vaseem Mahboob** - Endologix Inc. - CFO

Thank you, John, and good afternoon, everyone. As a reminder, unless otherwise indicated, the comparisons made in my remarks for the financial results for the third quarter of 2015 will be on a pro forma basis to include the results of both Endologix and TriVascular in the quarterly period.

Starting with revenue, total revenue in the third quarter of 2016 was \$52.1 million, a 10% constant currency increase compared to pro forma revenue of \$47.7 million in the third quarter of 2015. The US revenue in the quarter was \$36.3 million, which represents a 35% growth as reported, and a 9% pro forma increase versus last year Q3. The US results were supported by the recent launch of AFX2, and our increased cross-selling opportunities with an expanded portfolio.

International revenue was \$15.8 million, which represents a growth of 40% as reported, and up 12% on a constant currency pro forma basis for the same period last year. We saw some softness in Europe outside of the normal seasonality, primarily driven by a reduction in reimbursement in Poland and security issues in Turkey. We will continue to monitor these issues, which may continue to have a near-term impact.

On a positive note, we are pleased that the Ovation business is gaining traction in Europe, and came in ahead of plan in the third quarter. Overall we are pleased with our global sales performance, and continue to outperform the market growth in both the US and our OUS markets.

Switching gears to gross margins, gross margin in the third quarter of 2016 was 70.9% compared to pro forma 69.3% in the third quarter of 2015. Operationally, the adjusted gross margins were 74.8%, and represents an improvement of 6 points versus last year. This was driven by continued focus on improved processes and our phase-in/phase out of new products in Europe and international markets, manufacturing efficiencies in both Irvine and Santa Rosa facilities. We continue to make investments in manufacturing process capability and leverage Six Sigma and lean tools to drive margin improvements.

We had another strong quarter as it relates to our ability to manage costs and drive synergy commitments. We have made very good progress on our goals and our operating expenses at \$48.2 million, compared to \$53.8 million on a pro forma basis in the third quarter of 2015.

Third quarter 2016 operating expenses included approximately \$400,000 in one-time acquisition-related expenses. And excluding these items, operating expenses were \$47.7 million. The lower costs were in line with the communicated synergy plans and tighter cost controls across the Company. We continue to invest in the key priorities like the Nellix PMA, our international expansion into Asia, and critical new product development activities.

Year to date, we have now incurred a total of \$23 million in deal-related expenses and are projecting another \$1 million in the remainder of this year. This puts us at a total of \$28 million in deal-related expenses since the announcement of the merger in the fourth quarter last year.

On the synergy front, we are on track to deliver the \$17 million in merging synergies in 2016. G&A is down 14%. Sales and marketing are down 10%, and R&D down 12%, reflecting the cost actions and spending controls we have undertaken to achieve our cost goals. We continue to make investments in information technology and longer-term continuous improvement projects to drive operating leverage and gross margin expansion.

Our GAAP net loss was \$15.2 million or a loss \$0.18 per share in the third quarter 2016, compared to a pro forma net loss of \$24.5 million for the third quarter of 2015. Adjusted net loss for the third quarter of 2016 was \$9.1 million, or a loss of \$0.11 per share, compared to adjusted pro forma net loss for the third quarter of 2015 of \$20.6 million.

Adjusted EBITDA for the third quarter of 2016 was a loss of \$3.8 million or \$0.05 per share, compared to adjusted EBITDA net loss of \$15.1 million in the third quarter 2015.

Moving on to cash, we ended the third quarter 2016 with cash, cash equivalents and investments of \$63 million, compared to \$72.9 million as of June 30, 2016.

Now turning to guidance, we plan to increase sales about 10% in Q4, and expect to finish 2016 with a total revenue of \$198 million to \$201 million. This range is within our original guidance for the year, but at the low end of Q4 to accommodate any potential impact from the updated Nellix indications and headwinds in Europe.

We are reiterating our 2016 GAAP loss per share guidance for \$1.80 to \$1.85 per share, and 2016 adjusted non-GAAP loss per share of \$0.70 to \$0.75 per share. This guidance excludes purchase price accounting impacts related to the TriVascular merger.

Overall we had an outstanding quarter, with 10% revenue growth, expanding gross margins and operating leverage, coupled with a healthy cash position. This reflects the strength of our core business and the solid cross-functional effort by the team.

With that, I'll hand it back to John. John?

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**John McDermott** - Endologix Inc. - Chairman and CEO

Thanks, Vaseem. We delivered another positive quarter, and are extremely pleased with the TriVascular merger and the unique value proposition we bring to physicians, hospitals, and patients around the world.

