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PRESENTATION

Operator

Greetings and welcome to the Endologix Incorporated fourth quarter 2016 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 is being recorded.

I would now like to turn the conference over to your host, Mr. Zack Kubow of The Ruth Group. Thank you, Zack. Please go ahead.

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 and a replay of the call will be available on the Company's web site 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 & 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, February 22, 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 would now like to turn the call over to John.

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

Thanks, Zack. Good afternoon, everyone. Thank you for joining us for Endologix's fourth quarter 2016 conference call.

This afternoon, I'll provide a brief overview of our fourth 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 fourth quarter financial results, 2017 financial guidance and an update on our synergy plan from the TriVascular merger. After that, 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 fourth quarter, global revenue was $47.5 million, down 3% on a combined basis.

Starting with the fourth quarter, global revenue was $47.5 million, down 3% on a combined basis. This reflects the impacts of the narrowed Nelix IFU, the temporary AFX CE Mark suspension and the AFX shipment hold on our Q4 results. In the US, revenue was $33.7 million down 1% on a combined basis. This included double digit growth with Ovation offset by lower results with AFX.

Outside of the US, our fourth quarter revenue was $13.8 million, down 9% on a combined basis. This reflects the narrowed indication for Nellix and the AFX CE Mark suspension and shipment hold. Similar to the US, we saw double digit growth for Ovation offset by declines in Nellix and AFX.

While we faced several challenges in the fourth quarter that impacted our top line, we've made very good progress in the first quarter of 2017, highlighted by, first, the resumed shipments of AFX and AFX2, second, the reinstatement of the CE Mark for AFX and AFX2, third, the strengthening of our management team with the addition of Laura Nagel, our New Vice President of Quality. Fourth, the appointment of Dan Lemaitre as our Chairman of the Board and, fifth, completion of the enrollment in the LUCY clinical study. These accomplishments together with continued progress across all areas of our business give us confidence that will work through the current short-term disruption and return to a growth trajectory.

We believe that we have the best new product pipeline in the industry and look forward to launching many new devices and improving patient care over the next few years. Now I'll provide a more detailed update on each of our products starting with AFX. We received positive feedback on our December letter to physicians highlighting the improved type 3 endoleak rates current generations of AFX.

We also recently held a Physician's Consensus Meeting and we're very pleased with the level of engagement and continued support of the AFX platform. I would like to thank our customers for their support during this period and reiterate our unwavering commitment to patient safety and innovation. In terms of manufacturing, we're making enhancements to the AFX2 manufacturing process and plan to resume normal manufacturing capacity in margins in the second half of the year.

In the interim, we'll have to juggle our inventories but we think we've got enough AFX, AFX2, Ovation and Nellix to support the needs of our customers. Turning to Nellix, as previously discussed, in November we communicated a narrowed IFU for Nellix to customers in Europe and other international markets to help address potential device migration in patients with large amounts of thrombus. While this has impacted the Nellix sales, there continues to be a high level of are in EVAS for patients with low thrombus volumes and a very high level of continued interest in ChEVAS for the treatment of complex anatomies.

For patients that fall outside of the new Nellix IFU, we're moving physicians to either AFX or Ovation, both of which are well-suited to treat abdominal aortic aneurysm patients with a lot of thrombus. For those patients that are on IFU, Nellix continues to offer extremely compelling clinical results with the lowest reported rates of and type 2 endoleaks and a notable improvement in all cause mortality. In the US, we plan to meet with the FDA in May to review the Nellix two year IDE results and the proposed new IFU.

Once we have alignment and a clear path to approval, we will finalize and submit the Gen-1 PMA response to FDA, along with a request to restart enrolling patients in the cap with the gen-2 device. We anticipate the two year Nellix IDE data will be presented at the SVS meeting in June followed by a potential panel meeting in the fourth quarter. Assuming these timelines hold true, this would position us for a potential Nellix PMA approval in Q2 2018.

For the Nellix ChEVAS procedure, we expect to obtain FDA approval to commence an IDE clinical study in the third quarter with potential CE Marking for ChEVAS by the end of 2017. For Ovation, our team delivered good growth in the fourth quarter and we have positive momentum heading into

2017. During the quarter, we completed the certification of our US sales and clinical team on the Ovation platform and have seen a nice uptick in Ovation procedure volumes recently.

In addition, last week, we completed enrollment in the Ovation LUCY Study. Which is the first prospective study evaluating EVAR in the historically under served female population. The study enrolled a total of 225 patients at 39 sites in the United States and we anticipate the 30-day results to be presented at the SVS in June.

In the US, we're also looking forward to initiating enrollment in the Ovation Alto IDE study called Elevate. Elevate is a 75 patient study that is expected to begin enrollment in April and complete enrollment by the end of 2017. The study is designed to demonstrate the safety and effectiveness of the Ovation Alto system which is expected to have the broadest indication of any infrarenal endovascular AAA device in the world.

Turning to Europe, last month at the [LINK] Symposium in Germany, we announced positive three-year clinical data from the Ovation European post-market registry. Highlights from the 30 center, 501 patient study included the broadest range of patient applicability on IFU of all commercially available infrarenal devices, 99% freedom from aneurysm related mortality, 99% freedom from migration, rupture or conversion, 97% freedom from type 1 or type 3 endoleak, excellent freedom from secondary intervention for occlusion at 97%, type one endoleak at 97% and type two endoleaks at 95%.

