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Endologix, Inc. (ELGX)

Nellix EVAS System Update Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Incorporated Investor Update Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference call is being recorded. This conference call is also being broadcast live over the internet at the Investor section of the company's website at www.endologix.com, and a replay of the call will be available on the company's website for one year.

Before we begin, I would like to caution listeners that this presentation and the investor slides discussed today include statements that may be forward-looking statements. The words believe, expect, anticipate, project, forecast, and similar expressions among others generally identify forward-looking statements. Forward-looking statements used in this presentation include those with respect to revenue growth and path to profitability, new product launches, market opportunity and growth, filing for Nellix EMA and other regulatory approvals, anticipated product labeling, clinical acceptance of our products, and revenue and operating expense guidance for 2017.

Endologix cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include but are not limited to competition from other products, changes to laws and regulations applicable to our industry, progress of our ongoing clinical trials, clinical trial results, decision and the timing of decisions of regulatory authorities regarding our products and potential future products, delays in new product launches, market acceptance of our products, and risks relating to foreign currency fluctuation.

Additional information about the factors that may affect Endologix's operations and results is set forth in Endologix's annual and periodic reports filed with the Securities and Exchange Commission. Endologix undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or development except as required by law.

With that said, I'll now like to turn the call over to John McDermott, Endologix's Chief Executive Officer. Mr. McDermott, you may begin.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon, everyone, and thank you for joining us today. This afternoon our Chief Medical Office, Matt Thompson, will provide an overview of the Nellix IDE two-year clinical results that were presented a few hours ago at the SVS Meeting, and then he'll discuss the 30-day results from the LUCY Study that were presented this past Wednesday evening. After that, I will explain recent updates to the investor presentation that we posted earlier today, and then we'll open up the call for questions.

So with that, I'll turn the call over to Dr. Thompson. Matt?

Matthew Thompson

Chief Medical Officer, Endologix, Inc.

Okay. Good afternoon, everyone. What I'm going to do is walk you through the two decks that should be available to you periodically as I go through the results. I'll just give you a slide check to tell you what slide I'm on. I'm going to start with the Nellix IDE two-year results which was presented by Jeff Carpenter, who's the National Principal Investigator, this morning at the SVS Meeting in San Diego.

So I'm now moving on to slide two. So the EVAS FORWARD IDE at the moment consists of 333 patients, and I'm going to show you in the presentation the Kaplan-Meier curves. But I think most of you are familiar with now of the entire cohorts consisting of the 29 roll-in patients, the 150 in the pivotal cohort, and then the 154 that are in the [ph] CA (4:01). And just as a reminder, as most of you know this graft passed its safety endpoints at both 30 days and one year.

So moving slides now. In terms of the encouraging signs that we see throughout the IDE, as you know, Nellix was essentially designed to try and reduce type II endoleaks. You can see here that at two years, the type II endoleak rate remains commendably low. Essentially, 3% rates of Type II endoleak at two years, and most of these endoleaks are small in volume as reported by the core lab. In terms of clinical results, 99% freedom from rupture of two years even with the problems of migration and sac growth that I will address later on in the presentation.

Most of you are aware that we've seen signals with regard to low incidence of both all cause and cardiovascular mortality. Throughout the study, this has been apparent at virtually all Nellix EVAS registries. We initially saw a low all cause mortality signal in the global registry at one year. This has been confirmed in the IDE study where you can see there is a 6% all cause mortality at two years. If you look at most EVAR trials, patients tend to die linearly at about 6% a year. So this is a signal of low all cause mortality that we're continuing to investigate. Cardiovascular mortality, again, as you can see is just over 1% at two years. And, again, if you look at comparative trials you usually see cardiovascular death rates in the realm of 4% per year. So these are encouraging signs that we continue to see in the IDE trial and may clearly warrant further investigation to try and find an explanation.