Following are our key goals for the remainder of the year and into 2017. First for Nellix, we want to keep the PMA approval process on schedule by providing all the required information, and start enrolling the gen-2 device in the CAP. Second, we want to complete the Ovation certification of our US salesforce, and continue building the clinical competence of our team. We expect more good clinical data to be announced on Ovation at the VEITH symposium, and even more in 2017.

In Europe, we just started the launch of AFX2 and have received positive physician feedback. We're looking forward to the introductions of both Ovation Alto and ChEVAS in 2017, and believe these two products can begin to open up the complex aneurysm market for us.

And last, for Ovation Alto in the US, we expect to receive IDE approval in the fourth quarter of this year, and start enrolling patients early in 2017. As we execute on these priorities, we expect to deliver significant value to our customers and shareholders, while providing patients with the best possible device for the treatment of their abdominal aortic aneurysms.

We look forward to meeting with many of you at the upcoming Stephens, Stifel, Canaccord, and Piper conferences in November, and the Guggenheim conference in December. We're also hosting our annual Investor Meeting in New York on November 17th at the VEITH symposium, with the details of which are posted on our website.

With that, we'll now open up the call for questions. Operator?

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Brooks West, Piper Jaffray

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**Brooks West** - *Piper Jaffray & Co. - Analyst*

Hi. Thanks. Can you hear me?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. Hey, Brooks.

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**Brooks West** - *Piper Jaffray & Co. - Analyst*

Hey, guys. John, I guess the first question, can you talk a little bit about customer reaction to the IFU change and anything you can say about prevalence you've seen of the stem migration in the commercial cases you've done in Europe to date?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Well, I'll start with the last part of that question. The reported rate of migration in the commercial experience is low single digit. Now, we know, however, that there tends to be an underreporting in just the commercial day-to-day business. And the other thing about migration is it's just an imaging finding. So it's often the case where you can have migration that doesn't lead to any clinical consequence. So it's just one of those things you want to keep an eye on.

But what we saw specifically in the two-year data cut from the IDE trial is an increase in very specific anatomies, the ones I mentioned previously, which are those patients with large thrombus burdens and small flow lumens. And as we've outlined, we think it's a very easy situation to address just by narrowing for those particular anatomies which are easily treated with Ovation and AFX.

The physician response has been very positive. I think people are giving us a lot of credit for being so proactive and getting out ahead of it. I will say there are some physicians who think we're being a little conservative. But our view is, let's think patient safety first, and then we can see some ways to open up these patient criteria moving forward.



**Brooks West** - Piper Jaffray & Co. - Analyst

That's helpful. Thanks. And then Vaseem on the guidance, I just want to understand, anything else you can share on the scale or the dynamics of the European Nellix business. It sounds like that's where maybe you're contemplating some potential weakness, and just anything else you can share on kind of how you built up the guidance for Q4 and Nellix dynamics would be helpful.

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**John McDermott** - Endologix Inc. - Chairman and CEO

Yes, hey Brooks, it's John. I can give you a little bit of Nellix color. Of course, as you know, we don't provide the product line reporting. But Nellix was a little softer in Q3, due primarily to our continued efforts to pick appropriate patients. And we're also wanting to hold on price. We may see a little more softness in Q4 as the physicians adopt the updated IFU. But we expect it to pick up after that, as we start the phase 2 of the global registry, with the gen-2 device, and also prepare for the CE Marking of ChEVAS next year.

So we know we've got a ton of growth potential with Nellix. But in the near term, we want to focus on making sure we're getting great clinical outcomes and getting the PMA approved.

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**Vaseem Mahboob** - Endologix Inc. - CFO

And I think the only thing to add this here is the softness really that we saw was primarily two things in Europe this quarter. One was the reimbursement change in Poland. And the other one was some impact on [AFX] business in Turkey, because of the security issues there, but nothing too big.

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**Brooks West** - Piper Jaffray & Co. - Analyst

Okay. Thanks, guys. I appreciate the color.

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**Operator**

Rick Wise, Stifel

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**Matt Blackman** - Stifel Nicolaus & Company - Analyst

Hi, everyone. It's Matt Blackman in for Rick. Can you hear me okay?

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**John McDermott** - Endologix Inc. - Chairman and CEO

Yes. Hey, Matt.

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**Matt Blackman** - Stifel Nicolaus & Company - Analyst

Yes. So John, I thought first maybe if you could maybe size the impact of the IFU changes for Nellix on its addressable opportunity. Is it-- are we talking about 5-10% of the population? Maybe just an order of magnitude of what you think the changes will do to the addressable Nellix opportunity.