These real world results from Europe confirm the recently announced five-year Ovation IDE study results and build upon the positive results from the life study. To further leverage these great clinical results, we have submitted our regulatory application for CE Mark for Ovation Alto and expect a decision by the end of March. Although the regulatory requirements in Europe are getting more difficult with the new medical device regulations, we remain hopeful to get Alto approved in the second quarter and are planning to initiate a controlled market introduction in Europe in the third quarter of 2017.

We also plan to run a 300 patient post-market registry called Elevate II and expect to begin enrollment in June. This study will provide an opportunity to gather additional clinical data and introduce more physicians to this exciting new technology.

With that, I'll now turn the call over to Vaseem for his financial review. Vaseem?

Vaseem Mahboob - *Endologix Inc. - CFO*

Thank you, John. Good afternoon, everyone.

As a reminder unless otherwise indicated, the comparisons made in my remarks to financial results for the fourth quarter and full year 2015 will be on a combined basis to include the results of both Endologix and TriVascular in the 2015 quarterly and annual periods.

Starting with revenue, total revenue for the fourth quarter of 2016 was $47.5 million, a 3% decrease compared to combined revenue $49 million in the fourth quarter 2015. This reflects the loss of approximately $4.5 million in the fourth quarter due primarily to the temporary suspension of the CE Mark and the product hold with AFX and AFX2. For the full year 2016, total revenue was $192.9 million, a 1% increase compared to combined revenue of $190.6 million in 2015.

US revenue in the fourth quarter was $33.7 million, which represents 27% growth as reported and a 1% decrease verses combined Q4 last year. US results reflect a growth in Ovation sales offset by a slight decline in AFX sales and a pause in patient enrollment is in the Nellix cap.

International revenue was $13.8 million which represents growth of 8% as reported and a 7% decline on a constant currency combined basis versus Q4 last year. Sales in our OUS markets were down due to the temporary CE Mark suspension for AFX in European markets and delayed shipments to distributors related to the AFX manufacturing hold in our capital markets most notably, Japan.

On a positive note, we were pleased that Ovation business is gaining traction in Europe and grew double digits in the fourth quarter. Moving down the P&L to margins, gross margin in the fourth quarter 2016 was 62.1% compared to combined gross margins of 60.7% in the fourth quarter 2015. Gross margin in the fourth quarter was unfavorably impacted by approximately $3.8 million related to the AFX manufacturing hold.

The fourth quarter 2015 gross margin included an inventory write-off of $3.4 million for product transitions and an increase of our obsolete inventory as a result of the quality and process improvements. Looking forward, we anticipate approximately one point of gross margin impact due to AFX2 (inaudible) testing and sampling costs until we implement a new manufacturing protocol which we expect to have in place by the end of the second quarter this year.

On the expense side, we had another solid quarter as it relates to our ability to manage cost and drive synergy commitments, despite the added costs related to the stop ship and the loss of CE Mark at the end of the year. Total operating expenses in the fourth quarter 2016 were $51.7 million compared to $66.5 million on a combined basis in the fourth quarter of 2015.

Fourth quarter 2016 operating expenses included approximately $2.4 million in one-time expenses and excluding this operating expense in the quarter would have been $49.3 million. The lower cost were in line with our communicated synergy plans and tighter cost controls across the company.

We continue to invest in the key priorities like the Nelix PMA, our international expansion into Asia and critical new product development activities. In 2016, we incurred a total of $25 million in [deal] related and restructuring expenses. This puts us at a total of $30 million in deal related expenses since the announcement of the merger in the fourth quarter of 2015.

On the synergy front, we exceeded our $17 million synergy target and delivered over $20 million in merger synergies in 2016. Sales and marketing was down 9%, G&A down 16%, R&D down 9% and clinical and regulatory down 28%. 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 $24.9 million or a loss of $0.30 cents per share in the fourth quarter 2016, compared to a combined net loss of $32.6 million for the fourth quarter 2015. Adjusted net loss for the fourth quarter 2016 was $18.3 million compared to adjusted combined net loss for the quarter 2015 of $20.4 million. Adjusted EBITDA for the fourth quarter 2016 was a loss of $13.2 million compared to adjusted EBITDA net loss combined of $25.7 million in the fourth quarter 2015.

Moving on to cash, we ended 2016 with cash, cash equivalents, restricted cash and investments of $49.1 million compared to $63 million as of September 30, 2016. Now turning to guidance for 2017, we expect revenues will be in the range of $193 million to $200 million, representing reported growth of 0% to 4% over 2016 and constant currency growth of 2% to 5% for the same period. We expect our first quarter 2017 worldwide sales to be approximately $41 million which is down $6.5 million from the fourth quarter 2016.

This decrease is due to a $4.5 million previously communicated disruption caused by the CE Mark suspension in Europe, the AFX manufacturing issue at the end of the year, plus a $2 million seasonality drop-off in Q1 versus Q4. Moving into the second quarter, third and fourth quarters of 2017, we expect to see sequential growth with the second quarter revenues of approximately $50 million due to the following main factors.

One, (inaudible) reinstate their CE Mark in Europe, two, resume shipments of AFX and AFX2 to international distributors, three, continue double digit growth with Ovation globally and, most importantly, number four, returning stability to our AFX, AFX2 and Nelix business in a quarter that is seasonally our biggest quarter.

For the full year 2017 we anticipate a GAAP loss per share of $0.70 to $0.76 per share. This reflects the already captured and on-going synergies from the merger which positions us for full year 2017 operating expenses in the range of $170 million to $175 million.