Now, moving on to slide five now in the deck. As most of you are aware, we did start to see signals of mid to late-term failure modes in the IDE study and particularly in the core lab analysis at two years going forward. And the concerning mid-term failures were migration and sac enlargement, and both of these failure modes have been subject to a root cause analysis, so there's utilized engineering analysis, clinical review, and statistical modeling.

Moving to the next slide. We have described in previous calls the mechanism of migration that has been identified in the root cause analysis. I won't go into detail on this in this slide but, obviously, I'm happy to answer questions. Essentially, there are a particular sort of aneurysm that has a relatively low flow lumen relatively large from the [indiscernible] (7:14), and then in these particular aneurysms one tends not to get enough polymer in around the stents to give them sufficient rigidity to prevent lateral displacement and caudal migration at the proximal end of the endograft.

Moving on to sac growth. We've done a root cause analysis of sac growth and, essentially, this was a problem within the IFU of the original Nellix graft where we allowed sealing in the thrombus in the iliac. In retrospect, that was clearly a mistake. Sealing in thrombus allows retrograde pressurization of the aneurysm sac where you don't get good contact between the endobag and the native iliac tissue. This was recognized in retrospect and we obviously have a fix for this in terms of changing the IFU to mandate a seal zone distally.

So with those two root cause analyses completed, we were able to change the IFU for Nellix, and this is referred to as the refined IFU and is present on slide eight. So just to go through those very quickly, we have reduced the maximum diameter of the proximal aortic neck from 32 millimeters to 28 millimeters diameter to try and reduce the downward [ph] shelf (8:47) force on the implant. And actually, it's interesting in the last couple of months. There's been significant papers published in the general vascular surgery showing lengths greater than 28 millimeters but doing pretty poorly with all endovascular therapies.

We've adopted a more traditional approach to aortic neck classification, moving from a 20% allowed chronicity down to 10%. And then most significantly, we put a parameter on the aneurysm sac which clearly makes sense for a technology that is sealing within the aneurysm sac. The IFU should almost certainly include a parameter around that and we've identified a thrombus index of less than 1.4 defined as the maximum aneurysm diameter divided by the maximum flow lumen diameter. Finally, as mentioned on the previous slide, we've put a parameter around mandating iliac sealing with endobag contact with the iliac artery.

So if we move on there onto slide nine, what follows next is a whole series of Kaplan-Meier plots showing you the freedom rates both on and off the refined IFU, and I'm going to show you those for each of the individual parameters – type Ia endoleak sac growth and migration – and then I will show you the composite endpoint that we've referred to previously. So on slide 9, you can see the freedom from type I endoleak both on the refined IFU which is the red line and off the refined IFU which is the blue line, and actually you can see here these are on or off IFU. Type I endoleak is really not a failure mode for Nellix with a 1% rate at two years on IFU and actually just over a 3% off IFU. So, really, endoleak is not a failure mode for this graft.

Moving to the next slide which is slide 10 in the deck, this shows the rates of migration at 10 millimeters both on and off the refined IFU. Migration remains the primary failure mode if off IFU, but actually you can see if patients comply to the new thrombus index and the new neck parameters, then at two years the freedom from migration, 97.7%, as assessed by the core lab.

Moving on to the next slide, this shows you sac growth, again, on and off the refined IFU, and you can see at two years less than 2% of aneurysms shows significant sac growth defined as 5 millimeters. And actually, this would compare very favorably indeed to the rates of sac growth seen with a traditional bifurcated self-expanding endograft.

Finally, with regard to the Kaplan-Meier curves, I'm showing you here the composite endpoint that we've shown previously in the investor deck. This is a composite endpoint for freedom from type Ia endoleak, migration or sac growth. Two graphs you can see on this slide, one is derived from the IDE study and the other is an assurance

slide to make sure that our refined IFU is performing well across all parameters and across all geographies. This is derived from the global registry. You can see on the left-hand side that freedom from this composite endpoint at two years is 95.9%. I would just outline here that we can identify a root cause for the majority of the failures that occurred on the IFU and can attribute these to technical aspects of the procedure which I can address later if it needs be.