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**John McDermott** - Endologix Inc. - Chairman and CEO

Yes. We've run the new IFU across a few different data sets. And in aggregate, Matt, we estimate about 40% of the traditional patients that are diagnosed will be ideal candidates for the new indications with the gen-2 device. And again, for those patients that fall outside of the updated

indications, they're easily treated with AFX2 or Ovation. I think the other thing to keep in mind is that's just for the traditional patients. We think that Nellix with branches, or the ChEVAS procedure, could be another 20% of patients, which will bring the total for Nellix up to 60%. But for just this indication, and in the traditional segment, we think that the remaining will be about 40%.

We do already have in the works a more detailed patient inclusion criteria, which allows more patients than what we're talking about here. But we want to pressure test that a little bit, and make sure that it's as encouraging as it looks before we roll it out. But I think, to get the complete picture, I'd just strongly encourage folks to join us at the upcoming investor conference. Because I think you're going to get a great update on Nellix, and you're going to like what you hear.

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**Matt Blackman** - *Stifel Nicolaus & Company - Analyst*

Okay. And then, John, is there any sort of future design enhancement, whether it's Nellix 3.0, 4.0, or whatever that can address this migration issue?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

We could make some design changes to the current version. But candidly, we're already making such great progress on the next-generation platform that embodies some of the best elements of all the platforms that we think we can get great results with the gen-2 device in its current configuration and just with this narrowing. And then we want to move into the next version of products. Because any changes we make at this point, it seems that they could require clinical trials. And if we're going to go back into clinical studies, we'd rather do it with the next-gen platform.

So again, we think we can get great outcomes with these indications with the current device, and plan to stay on that path. And then the next generation products, those will include design elements from all three of the current platforms.

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**Matt Blackman** - *Stifel Nicolaus & Company - Analyst*

Okay. That's very helpful. And I'm just going to sneak one last quick one in. I think you definitely mentioned that we'll see the updated ChEVAS data, the ASCEND data at VEITH. Did you say anything about the updated look at the [larger] registry data at VEITH? I may have missed that.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

What registry? Matt, I want to understand the last part of your question.

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**Matt Blackman** - *Stifel Nicolaus & Company - Analyst*

Sure. The ongoing global Nellix registry, if we're going to see an updated-- any updated look. I mean we obviously saw the last look at Charing Cross. I'm wondering if we're going to see another here at VEITH.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. Yes. Dr. Holden-- he's on the schedule to present the latest data cut for the global registry for EVAS.

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**Matt Blackman** - *Stifel Nicolaus & Company - Analyst*

Okay. Thanks so much. That's it for me.

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**Operator**

Mike Weinstein, JPMorgan

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**Unidentified Participant**

Hey, guys. This is Andrew in for Mike. Can you all hear me?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes, we can hear you fine.

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**Unidentified Participant**

(Inaudible) go back to maybe setting some expectations as far as what's going to be submitted, and whether or not the data that we'll see in the filing will be any different than maybe what we saw in June with the 12-month data, given your cutting (inaudible).

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

We started to lose you there at the end, Andrew. But I think we got most of your question. So I think it's important when we think about the PMA approval to keep in mind what you just said, which is we did have a successful clinical study, and met the endpoints in the trial. So actually when we've interacted with the agency so far on the updated indications, they've responded favorably. They had some questions about migration and a curiosity if it was progressive. So we're kind of taking that issue off the table.

So we will-- we'll use all of the clinical data, both in the pivotal as well as the CAP and the roll-in patients as a part of the study population that they'll evaluate. But as I pointed out in the prepared remarks, when we apply the new IFU to those data, the results are fantastic. So I think you're going to see some very encouraging clinical results presented at the panel meeting.

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**Unidentified Participant**

Okay, great. And then just one on gen-2. I don't know if you've provided any color on what the FDA is expecting as far as follow-up. Is it 3 months, 6 months, 12 months? Any help would be-- that would be helpful. Thank you.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes, Andrew, I hope to have at least an estimate of that at the VEITH meeting. We don't have that complete agreement yet on the number of patients and the follow-up. We're encouraged though that the agency has been positive with us about enrolling the gen-2 device in the CAP, which has a little under 100 patients remaining, and using the updated indications on those patients. We just don't know at this point if that's in and of itself is going to be enough patients. We think it probably is. But we don't know for sure, and we don't know the follow-up.

At this point, if you look at our product launch schedule that is posted on the website, we estimate that the gen-2 device would get approval about 1 year after approval for gen-1, based on what we know today. As soon as we get more definitive feedback from the agency, we'll update that.