This level will allow us to continue investing in growth programs and deliver our 2017 commitments. Finally, we remain very optimistic and confident in our ability to manage our liability as it relates to the outstanding $86 million convertible bonds due in December 2018 which we plan to refinance this year.

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

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

Thanks, Vaseem. We have several key milestones this year to strengthen the business and increase shareholder value. Following our key goals for 2017, first is the successful market introduction of Ovation Alto in Europe and other international markets.

We think Alto has the potential to treat more patients, expand the EVAR market and increase our market share. Second is to continue driving the Nellix PMA process toward approval and initiating the IDE clinical study for the ChEVAS indication. Third is to complete enrollment in the Elevate IDE study and obtain future US approval for Ovation Alto.

Fourth is to gain CE approval for ChEVAS with Nellix and begin expanding the market for patients with complex AAAs and last is to further strengthen our regulatory process's, quality systems, and manufacturing operations to provide timely approvals and exceptionally high quality devices at all times.

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 conferences including the Oppenheimer conference in March and the (inaudible) Cross meeting in April.

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

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions). Our first question comes from the line of Brooks West with Piper Jaffray. Please proceed with your question.

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

Hi. Can you hear me?

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

Yes. Hi, Brooks.

Vaseem Mahboob - *Endologix Inc. - CFO*

Hi, Brooks.

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

Hi, guys. I guess a couple of questions from me. John, can you talk about how Nellix volumes have changed since the narrowing of the IFU? I seem to remember you saying that the changes to the IFU roughly took your treatable patient population from 50% of traditional down to 40% of traditional.

Are you seeing case volumes kind of follow those parameters?

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

Yes, a little bit more than that, Brooks, because there were clearly physicians using Nellix more aggressively than that. So, I think when Nellix first got introduced, since it has the capability to do so much that other devices can't do, that physicians were using it to solve a lot of problems, some of which were outside the IFU. So as we've gone out with the more narrowed indications, the physicians are responding favorably and using it on IFU but that reduction is more than just that change between the original indication and the new indication.

So the Nellix business is down more than just that 10% delta. That said, I can tell you that for those patients that do fall within the IFU, Nellix continues to be the best solution and, in fact, these anatomies with limited amounts of thrombus, large aneurysms with patent lumbars and other side branch vessels are challenges for all of the other devices and it's kind of a sweet spot for Nellix. So this continues to be a lot of interest in Nellix especially, also for ChEVAS.

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

And then can you remind us the label you hope to get for ChEVAS? And again, what will that allow you to do in terms of treatable patient population both within the traditional market, maybe recapturing the little bit more aggressive cases that you were getting before and also the expansion into non-traditional markets, so to speak.

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

Yes, so the current targeted indication for ChEVAS will be to include aneurysms up to and including the two renal arteries, so we can treat truly juxta pararenal aneurysms, indications well beyond what any other devices can currently treat. Some physicians have done procedures with three and four vessels but the initial indication will be for two.

So it really won't have a traditional infrarenal indication at all. It will be for complex anatomies.

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

Okay. And again, I'm thinking about, kind of, modeling growth associated with that launch, how should we think about that in terms of maybe recapturing or expanding on the labeled patient population that you lost last year.

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

Well you know, we didn't really have it indicated for those anatomies before. I would say there are still some physicians who were doing ChEVAS that continue to do it because they think it is the best option for the patients. I think what we've seen in terms of our procedure volumes has been more infrarenal than complex.

Because, again, Nellix is really the only solution for some of these patients. Whereas with these other more thrombus built anatomies that are infrarenal, you could use other devices including AFX or Ovation. But, as we've talked about in the past, if we stick with just the two vessel branch

system, the device is well-suited to treat about 50% of the complex market segment. Which is probably in dollar value terms, you know, worth as much if not more than 40% of the traditional segment.

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

Okay. Then I guess last for me is with Ovation Alto potentially launching in Europe and then second half, kind of the same question, labeled indication.

Does that potentially become your workhorse device? I'm just curious on how you're going to position that within the portfolio versus the other devices. Thanks.

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

Yes. It's going to likely be indicated, Brooks. We're still going through the regulatory approval process. But the likely indication is a seven millimeters, the seal zone seven millimeters below the lowest renal artery. That indication would give it the broadest label of all infrarenal devices.

So it certainly has all the right characteristics, lowest profile, broadest IFU, most flexibility, great clinical data, particularly all of this new and emerging data on aortic neck dilation, it's got all the right characteristics to be a workhorse graft and that's how we will position it and take it to market.

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

Okay. And then still 2019 for the US, is that the timeline?

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

That's correct. We expect to start enrollment in April in the US IDE, complete at the end of this year, then we are to follow those patients and submit -- we've got time for one round of questions. It gets us to approval in the early part of 2019.

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

Okay. Thanks, guys. I appreciate the comments.

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

Yes.

Operator

Our next question comes from the line of Mike [Weinstein] with JPMorgan. Please proceed with your question.

Mike Weinstein - *JPMorgan - Analyst*

Thanks. Good afternoon, guys. I probably have a few more questions than usual. Let me just start with the kind of cadence of your outlook first quarter, second quarter and obviously we all understand the issues impacting the first quarter.

But, can you talk about your visibility at this point, calling for the second quarter recovery, and part of the reason why I ask is obviously the tone of the business has been stepping down over the last few months from kind of when things started to become an issue with Nellix and then AFX and so we've had these gradual step-downs of your expectations.

Here we are in mid-February. How good is your viability and your confidence on that Q2 guide?

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. Mike, let me take a crack at it. John, you can add.