You can see from the graph on your right-hand side, however, that the figures are very similar in the global registry demonstrating that this refined IFU appears to work in different populations and different geographies. I'd also like to draw your attention to the fact that the rates on the IDE have pretty much remain unchanged since we first showed this composite endpoint last year despite many more patients now getting to the two-year time window.

So this is the last slide of the presentation that Dr. Carpenter gave this morning, the conclusion slide 13. And what can we say, we still have low rates of endoleak rupture and both all cause and cardiovascular mortality through two years. We're satisfied with our root cause analysis that principally implicates the thrombus burden in aneurysms in which Nellix has shown migration, and we have shown that the IFU refinement continue to demonstrate good results including low rates of migration, sac growth, and also type Ia endoleak at two years. These rates have remained relatively unchanged since the IFU has been refined, and we see the IFU refinement performing to a high level of discrimination in different geographies and a different patient population using the global registry.

It's important, I think, not to forget the very good results that we see. Nellix is the first endovascular therapy to effectively reduce all endoleak, and particularly type II endoleak. And I would just draw your attention again to the observation that we're seeing very low all cause mortality rates and extraordinarily low cardiovascular mortality rates with this therapy which clearly is a focus of further investigation for us.

So I'm now going to swap away from EVAS and talk about the LUCY Study. I'm going to use, again, the deck that is available to you, and I'm going to start the presentation at slide five which is entitled Management of Aneurysm in Women Needs Improvement (sic) [Management of AAA in Women Needs Improvement] (15:02). We can go through the actual study investigators later if anyone wants to. So just to comment, really, on the contemporary nature of this particular study, LUCY as you know has been designed and has been recruiting over the last couple of years, but interestingly in the last couple of months there's been some significant papers in the vascular surgical literature identifying the need to improve the management of abdominal aortic aneurysms in women, and in particular to improve the management of cardiovascular disease in women.

The hypothesis of the LUCY Study was that the ovation graft has specific features that make it very attractive for treating the anatomical challenges that are seen in women with aneurysms, particularly with regard to the low-profile nature of the graft and the ability of the ring at the top to provide optimum and customized sealing in proximal aortic necks.

With regard to placing this study into contemporary context, we know that women do worse with abdominal aortic aneurysms with men. The growth rate to their aneurysm are higher, their rupture rates are higher, so their eligibility for EVAR are reduced in comparison to men due to challenging proximal access and also challenging proximal necks. We also, though, know that their acute results are worst at 30 days in women than men, and that they have higher complication rates. Now, these factors have been known for a little while but they are reviewed in this recent paper in The Lancet that actually identifies that women are less eligible for EVAR than men, more women than men are declined intervention when they have an aneurysm, and both 30-day mortality and morbidity rates are higher.

Moving on to slide six. We also know that women are vastly under-represented in trials of EVAR therapy. Women represents broadly only about 10% of patients enrolled in most IDE studies whereas the prevalence of aneurysm in those populations in women are approximately 20%. So they're pretty much half as represented as they should be.

Moving on now to slide seven. This, of course, was the reason for the LUCY study which is the first-ever prospective study to specifically evaluate EVAR in women. This utilizes the Ovation stent platform, which you can summarized on slide eight, and which is a very attractive endograft to utilize in women and, hence, the hypothesis that if utilizing the ovation graft EVAR results may not be worse in women than men. And of particular relevance is the low-profile nature of the graft and the fact that our polymer field proximal sealing ring creates a custom seal and will protect the aortic neck.

I'm going to move on now to slide 10 which shows you the study design. This was a prospective multi-center post-market registry that recruited women specifically in the ratio of two males to one females with the males acting essentially as the control group. The primary endpoint was 30-day major adverse events, and this is relevant in this study because the majority of studies that have looked at EVAR in women have reported worse outcomes at 30 days. Patients are going to be followed up, however, for a year and those results will be available later.