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**Unidentified Participant**

Thank you.

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**Operator**

Chris Pasquale, Guggenheim

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Thanks. John, you mentioned that this issue can be clinically silent. How often do these patients need to be intervened on to stabilize the aneurysm? And what's the typical treatment strategy in those cases?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. Well, we can use the IDE results as an indication, Chris. We had a rate that was presented in June, I think of 2.3%, and no clinical interventions related to migration. So we'll need longer-term follow-up, frankly, to know how that changes over time. But assuming the physicians are following them with good clinical follow-up and getting good imaging, they can start to detect movement of the devices and assess whether or not they think that movement is going to potentially lead to an endoleak or sac expansion. So it will be very individual for each patient.

At this point we don't have enough long-term follow-up to have a percentage of patients that will require a re-intervention. So far that number is extremely low for the number of patients that have required any kind of re-intervention related to what we can specifically pinpoint a migration to.

And if they have to do-- I'm sorry-- I'll answer the second part of your question. If there is a re-intervention, it really depends on how much movement there's been in the device. If there's still adequate neck, they could use the same procedure that we use for other type 1A endoleaks, which is what we call endoleak sealing, where they'll use a coil and glue. And then we'll see if we can work with the agency ultimately to have them be able to use Nellix and Nellix, where we can add Nellix proximal extenders to the top. That's not in the current protocol. But it's something we're interested in exploring with the FDA moving forward. It's a solution that's been used in Europe with good success.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Okay. Thanks. That's helpful. And so I mean at this point can you say how many of this type of patient was enrolled in the US pivotal trial? You talked about the 1-year results, which obviously look very good. But just to try and handicap the risk that this causes some deterioration of that data as follow-up progresses longer term.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

No. We can't really get into any of the data details at this point in time. Obviously we've got to preserve the integrity of that data and save that for the FDA and the panel meeting. But what I can tell you is that the re-interventions related to this issue are extremely low.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Okay.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

And the other thing, Chris, I'm sorry to interrupt you. The other thing, just to point out, is that again, the approval that we'll be seeking will be with the new indications. So the data analysis will apply, and considering the new indications. And those data are exceptional. In fact, we beat all the



other EVAR devices 1-year results handily when we apply the new criteria even to the 2-year KM curves, they're considerably better than any of the EVAR data we've seen out to 2 years. So we feel good about those results longer term, based on the patients that have been out 2 years.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Thanks for adding. It's important for people to keep in mind. Just one last one from me; were you actively doing these cases internationally right up until the label change? I thought that this was an issue that had been speculated about as a potential weakness for Nellix, even going back a ways here. So were physicians already starting to shy away from these patients in the commercial setting, or was it something that was still actively being done?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

I would say honestly, probably a mix. For physicians that have a lot of experience with Nellix since its earlier introductions a few years ago, to the extent that they had experienced any of this themselves, some of them had started to narrow a bit naturally, while we were gathering information to determine what were the optimum inclusion criteria. So I think there was a little bit of that happening organically.

And meanwhile, other physicians were starting to gradually adopt more ChEVAS. We think that the ChEVAS opportunity will also be very significant, especially when we get the indication for that.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Thanks, John.

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**Operator**

Joanne Wuensch, BMO Capital Markets

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**Joanne Wuensch** - *BMO Capital Markets - Analyst*

Thank you for taking the question. Have you seen any change in physician behavior, in either the ordering or the usage pattern of AFX and Ovation now that Nellix has been pushed out a little bit?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

That's a good question. Not that is noticeable. Like Vaseem pointed out, we have seen a nice uptick with Ovation in Europe, albeit on a small base. So I'm just thinking of those markets where we have-- oh, are you talking specific to the US, Joanne?

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**Joanne Wuensch** - *BMO Capital Markets - Analyst*

I'm leaning towards the US. But I'd like the OUS too.

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**John McDermott** - Endologix Inc. - Chairman and CEO

Yes. Well, you know, AFX and Ovation have both done pretty well, as you saw by 9% growth, which is probably 3 times the market growth in the US. So both of those products are clicking along pretty nicely. I wouldn't say it's changed really with any of the timeline shift with Nellix at this point.

And then for OUS, maybe a little bit more growth with AFX and Ovation, but I don't know if it's really anything I'd call a trend. What do you think?