Right now, we have a good line of sight to the $41 million. Obviously we have almost three weeks of February in, we've got the January actuals. We've got good line of sight to product availability in some of the cases coming into the pipeline for the rest of March.

So we feel very confident about the $41 million. Now to walk it to the step up of about $50 million, you know, second quarter, as I mentioned in my comments, is our bigger quarters. And usually we see a seasonality of 10% to 12% increase from Q1. So that's about $4 million.

Now on top of that $4 million of seasonality, if you guys remember, we had talked about $3 million of orders that pushed from Q4 into Q1. Now as a conscious choice and having good visibility to our channel inventory levels, we decided to push those orders from Q1 to Q2 so there is a $2 million bump up from that $41 million because of that OUS distributor orders that we had at the end of the year.

And then there's $3 million of product availability primarily related to AFX2 coming back online and also the step up on the January CE Mark which comes into the run rate in the second quarter. So all in all, you do the math here. Mike, we have good visibility to the $50 million.

Now obviously you know, the core business has got to continue to deliver but at this point, we're very confident that we can get to the $50 million in the second quarter and then sequential increases after that for the rest of the year. And the fourth quarter will be a good growth obviously versus the weaker comp.

So we feel pretty confident on the range that we put out there and that we have good visibility through Q1 and pretty good line of sight to the second quarter number.

Mike Weinstein - *JPMorgan - Analyst*

Okay. That topic to SVS, will we get the full cohort of two-year data from the Nellix IDE at SVS?

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

Yes, Mike, the presentation isn't done yet so we've got to work with the investigators in the study. What we would like to do is get, in addition to just the two-year data, a particular focus on the two-year data with the new IFU. So those slides are not prepared yet. But they will be over the next few weeks.

So I think you'll probably get visibility to both, the complete data set as well as the sub set of patients with the new IFU.

Mike Weinstein - *JPMorgan - Analyst*

So you're going to do a cut of the data to say if you followed the new IFU, these are the outcomes?

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

Yes. Yes.

Mike Weinstein - *JPMorgan - Analyst*

Okay. I assume naturally the guidance for the year in the second half outlook essentially reflects what you're hoping is a positive update at SVS from the Nellix data set.

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

Yes. Although I wouldn't say that we necessarily built the guidance this year with any assumed bump in business related to positive news. We just took our historical knowledge of the business, our productivity expectation, some of the factors that Vaseem just mentioned.

We also expect positive clinical data at SVS from the LUCY study. Another thing Vaseem didn't mention is we'll have a nice sequential bump from Q1 to Q2 with just the Ovation, the run rates we're seeing right now.

Mike Weinstein - *JPMorgan - Analyst*

I think -- reviewing that two-year data set is more risk to the second half than necessarily a positive opportunity. The migration issue becomes a bigger concern on the two-year data set. I think that was the gist of the question.

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

Oh, I see. So it is a question about our results with Nellix OUS?

Mike Weinstein - *JPMorgan - Analyst*

Yes.

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

Okay. I missed you. I got you.

I think by the time we get there, Mike, that adjustment in treating patients on IFU will have already happened in Europe. In fact, we have, in March, we've got a meeting, an annual meeting called SAS, the Society for Aneurysm Sealing. It is a unique invitation only meeting that is going to provide an update to all of the Nellix users globally about the outcomes and the patient selection.

I think we're kind of turning the corner, honestly, on this IFU. And the results are so good by staying on IFU and physicians who appreciate they get such great outcomes and carefully selected patients that I think by the time we get to June whether it's positive or neutral, that's not going to have an impact OUS on the Nellix business.

Mike Weinstein - *JPMorgan - Analyst*

Okay. Last question then I'll let others jump in here. Last question is the balance sheet question.

So you commented you expect to replace the December 2018 convert in 2017. Are you assuming that you do -- that you upsize it relative to the existing convert? Because you're going to need the cash. And then, how are you thinking about where you exit 2017 with your balance sheet? Thanks.

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. So just from the cash perspective here where we think we'll end up, as you can see, in the $170 million to $175 million guidance so (inaudible) is significantly lower than where we ended the year for 2016.

If we look at on an average, we were operationally running at a $13 million per quarter cash burn of all of 2016. If you extrapolate that and as you've no change that, gets you to $52 million of cash but then with the lower Opex number, that gets us to that $20 million to $25 million of cash in the bank.

So plus the revolver that we have at mid cap which is -- has a zero drawn at this point. Gets us to about $60 million of available liquidity. So I just want to make sure people understand, so we don't have a cash issue at this point other than the fact that we have to refinance our convertible debt.

And we have done some benchmarking and realize that companies typically do that anywhere from 18 to 36 months out of maturity and that's what we're doing at this point, Mike. We're educating ourselves on various options.

But having said that, we have considered that if we do refinance that, we would increase the size of the line, (inaudible) the $86 million we would upsize it in light of the fact on what happened with AFX2 and some of the uncontrollable risks that are out there.

But again, we're not talking $50 million. We're talking anywhere from $25 million to $30 million. That's our current thinking it would change. But we are yet to kind of go through the process and understand what that size would be.

We will probably do that in the least -- the cost of capital and the dilution are two key things we're considering. So we'll balance that out. At this point, you know, we are in early stages.

Mike Weinstein - *JPMorgan - Analyst*

That's very helpful. Thank you, guys.

Vaseem Mahboob - *Endologix Inc. - CFO*

Thanks, mike.

Operator

Our next question comes from the line of Rick Wise with Stifel. Please proceed with your question, sir.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Good morning. It is Matt Blackman in for Rick.