Moving on to slide 11. This shows you the study enrollment, and the data that I will present in the results section concentrate on 76 women who underwent EVAR with the Ovation device as compared to 149 men that underwent a similar procedure. Moving on now to slide 12. This shows the patient demographics that, essentially, the populations were well-matched in women and men for all of the classic demographic features that we look at in aortic trials.

Moving on now to slide 13. This shows you the vascular characteristics, and the important parameters here are the last three lines on the study which demonstrates that in women they have more adversity with regard to the diameter of the aortic bifurcation and in particular, and of significant relevance, the diameter of the iliac arteries much more in women by approximately 2 millimeters. This is clearly challenging access. And moving on to slide 14, these show you the anatomical characteristics broken out as the males and females but confirms the difficult access seen in the women in the LUCY Study.

Moving on to slide 15. This addresses purely access issues and shows you the benefit in terms of patient applicability that arises with a low-profile graft. And when Ovation is compared to the other common grafts utilized to treat patients, you can see increased applicability due to the now low-profile nature of the endograft.

Moving on now to the results section, this is slide 16 which demonstrates equivalents in terms of procedural outcomes between males and females. Moving on to slide 17 (sic) [slide 16] (20:59), again, no significant difference with regard to length of stay, ICU admission or 30-day readmission.

And then moving on to slide 18 (sic) [slide 17] (21:10) which is really the key slide in the presentation demonstrating that major adverse events in terms of mortality and major morbidity are equivalent between males and females. And I've just stressed here that pretty much all other studies that have made a comparison have shown more adverse outcomes in women at 30 days. Moving on to slide 19 and then slide 20 (sic) [slide 18 and then slide 19] (21:36), these show the effectiveness analysis of the graft and, again, males and females in this study showing no difference in terms of effectiveness or on, slide 20 (sic) [slide 19] (21:51), in secondary intervention.

So just two or three slides now on another analysis performed looking at gender outcomes with the Ovation graft, and this shows you a subgroup analysis in the next two slides based on the Ovation European Post Market Registry. This registry has 14% female participation and, again, if you look on slide 22 (sic) [slide 21] (22:19), the iliac challenges are significant as are the proximal aortic challenges in women. But despite this more adverse anatomy, if you look at slide 23 (sic) [slide 22] (22:30) there is no difference in terms of freedom from rupture, aneurysm-related mortality or all cause mortality in this study. Finally, slide 24 shows you the conclusion in the discussion from The Lancet article that actually identifies polymer sealing technology as being a particular attractive advantage in female patients.

So to conclude this part of the presentation, the LUCY study has demonstrated that women traditionally have limited eligibility and worse outcomes after EVAR, and in this first female study we've demonstrated similar procedural outcomes from men and women using the Ovation grafts, a low rate of 30-day major adverse events which is equivalent in the two genders, and similar rates of effectiveness.

I'll now turn this back to John.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Okay. Thank you, Matt. Earlier today, we posted an updated investor presentation and I'd like to take a few minutes now to describe the changes. So if I could ask everyone to please open the updated investor presentation dated June 3, and we'll get started.

The first change is on slide number three where we have reworded the bottom section to highlight our path to positive cash flow. The next change is a new slide number eight titled Management of AAA in Women Has Been an Important Unmet Need. This slide and the content of this slide was reviewed in Matt's presentation, and it highlights that fewer women with AAA get treated and that they have worse outcomes than men. Slide nine is also new. It includes the LUCY clinical results and replaces the previous slide with the excellent clinical results from the LIFE Study that was presented last fall. Slide 10 is also a new slide and provides an overview of the Nellix IDE two-year results that Matt just reviewed.

The next slide that changed is number 14 which is now titled New Product Pipeline: Estimated Regulatory Approvals. We've changed this slide based upon investor feedback that the former design was creating some confusion. So what we're doing now is providing an estimate in either the first half or the second half of the year if our estimated approval is expected to occur within the next 12 to 18 months. If it's longer-term than that, we're simply providing the full year in which we anticipate receiving regulatory approval because it's challenging to be precise with regulatory timelines that far into the future.