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**Vaseem Mahboob** - Endologix Inc. - CFO

No. I think, Joanne, on the OUS side, as we have talked about previously, what's really driving some of the Ovation numbers is the indirect channels that had kind of gone offline is starting to come back up, I think is one. And I think in the US, what you're seeing is the-- as we train our guys on the Ovation product line, we're expecting to see an uptick in those cases and more Ovation adoption across the board here in general. So outside of that, no real mix change, if you will, that's a trend at this point, or that we can comment on. But we'll continue to watch that here in Q4 and give you guys an update on the next call.

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**Joanne Wuensch** - BMO Capital Markets - Analyst

And given the numbers, it looks as if the integration with TriVascular is doing quite well. Is there anything qualitatively that you can share with us, particularly around the stability of the salesforce? Thank you.

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**John McDermott** - Endologix Inc. - Chairman and CEO

Sure. Well, the sales team continues to be very stable; low, low, low turnover, well below market averages. So I think everyone's busy integrating, getting good at selling two products, and looking forward to adding a third. And what we do see is although we're not yet 100% certified with Ovation, we do continue to get encouraging anecdotes from the field about situations where they're able to provide the best device for an individual patient. And so we know this is a winning formula. And we look forward to getting the team fully trained and clinically comfortable with both devices, so that then we're ready to add a third device in [the fall].

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**Joanne Wuensch** - BMO Capital Markets - Analyst

Thank you.

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**Operator**

Jason Mills, Canaccord Genuity

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**Jason Mills** - Canaccord Genuity Inc. - Analyst

Hi, John. Hi, Vaseem. Can you hear me okay?

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**John McDermott** - Endologix Inc. - Chairman and CEO

Yes.

**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Super. I'd like you to start by going back to Matt's question just, John, your commentary about the addressable market for Nellix in light of the IFU change. You talked about sort of addressing 40% of traditional and then additional 20% with ChEVAS. Could you talk to us a little bit about what that's changed from, given the upper band-- upper end of 32 millimeter? I know it wasn't all of the patients to begin with. But what sort of degradation in the targeted addressable market are we talking about here specifically?

And then as sort of a corollary to that question, may we talk about the addressable market with Ovation and AFX2 combined? Does this change in IFU better enable you to dichotomize the market for your customers, and better sort of market the advantages of each product across a certain patient population?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. It's a great question. And the last part of it is, I think, important that it does exactly that. Because these specific anatomies that we're targeting, which are these small flow lumen anatomies, with a lot of thrombus; these patients tend to not be at high risk for type 2 endoleaks. Because they've already got an aneurysm full of thrombus, which is evidenced for lower blood flows in the aneurysm sac.

So AFX and Ovation are great devices to treat those technologies. The harder aneurysms to treat are, in fact, these larger aneurysms with open space. They're more prone to type 2 endoleaks. And they're also more prone to device movement, because there's more open space.

So those anatomies are actually much more challenging for EVAR, and that happens to be the sweet spot in Nellix. So they're very complementary in terms of the overall portfolio. And in terms of the overall portfolio, we don't lose anything with the tightening. We just narrow in on those anatomies that are really ideally suited for Nellix.

In terms of what it was before, Jason, we're estimating it was in the 50% to 55% range. But we're actually doing some work that we'll roll out at the VEITH meeting to provide kind of a stack-up chart so you can see specifically how the product portfolio adds up relative to ability to treat patients on IFU, compared to our estimates of the competitors. So we'll have that for you in a couple of weeks.

But there aren't any patients that are slipping through the cracks with this update.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Great. And so just to clear, the 50% to 55% is on the traditional side going to 40%, correct?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

That's correct. Yes.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Okay. I just wanted to clarify that. And then--

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

The other thing, Jason is-- sorry to interrupt you. And we'll talk a little bit more about this at VEITH. But we've already got-- we wanted to get out quickly with an initial indication. We were already working on an enhanced version of that. We've made some good breakthroughs on that just

recently, which we think can open that number back up, and get that 40% to a bigger percentage. So we're just-- we're testing it now to make sure that it's as good as it looks on paper so far. But I don't think we're going to be at this 40% for very long.

So I can't give you the details of that right now. But through looking at a variety of anatomical features, we think we'll be able to broaden this in short order. So I wouldn't get-- I wouldn't spend too much time analyzing this level of detail. Because I don't think it's going to be with us that long.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Okay. I'll look forward to the update at VEITH then. On this call, John, you're obviously a bit more confident-- I don't know if that's the right word-- but it seems like you're confident you're going to meet a panel. Could you talk about where that guidance is coming from with respect to your conversations with the FDA, and then your confidence in acute 3 approval if in fact you do see a panel in the spring, a turnaround of less than 6 months? And sort of as we think about modeling 2017, and Nellix's inclusion in our models for the US market, sort of any qualitative guidance you could give us there would be helpful.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Sure. Well, as it relates to panels, we have-- the agency hasn't changed any of their messaging to us. So I'm not sharing any new information with you. The only thing that leads us to believe that panel is more likely is our interactions with the firm that we're working with for our panel prep who's been through many, many, many panels with the cardiovascular group suggested in our recent activities that with an indication change, even though the results are even better, that you've got a clinical question which would increase the likelihood of panel.