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

Hi, Matt.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Hi. John, maybe I'll start with you. Sort of a big picture, maybe, take a step back type of question. Maybe just characterize the state of the business today.

Is it stable? Are you still on the defensive? Do you feel like you're through the worst of the AFX2 and the Nellix EU commercial headwinds? Just give us a flavor for where you are in all of this.

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

Yes, I definitely see things on the uptick, Matt. It was a pretty tough couple of months. But we since had several employee meetings and our sales meetings both in the US and Europe, spent a lot of time with physicians, getting the CE Mark reinstated. Starting to make headway on shipping AFX2 devices, folks are getting a bounce back in their step. Everybody continues to be excited about the pipeline and what's coming.

So my sense for it is the business is stabilizing and people are looking forward to getting back on a growth path.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. That's helpful. On that same note, any change in sort of sales force attrition rates? Is your sales force largely intact? Has there been turnover because of the recent issues. Any sense there?

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

Yes. No, the sales teams have been stable. We've had a little bit of turnover but nothing that I would characterize related to any of the recent events. And none of the turnover that we've experienced has been competitively related. So nothing outside the norm and the team looks solid and intact.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. And, maybe Vaseem, I'm not sure you're willing to give a hard number for Nellix in Europe in the quarter. But obviously I heard Brooks' question and your response to it.

Any sort of directional flavor? Obviously 10%, you said was a little bit more intense pressure than that. Just sort of directionally with the business down 15% in the quarter? I'm just trying to get some semblance of direction of Nellix post the changes to the label.

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. We're kind of short of giving specifics here, Matt, what I can comment on Nellix is when we look at the impact of the FSN, what John said, we have seen the European Nellix number stabilize now. In fact, it was slightly higher than where we left off in Q3.

So the actual Nellix units in our direct business were up from Q4 to Q3 sequentially. And we continue to see the impact of the destocking in channel where the distributors have built up inventory and now they're consuming all of that inventory knowing that it is a narrowed indication. But I would say even when I look at the trends in January and some in February, the Nellix business is stable.

I think there's that set of physicians that were using Nellix off label a lot, are now starting to come back because of the FSN. And there were some that had already stopped or slowed down the use of Nelix in their practices and now are starting to use Nellix back on label. It is actually stabilized in a place where we expected it to be.

And as we get -- we didn't expect that number to be down 30%. We're hoping that it stays there and I think everything we look at right now points in that direction. I hope that helps.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. Yes, no, that's helpful. Thank you, guys.

Vaseem Mahboob - *Endologix Inc. - CFO*

Thanks, matt.

Operator

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

Joanne Wuensch - *BMO Capital Markets - Analyst*

Good evening, everybody. Two questions.

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

Hi, Joanne

Joanne Wuensch - *BMO Capital Markets - Analyst*

Hi. The first one has to do with the FDA. Could you give us a little bit more color on the quality or quantity of your conversations with the FDA? I know in our conversations with investors, one of the things they're concerned about is that you go through all of this for the two-year moment and then they come back and say and now what we want is... And ask for something else.

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

Yes. Obviously that potential always exists, Joanne. That said, we've been into this so deep now, it is not -- certainly not obvious to us what they could come back and ask for that we haven't already either provided or have plans to provide in the May meeting.

So I can't think of any big information gap that still sits out there. As we've talked about in the past, the plan is to go to FDA in the May time frame, provide visibility to the two-year results as well as show the agency how those results look in the context of the new IFU. And we also plan to further test that IFU in a set of patients from Europe.

There is a 300 patient data set of Nellix patients that we're gathering access to right now through a group of physicians. And we want to provide further evidence that this new IFU is very effective at significantly reducing migration, endoleak or sack enlargement. That's the plan.

I can't think of anything else that they could ask beyond that. Now, they might have some questions about the new information but I don't believe there's any big, obvious gaps. It will just be a question of if they're comfortable accepting the data that we provided with the two-year follow-up or would they like a new prospective study and we won't have that answer until we get into that meeting with them in May.

Joanne Wuensch - *BMO Capital Markets - Analyst*

That's very helpful. As a follow-up, should we think about the TriVascular integration as "done"? I mean the organization has sort of taken on some body blows, we'll call it, over the last year. How do you think about integration and stability from here forward? Thank you.

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

Yes, I'll comment on that, Vaseem, if you have anything to add. I think that the integration culturally and otherwise is complete. There are still synergy opportunities that exist.

There's a lot of technology in the Santa Rosa facility that we haven't yet fully leveraged. But in terms of one company, one culture, one set of goals, all of that integration is done. One sales team.

All of that work is done. Now there's just more value, frankly, to extract over the coming years with the combined businesses.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Very helpful. Thank you.

Vaseem Mahboob - *Endologix Inc. - CFO*

I think the only thing I would add to that on the synergy side, John, we saw north of $20 million in synergy. If you look at the new Opex plan that we have built here and the line of sight we have created, a lot of that is driven by some of those continued synergy opportunities. I think that will help us get to that new number that we have put out there.

So, overall, financially, it has been a big success.

Operator

Thank you. Our next question comes from the line of Chris Pasquale with Guggenheim. Please go ahead.

Chris Pasquale - *Guggenheim Securities - Analyst*

Thanks, guys. A couple of questions on the AFX2 manufacturing issue. So what steps need to happen for you to get back to normal there? Do you know what the fix is at this point or is that still being worked out? And if you know what it is, why does it take six months to implement?