We've also simplified the slide for the markets in Asia where we previously had target dates for Japan, China, and other Asian countries. We've now consolidated those into one estimate for APAC, Asia Pacific, and as a result it should be much easier for you to track our progress. Importantly, none of our expected regulatory approval timelines have changed since our last call; we've just updated the format based upon feedback from investors.

Next is slide 15 which changed slightly because we've added the IDE supplement for Nellix and also removed the ELEVATE II Post-Market Registry which we don't anticipate will start this year. And lastly, slide 17 has been updated to highlight our growth drivers over the next few years. As you can see from this slide, we expect to drive growth with our current portfolio and positive clinical evidence this year and in 2018. Then in 2019 we expect to launch Alto, our next-generation Ovation device. In 2020, we plan to introduce our gen-2 Nellix device in the U.S.

And in 2021, we expect to launch ChEVAS. These launches together with our growing positive clinical results are expected to provide nice top line growth opportunities over the next few years.

Finally, one more topic before we go to Q&A. We got very good news from the FDA yesterday. The agency has notified us that they have reviewed and approved our new manufacturing processes for AFX 2 which enables us to resume normal supply to the U.S. market which is consistent with our original plans.

So with that, we can now open up the call to questions. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you, sir. [Operator Instructions] We'll go first to Matt Henriksson of BMO Capital Markets.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Hi. Good afternoon. Thanks for taking the questions.

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

A

You bet.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

With regards to the Nellix and the about 40% that is qualified for the IFU, can you probably provide a little more color on the global registry? Based on my math, it looks like about 20% of that registry was qualified for the new IFU?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hi. It's Matt. Yes, I can help you there. So the important distinction between the global registry and the IDE is that the IDE was a group of patients who were unlabeled for the original IFU. The global registry was run as a typical post-market registry which was essentially old comers, so it included somewhere in the region of 40% of patients who were off-label for the endograft to start with and also included a number of patients who were treated with ChEVAS who had iliac aneurysms, who had ruptured aneurysms, et cetera. So, really, the difference in applicability there is due to IDE was unlabeled, global registry was old comers, and about 40% were off-label at the commencement of the registry.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Great. Then just moving onto the LUCY data as well, and basically the slide that show that about 30% of women who qualify for EVAR versus the 50% from men. How soon will that gap be covered based off of this trial base? Kind of your observations?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Looking at the applicability data, we're pretty bullish about that. So if you look at the reasons why women are less suitable for endovascular therapy than men, you can pretty much break that down into two aspects. One is the access issue which is obviously addressed by Ovation being much lower profile than pretty much any other bifurcated endograft on the market, and there's also the issue about applicability to the proximal neck with women being known to have shorter and more angulated and usually more diseased necks than men. It's kind of difficult to give you an absolute figure on the closure of that gap because, obviously, all of the other endografts with regard to the proximal aortic neck define the aortic neck differently and also define their IFU differently in terms of the requirement for the length of neck. But I think it would be safe to say that, as a conservative estimate, you'd probably close that gap by at least 50%.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Great. And then if I could just squeeze one final one in. Has there been any updated conversation with the FDA about whether or not the new IDE study is going to be a one-year or a two-year study just based off of the positive data that was presented today?

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

A

There hasn't been any discussion with the FDA subsequent to our meeting with them a few weeks ago. But in that meeting, they were very clear that their intention for the evaluation of aneurysm repair devices was a one-year follow-up.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Great. Thank you very much.

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

A

You're welcome.

Operator: We'll go next to Michael Weinstein of JPMorgan.

Q

Thanks for taking our question. This is actually [ph] Andrew (31:15) in for Mike. Can you all hear me?

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

A

Yup. Hey, [ph] Andrew (31:18).