So we have assumed, and we will continue to assume, and we will continue to prepare as if we're going to panel. So with that baseline, again, the agency hasn't said anything. But we're preparing for that. We estimate, based on the current timeline and getting all of our information sent in by the end of this year, that that would happen in the April-May timeframe. And then just based upon the average approval timeframes following panel, that's what gets us into the Q3 time period.

I actually think updating the IFU now takes one clinical question off the table for the FDA. So I actually think it is positive as it relates to the FDA. But we'll have to see. That's our perspective. And then I can let Vaseem comment on the guidance piece.

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

Yes. And I think, Jason, just to kind of maybe backup what John said, our outlook on 2017 is totally unchanged in light of this IFU change. So consistent with what we have said in the past, was that if we were in kind of the April 1st timeframe for approval, we would be 15% to 20% top line. But if it was October 1st, it would be in the 5% to 10% range. So there's no meaningful impact of this IFU change on what we've been talking about in terms of the impact on the 2017 model, if you will.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Great. And I'll just slip in another one, to push back a little bit, John, you sort of answered this question I was about to ask. But you're addressing one clinical question. Couldn't one surmise that perhaps the possibility of panel declines if you're narrowing the IFUs and the analysis of the data is more transparent? And frankly to your point earlier, significantly better data off of data that was already pretty good?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. I mean that's a-- I want to believe that in the worst way. But I just want to be ready for the other way. So we're going to be-- we're going through mock panel meetings and we're doing all the stuff to be exceptionally well-prepared. If we get a positive surprise, that's great. But I also want to

be careful that we manage, we set and manage expectations. I don't want too many people hanging onto a Q1 approval, and then having a disappointment related to that. So that's why we're really leaning more toward Q3.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Fair enough. Lastly, also you seem pretty bullish about that. As you run through the enrollment, your expectations for enrollment for Alto, run us through the next couple of years and what your timelines are for that. And thank you for taking all my questions.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

You bet. So the current timeline is to get the IDE approved this quarter. So we have already submitted the IDE, and hope to get that approval this quarter. We'll probably kick off enrollment in the first part of the year. We'll provide more of the details of the study and the study design and some of those elements at the investor meeting. But we'll enroll that study in 2017. Follow those patients for a period of time, and then expect approval in the first half of 2019. That's our current estimate.

And then that's in the US. In Europe, we actually anticipate a much earlier approval, and are looking at the first half of next year for CE Mark.

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**Jason Mills** - *Canaccord Genuity Inc. - Analyst*

Thank you.

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**Operator**

Steven Lichtman, Oppenheimer

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**Steven Lichtman** - *Oppenheimer & Co. - Analyst*

Thanks. Hi, guys. John, can you talk to Europe next year with ChEVAS and Alto launching, how much of the market does that open up for you with ChEVAS, or is that both juxtarenal and suprarenal that you'll likely get indication for?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. So we-- our initial targeted indication for ChEVAS will be two branches. So-- and Alto complements that. So for most patients, you could treat-- you could use ChEVAS to cover the full indications of Alto. But the benefit of Alto, of course, is that you don't have to involve the renal arteries. So again, it would be the only infrarenal device with that short of an aortic neck. So if you can avoid getting into the visceral vessels, you will.

So our view is that Alto will really-- should become the short-neck device of choice and that when you just run out of neck, you'll then go to ChEVAS. And we'll provide kind of a stack-up chart to show you how those indications build, and the portfolio builds and compares to competitive offerings at the investor meeting.

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**Steven Lichtman** - *Oppenheimer & Co. - Analyst*

And in terms of training for ChEVAS, chimneys are already pretty prevalent in Europe. So this is just a different way of doing it versus obviously comparing-- connecting the chimneys with traditional EVAR. So do you anticipate a lot of training required?

**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. You're right. There is quite a bit of chimney work being done. But we'll still probably want to deploy a very rigorous training program. At least that's what we're designing. And for those physicians who already do quite a bit of ChEVAR or chimney work, they'll be quick studies. But we're going to build a robust plan and just make sure we're focused on getting great outcomes.