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

Yes, Chris. I would say we've gone through an exhaustive root cause analysis, 90% level in terms of certainty. There's a clear line of sight about the enhancements that need to be made.

It is a combination of process and maybe a few minor design enhancements. And to the extent that the ultimate solution involves any design tweaks, that's what takes more time. Do we have to change a mold? Do we have to make any submissions to FDA? Those are the longer lead times that require six months.

If it was just process stuff and it was just within the process specifications and the procedures, that would make it faster. Obviously this is the kind of thing we never want to have happen again. We'll fix it right. And if it takes a little longer, then so be it.

Chris Pasquale - *Guggenheim Securities - Analyst*

okay. That's helpful. And then sort of on a related note, Vaseem, you cited the resumed shipments to OUS distributors as one of the drivers of the revenue step up from Q1 to Q2.

I would think you would need to have the manufacturing changes in place to build the inventory to support those orders. Is that right? And so, are you assuming you have enough time to both implement these changes and then build that inventory within Q2?

Vaseem Mahboob - *Endologix Inc. - CFO*

No. Chris, it's slightly different. So let me give you some color on that. The $3 million that we pushed from Q4 and we were hoping we would get it in Q1, it was about $1.2 million of AFX2 and $1.8 million of AFX1.

The reason we decided to push those $1.8 of AFX1 to Q2, is because today to supplement the large diameter size -- AFX2 cases in the US, we're using AFX1 inventory. Because these are docs that have been doing AFX1 cases for a long time. With limited availability, we didn't want to put us cases at risk, especially in light of the fact that we had enough inventory in our indirect channel in OUS markets that it was not an immediate need.

We decided to prioritize, push them to Q2 but make sure inventory was available to do the US cases. And then the $1.2 million AFX was related to getting the Japanese team ready for the AFX2 launch. We still hope to get the approval for AFX2 here in the near future and Japan.

We will push the launch of AFX2 in Japan to the second half when we have enough AFX2 product availability. We just didn't want to launch a product and not have the product available.

Chris Pasquale - *Guggenheim Securities - Analyst*

Okay. Thanks for that. That makes sense. And then Vaseem, last one for me. I didn't hear any guidance specifically on gross margin which is a pretty important component given all of the moving pieces here on the manufacturing front. Can you give us any direction on what you're expecting for 1Q and the 2017 overall?

Vaseem Mahboob - *Endologix Inc. - CFO*

Yes. So what we have baked into our plan here internally is that we would -- we're right now going through sample testing. And we will be in the (inaudible) testing methodology as we ramp up AFX2. So we think there will be a $2 million impact on margins this year relative to where we need it to be.

So it is about a point, point and a half -- about a point of margin at the end of the day, Chris, that we think we'll burn up because of this (inaudible). So we think that what you should be thinking about as margin this year versus 2016 is a flat gross margin, not accretive gross margin too because of the sampling methodology where we'll have to burn some cash.

Chris Pasquale - *Guggenheim Securities - Analyst*

Thanks.

Vaseem Mahboob - *Endologix Inc. - CFO*

You're welcome.

Operator

our next question comes from the line of Jason Mills with Canaccord Genuity.

Unidentified Participant - - *Analyst*

This is actually Cecilia [Furlong] on for Jason. If I could just kind of follow up on the gross margin question, as we think out past 2017, what should we think of as more normalized gross margin levels?

Vaseem Mahboob - *Endologix Inc. - CFO*

Well, we had talked about, you know, a couple of years ago and when you put out that long-range forecast, we wanted to deliver 74% gross margins over the longer term. I think with the delay in Nellix, we have taken a little bit of a gross margin hit because, obviously, we don't see the volume leverage in the near future. But as we think about launching Nellix, volume has to pick up and we have to have a good impact with that on our margins.

More importantly, some of the assumptions that we had made on gross margin as it relates to some of the integration projects with TriVascular for example, stamped manufacturing, hydrophilic coating, I think all of those are going to start (inaudible) once Nellix comes in and also we have a meaningful volume there.

So, I would say at this point for 2017, I would model what I just said. Essentially a flat gross margin year-over-year after the impact of the [law] testing and then we should assume that we grow our margins continuously about a point every year. I think that will be a safe presumption at this point.

Unidentified Participant - - *Analyst*

Okay. Thank you. And then just turning to growth for 2017, how should we think about the relative growth mix of US and OUS revenue throughout the year?

Vaseem Mahboob - *Endologix Inc. - CFO*

Well, you know, we have built some models internally on how the disruption is actually going to play out. I would say for now, you know, I would say the US business is going to be flat year-over-year with the disruption. I think the European business is going to continue to do well with the launch of Alto here in the second half of the year. And then with the stable Nellix.

For us, the real wild card will be some of our approvals and our ability to launch, for example, AFX2 in Japan and the timing of that. So I would say US would be flat and the rest of the growth is going to come from OUS markets.

Unidentified Participant - - *Analyst*

Okay. Thank you very much.

Vaseem Mahboob - *Endologix Inc. - CFO*

Yes.

Operator

Our next question comes from the line of Steven Lichtman with Oppenheimer. Please go ahead.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Thanks. Hi, guys. John, you're going to be launching two products in Europe this year and to the complex segment obviously with Alto and potentially ChEVAS.

Can you remind us how much of the market those products open up for you and then maybe do a little bit on the compare and contrast which patients those two patients are going to more specifically go after within the complex market.