I think the Alto training, based on what I've seen so far, is pretty straightforward. It will be very easy for physicians that are familiar with Ovation, and actually pretty straightforward, I think, for new doctors as well. So we're pretty excited about both of those products. I would think in terms of cadence as Alto first half, ChEVAS second half.

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**Steven Lichtman** - *Oppenheimer & Co. - Analyst*

Got it. Great. And then lastly, following the LIFE data at VIVA, anything-- any anecdotes or anything that you can provide in terms of feedback from the field and how that's positively impacted perceptions on Ovation, if at all?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. It's just anecdotal, but the feedback has been very positive. There's been several follow-up meetings and discussions, and WebEx calls with the physicians that were involved. We'll have more of that activity. Actually, we've got a nice Ovation investigators function planned at VEITH. So the data for the Ovation platform continues to build and continues to be positive. So we'll announce at VEITH the 5-year follow-up from the IDE.

And then there's the LUCY study, as I mentioned. That will complete enrollment at the end of this year. So we would expect to release some data at the SBS next year. And so there continues to be a nice pipeline of good, clinical evidence for Ovation. And the feedback continues to be positive from the field. So we're going to continue to build momentum with that product. We see a bright future for the platform.

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**Steven Lichtman** - *Oppenheimer & Co. - Analyst*

Okay, great. Thanks, John.

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**Operator**

Glenn Navarro, RBC Capital Markets

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

Hi. Good afternoon, guys. Just one follow-up question on the IFU. Because John, you said that 40% of the traditional patients would still be treated with the IFU change. Then you said 20% of the complex patients would be ideal. So you gave us the 40% is down from 50% to 55%. Is that 20% that you gave us, is that down from something? Or is that unchanged?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

No. And let me clarify, Glenn. Because maybe I didn't communicate it very clearly. That 20% for ChEVAS is 20% of all diagnosed aneurysms, not 20% of the complex segment.

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

Okay.



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**John McDermott** - *Endologix Inc. - Chairman and CEO*

So when I talk about the 40% for Nellix, I'm talking about all aneurysms. But what I'm saying is of the exclusion, it's just a subset of the traditional. But the 40% applies to all diagnosed aneurysms, to be clear. And we pick up another 20% on top of that when we include ChEVAS.

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

Okay. All right. Thank you. And then just Vaseem, just to clarify your comment, because you said that the 2017 outlook is unchanged based on Nellix's timing. Can you run through those numbers again that you gave in terms of the top-line growth rates?

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

Sure. So what we have said consistent with what we have said in the past here, Glenn, which is if we get the April 1st approval, as you mean no panel, we would be growing 15% to 20% is what we have said, assuming that April 1st launch. And if we do have an October 1st launch, then we would be able to grow that 5% to 10%, which is essentially just one quarter of Nellix, which we have said in the past was \$7 million.

So there's no real meaningful change of this IFU impact on our guidance for 2017.

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

And let me just ask you on that \$7 million number, because timing of FDA panels, it can be 3 months. Sometimes it's 6 months. It sounds like your consultants are telling you 3 months. But if it does turn into 6 months, now you're looking at maybe just one or two months in the fourth quarter. So I'm wondering if the Street should really have \$7 million in the model for next year. Number one, just because of how hard it is to predict the FDA and its timing, but also I wonder how the rollout will go in the fourth quarter of next year, just simply because my guess would be that you'll take a more measured approach to the rollout, making sure that you train the centers that the patients are picked.

So maybe talk about, should we really be-- should we really have \$7 million in the model for next year, and maybe talk about how you see that first quarter rollout occurring. Thanks.

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

Yes. I think it's a great question, Glenn. And I think it's been a conversation we've had with quite a few of your peers. And I think there's some people, like yourself, who have already taken Nellix revenue out from the 2017 models. I think our view has always been that it would be a limited market release in Q4, as we would ramp into that Nellix launch.

So if as we are trying to set the stage for 2017 to a conservative setting, as John mentioned earlier, with the idea that we might go to panel. I think it's not a bad idea to be factoring that in. And internally, we are trying to de-risk it and say, you know what. We'll take the Nellix revenue out. If it happens, it happens. If not, it will be upside to the quarter. So I think it's a point of discussion. I we'll be having those conversations as we think about now until JPMorgan, when we finally give out the guidance.

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

Okay. But I guess what I'm hearing is it's best to be conservative, if you're building your models for 2017. Okay, great. Thank you.

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

Yes. Absolutely, yes.

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**Glenn Navarro** - *RBC Capital Markets - Analyst*

Thank you.