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

Yes, well in terms of timing, hopefully the regulatory approval process goes well with both these devices. But we're expecting feedback from our notified body at the end of March for Alto. That will be an infrarenal solution that can treat short necks and then as we talked about before, ChEVAS, that timeline sticks would be around the end of the year.

I don't think we'll have much of an impact on sales this year with ChEVAS but it should have more of an impact in 2018. But in terms of what it opens up, these are really new -- completely new and incremental indications for us. Because right now, if you look at the Ovation IX, even though it has a very broad indication and can technically be used for complex patients, Alto simplifies the procedure planning and procedure execution to a whole other level. It can be used for both complex as well as standard anatomies.

So if you look -- if you go to our slides, the investor deck which I think will probably be posted here in a few minutes, the complex market segment, as we've talked about in the past is worth well over $1 billion. We think the combination of Alto and ChEVAS uniquely positions us for well over half of that. So at least an incremental $500 million opportunity for us. So we're pretty excited about it.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Okay, great. Thanks for that. And then you mentioned potentially AFX2 launch in Japan in the back half of the year. Just broadly, can you give us an update in Japan. I know you've had a new partner there over the last few quarters. What's the outlook on that business?

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

Yes, I'm not going to give you the details for competitive reasons, Steve. But I can tell you they have exceeded our expectations. Japan Lifelines are an outstanding partner.

They went from zero to a relatively meaningful market share position quickly. And are anxious to get their hands on AFX2. That business is growing very nicely and the outlook is positive. We just need to get through this near-term manufacturing stuff and load them up with AFX2 so they can go launch that device. So very bullish on Japan as well as our business in the other Asian markets, which looks really good right now.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Okay, great. Thanks, John.

Operator

Our next question comes from the line of Glenn Navarro with RBC Capital Markets. Please go ahead.

Glenn Navarro - *RBC Capital Markets - Analyst*

Hi. Good afternoon, guys. My first question is for Vaseem.

Vaseem, can you help me fill in the quarterly revenue cadence? You gave me $41 million for 1Q. You gave me $50 million for 2Q. Should I assume 3Q, you're sequentially down? That's seasonality to somewhere in the $45 million range and should I assume somewhere around $60 million for the fourth quarter, when you add that all up, you get in the middle of your guidance range.

That's my first question.

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. So, Glenn, you know, we hadn't given out like quarterly specific numbers but this is the first time we do. I think recognizing there is a lot of disruption and we want to get the models right here.

The $41 million ramps up to about $50 million in the second quarter. Like I said, I explain the walk for a couple of questions earlier. If you remember, the reason I said was that the step up from Q1 to Q2 included this $2 million of the push on the OUS markets, the indirect orders.

There was also a $1.2 million step up that we had from Q4 for AFX2 for Japan and now with pushing out the launch into the second half of the year, that actually goes in as product becomes available in Q3. I would say you know, you go from $41 million to $50 million to flat in Q3 and then the rest of it would be in Q4. So that's the sequential growth that we've been talking about.

We could be slightly higher than Q2 but at this point, I would say -- I would model flat and then hopefully Q4 with a lot of the capital that John talked about here, we get back to hopefully double digits.

Glenn Navarro - *RBC Capital Markets - Analyst*

Okay. No, that's great. That's very helpful.

Just as a follow-up, you know, we're expecting another list in sales in the fourth quarter. I would imagine part of that is going to be driven by having full supply of AFX2 in the second half of the year. But I would imagine between now and whatever it is August, September, some surgeons are going to probably use Medtronic or Cook or [Gore] as an alternative.

So my question is how easy will it be to get those surgeons back if they've gone off to one of the competitor grafts? Thanks.

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

Yes, good question, Glenn. Our goal is to not open that up. If they do want to -- if they want to use an AFX platform in the near term, we can supply them with AFX1.

Now that's a step backwards because the feedback on AFX2 has been really positive. But a lot of these physicians that use the AFX platform really like it. In fact, we were looking at some account analytics recently and found that in our AFX customers, we have about 35% of their total case volume.

So those sales of AFX are pretty sticky. And while I agree there may be some utilization of some other devices, hopefully the other device will be Ovation, but if it is not, I think we can them back if we do have some lost cases in the meantime, if they are as sticky as we've seen that base of business historically.

Glenn Navarro - *RBC Capital Markets - Analyst*

Okay. Great. Thanks for answering my questions.

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

Thanks, Glenn.

Operator

Our next question comes from the line of Ravi Misra with Leerink Partners. Please go ahead.

Ravi Misra - *Leerink Partners - Analyst*

Hi. Great. Thank you for taking the questions. Can you hear me?

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

Yes. Hi, Ravi.

Ravi Misra - *Leerink Partners - Analyst*

Hi. So just one question on the Opex, I think the guidance that $170 million to $175 million is a lot better than what we were actually modeling. Just wondering if you can give us color as to where that upside, at least versus (inaudible), is coming from and how should we think about that as you prepare for if everything goes right, the Nellix launch in 2018. Are we going to see -- it seems to me a lot of the savings might be in S&M. Are we going to see a step back up in that in 2018 as you work on Nellix commercialization? Any thoughts on that?

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. So, Ravi, first of all, I think a lot of the synergies that we executed on throughout the year, which is reflected on -- when you look at earning down 5%, clinical reg down 28%, G&A down 16%. A lot of these were synergies that happen all through the year. So what you see here in the

number -- normalized or an annualized run rate of that reflecting in the lower number. So I think that's one big driver of why the Opex number is smaller.

Second, we have, you know, put together a plan where we continue to make investments in information technology and some of our systems and our processes to, kind of, really drive the manual non-value added work out and so that's reflected in some of these numbers. Also you know, last year, as part of the merger, what we carried in our run rate for a long time were cost related and also from some reps that we had kept back on, you know, to help with -- get coverage on certain accounts.

So as those people left off in September or ended those contracts in September, you were seeing a pretty nice bump in the sales and marketing line. So I think at this point, I would say whatever actions that we have to take to kind of deliver the $170 million, $175 million are complete from a people perspective. We are continuing to focus on our discretionary spend on purchase services and program (inaudible) to make sure we're spending the money on the right activities.

For example, the Nellix PMA is important so that's all funded. The panel prep for Nellix is funded and we're executing down that path. So those initiatives are in the run rate.

Now, having said that, as we get closer to the launch next year, if there are investments that we have to make to make it a flawless launch, we'll add those back in on the sales and marketing line. But at this point, I would say $170 million, $175 million is the number for next year. I think we'll continue to look at the investment opportunities for some of the longer term growth programs.

Ravi Misra - *Leerink Partners - Analyst*

Great. Thanks. And then just a couple more. Help us think about maybe the market.

You talk about AFX approval in Japan hopefully soon or AFX2. Can you help us think about what the market opportunity is there and the competitive outlook in that space? And then, just one last one, how should we think about -- what kind of step up are you baking into guidance or Alto in Europe? It sounds like that should be -- it sounds like you're signaling it is more of a fourth quarter thing rather than third quarter. Any color or help there would be great. Thanks.

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

Yes. First of all, going to AFX2 in Japan, we've got the Japanese market scoped in the [120] to [140] range. I'm not going to give you our exact market share right now just for competitive reasons. But I can tell you we have a lot of upside there.

This product platform is unique to Japan and being well adopted based upon the good work being done by our partners. We're off to a very good start there. It is a good size market with a lot of growth potential, it's one of the top five markets in the world so that's going well. I want to make sure I understand your second question, Ravi, was it about Alto and approval?

Ravi Misra - *Leerink Partners - Analyst*

No. It was just around the European launch. I'm trying to figure out should we be thinking of that more as contributing to sales in the fourth quarter or third quarter or more significantly in the fourth or evenly split in the back half? How do we -- how would you suggest we model revenue there?

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

Yes, well initially, we'll go with a limited market introduction. So we won't go right to a full-blown commercial launch. While the product is very, very similar to Ovation ix, it can treat more complex anatomies and we want to take it slow and make sure the physicians have the great outcomes that they should expect.

We'll start out in the second half with the limited market roll-out and that will probably start to build some momentum in the fourth quarter and in that same time frame we'll be starting to enroll this post-market registry study of 300 patients. I don't expect us to enroll that whole study in the second half. But between gradual build and the commercial activity and enrollment in that post-market registry, I think you start getting some decent numbers going in Q4.

Ravi Misra - *Leerink Partners - Analyst*

Okay. Thank you.

Operator

Your next question is a follow-up from Brooks West of Piper Jaffray. Please go ahead. Brooks, your line is live.

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

Sorry about that. Can you hear me?

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

Yes.

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

Okay. Just a quick follow-up on the IDE data that we're going to see at SVS potentially this summer. So if we -- John, if we see a migration rate in the general patient population that is comparable to or maybe worse than traditional devices but you prove your thesis on the narrowed IFU and you show benefit there, I guess, a, is that a scenario we should be prepared for and, b, if that's what the data does show, what do you think the reaction to that within the clinical community is going to be?

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

Brooks, I want to make sure I understand the question. When you say the migration rate with the new IFU, did I catch that right?

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

No. I said -- because I think I'm trying to re-ask a question I was asking earlier. If you see a migration rate within the broader population, that is comparable to traditional devices but within the narrowed IFU, you showed good results, how do you -- a, is that something we should be prepared for and, b, what do you think reaction to the data set would be within the clinical community?

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

Well, I don't think you should expect a migration rate in the broader population that would be comparable to the migration rate of other devices. If that was the case, we wouldn't be going through this effort, right? So we already know that the migration rate for the entire data set will be higher than we see with EVAR comparisons.

That said, what we should expect to see, what we've seen so far, is the migration rate in the new IFU that is comparable to EVAR. If I'm understanding your question right. So what we've seen so far is the migration, sack expansion and endoleak (inaudible) curves with the new IFU look very good, in fact compare favorably to traditional EVAR devices in other IDE studies.

So that's what we expect to see. The data is not completed and we haven't done the prospective tests on the European data set but that's kind of what I'm thinking we would see in broad strokes at the SVS.

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

Okay. And you're confident, I mean, that's what you need to have success with the device if that's going to be accepted by the clinical community.

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

Yes. I think the clinical community is going to want evidence that the IFU is effective. And I would expect -- I think we'll be able to deliver that.

We'll be able to show specifically what kind of anatomies are well suited for Nellix infrarenal and which ones aren't. In fact, that kind of information is already circulating in Europe and will be reviewed extensively will at the SAS meeting next month. So I think there's -- the evolution of the best patient selection for Nellix is happening now.

And that data will be -- I think that will be clear in the middle of this year in the IDE and hopefully that's enough to get the FDA to feel good about approving the gen-1 device.

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

Great. Thanks, John. Appreciate it.

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

You bet.

Operator

We've reached the end of our question-and-answer session. I'll turn the call back over to management for any final remarks.

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

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

Operator

Ladies and gentlemen, this does conclude our call for today. We thank you for your time and participation and you may disconnect at this time. Have a wonderful rest of the day.