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**Operator**

Ravi Misra, Leerink Partners

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**Ravi Misra** - *Leerink Partners - Analyst*

Hi. Thank you for taking the questions. And I just wanted to follow up on the migration commentary. I appreciate all the information you're giving out there. That 2.3% rate, how does that compare to-- or does it compare to other devices on the market? And sort of what are the re-intervention rates of non-EVAS products when they do have migration?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. The 2.3%, if you did a literature search on migration, Ravi, you'd find rates between zero and 5%. So the 2.3% falls within the published literature. That said, I would-- I think contemporary devices, the rates are low, more in the 1% range. So while it was within the range, we still-- it was something to monitor. I don't know, to be honest off the top of my head, what are the re-intervention rates associated with migration in other devices. My guess is they're very low.

But the big difference, and the value proposition, of course with EVAS is the associated endoleaks. So what you see if you look at the results, is you have 50% of the rate of endoleaks compared to EVAR, and a substantially lower re-intervention rate. So even if you did have a slightly higher rate of re-interventions related to migration, they would be more than offset by the reduction you'd see from the significant drop in endoleaks.

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**Ravi Misra** - *Leerink Partners - Analyst*

And is that something that you were maybe implying about the 2-year curve presentation that you're going to be showing over at the Analyst Day? Could we expect more clarity or detail around this?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. Well, I can tell you what the numbers are. So what we did is we took all of our data, and we applied the new indications and looked specifically at migrations. We looked at actually migrations down to 5 millimeters, even though the SBS guideline is 10, we went to 5. Because we wanted to play it safe.

Then we included sac enlargement, and then we further included type 1A endoleaks. And we did a 2-year KM curve by applying these new criteria. And we ended up with a freedom from all of those events out to 2 years. It was just about 97%.

And if you wanted to benchmark that, it's kind of hard to find that exact benchmark metric with other EVAR devices. But as you go through their published data, you would find rates that would be comparable in the low 90s. So, those results are actually superior out to 2 years with the new IFU.

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**Ravi Misra** - *Leerink Partners - Analyst*

Great. Thanks. I appreciate that detail. And then maybe one on the model. Just how should we think the US-OUS split, given the dynamics that you've been citing here? Historically it looks like when you were a standalone company, fourth quarter was about in line, at least US with the third quarter. Should we think about the same sort of pattern here in the fourth quarter, or is there something that you want to point out as we update our models? And then one follow-up question.

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

I think Ravi, as we looked at a few years' worth of data here, I think the business was kind of evolving consistently in the 70% to 30% range, 70% US, 30% OUS. I think the big mix change was going to happen with the launch of Nellix in the US. So for now, at least on a forecasted basis, I'd kind of keep that mix the same. And if it does change, we'll obviously continue to give you color as we go through the quarters.

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**Ravi Misra** - *Leerink Partners - Analyst*

Great. No. But I was saying for this coming fourth quarter, should we expect more in line with historical patterns in terms of--?

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. I think so.

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**Vaseem Mahboob** - *Endologix Inc. - CFO*

Yes. I think so.

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**Ravi Misra** - *Leerink Partners - Analyst*

Okay. And then maybe one last one on Nellix. The value analysis committee aspect, how have you guys factored that into that \$7 million assumption? I mean does that bake in? It seems to me that the way to go after this would be going after your key initial accounts who have experience with the product. But then can you talk a little bit about what you're putting together to address the VAC committees and how long that process takes? Thank you.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Yes. So, as you pointed out, the starting point is the install base. So we will have roughly 60 physicians trained and certified on Nellix out of the gate. And those hospitals that are already IDE centers will be well advised about Nellix.

We do have, and have continued to put together a compelling package of information relative to the value proposition on the economics and the technology assessment committees and the hospitals. But to be honest, I don't think we'll need it to get to \$7 million in a full quarter. My experience is that the device is novel enough, the data is good enough that I don't think we're going to run into that too early. I think that's something that we'll start to-- it will take time in some institutions. But I think that there's going to be a lot of interest outside of that in the early going for sure.

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**Ravi Misra** - *Leerink Partners - Analyst*

Great. Thank you.



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**Operator**

Thank you. We have reached the end of our Q&A session. I would like to return the call to management for closing remarks.

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**John McDermott** - *Endologix Inc. - Chairman and CEO*

Okay. Well, thanks, everyone, for joining us on the call this afternoon, and your continued interest in Endologix. We look forward to seeing you at the upcoming conferences and our Investor Meeting. Have a great evening.

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**Operator**

Thank you. This concludes tonight's teleconference. You may disconnect your lines at this time, and thank you for your participation.

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