Q

Hey. Thank you, John. I just wanted to go through some of these data points and just make sure that I understand. So I know there's a 97% freedom from type II endoleak rate. There were no secondary interventions in that patient group. But how do we think about the patients who had migration greater than 10 millimeters or sac expansion greater than 5 millimeters? Were those patients treated? We're they clinically significant? How do we think about that?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Okay. Hi, it's Matt. So let me take those separately. Migration, as you know, was a relatively late event in the IDE. There haven't been a great number of reinterventions for migration at the present time. The issue is that we have a slight disparity at the moment in terms of what's available in Europe as compared to what's available in the U.S. So we do understand the root cause for migration, we also have a pretty good comprehension that there is a fix available for migration. And when I talk to docs about this, you can essentially break reintervention for migration down into just a conservative approach. If you got a long neck and a long ceiling zone still existing, it's actually reasonable to treat these patients conservatively because we actually know that migration, if it's a primary phenomenon, slows down after about 12 to 18 months.

We've also got a fix with docs in that, as I said earlier, the root cause of migration is really lateral displacement of the graft. So if you stiffen the graft by putting another stent inside, essentially using another Nellix endograft, then we think that will actually mitigate migration and slow or abolish the rate. And then finally in Europe, if you've got significant migration we can actually extend more approximately. So it would be reasonable to think of sort of reintervention being slightly different in Europe as opposed to the U.S.

What we're actually doing at the moment is we are having a dialogue with the FDA about allowing the use of the secondary interventions in the IDE patients, and we're hopeful that that will be approved in the not too distant future. In the intervening period, we do actually have an arrangement where patients can be considered on an individual compassionate basis. So we've got a pretty broad understanding and a clinical fix for the majority of patients who have migration.

In terms of sac growth, then actually that's a little bit easier in terms of intervention. We do know that the vast majority of patients who have sac growth have their Nellix implanted in thrombus in the iliac artery, and we have good evidence from anecdotal clinical reports from both Europe and New Zealand. But if you extend distally and actually get a seal in the iliac artery, then sac growth pretty much stops. What we are saying to sites though is that if they do see sac growth, then this should be treated sooner rather than later.

Q

Great. And then to follow-up, I just want to make sure when you do – and what the conversation is with the FDA in terms of migration, whether it's going to be greater than like 5 millimeters, or what is it in the data regarding patients that migrated greater than 5 millimeters? So that's two questions there. What the FDA is going to require? Is it greater than 5 millimeters? And if so, what was the percentage of patients that had migration greater than 5 millimeters?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Well in terms of the protocol definition, we obviously need to go back and forth to the FDA with our trial design and, traditionally, in the reporting standards migration is defined at 10 millimeters and so that's really what we've

shown you today. In terms of the proportion of patients that are somewhere between 5 millimeters and 10 millimeters, I don't think I can give you those data today. They're not available on our K-M curves.

Q

Thank you.

Operator: We'll go next to Chris Pasquale of Guggenheim.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. John, just a quick question to start. On the AFX 2 announcement and the timing here, can you clarify what the guidance had previously assumed in terms of your return to market?

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

A

Yeah. We assumed is that we have full availability of inventories in the second half, and so this news is consistent with our original guidance and our expectations.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay, and I think that sort of partially answers my follow-up which was now that you have the approval, how long does it take you to actually replenish inventory and get back to a situation where it's business as usual.

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

A

Yeah. We have been in anticipation of this approval already started to scale up our operations, so we expect to be able to supply the market consistent with the original guidance. So it's good to check the box and very collaborative process with the FDA, so it's good news.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay. And then you highlighted the change in language around a path to profitability versus a path to cash flow breakeven in the slide. Can you just spend a minute on what's really changed there and your thinking and do you need to reevaluate the cost base of the business now that we're in a world where Nellix isn't going to be on the U.S. until 2020?

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

A

Yeah. We do have Vaseem also on the call. Vaseem, I'll let you answer that one.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So, Chris, as we talked about last time, we did push the cash flow breakeven to the second half of 2019 versus 2018 which was the original plan prior to the delay. Now, in terms of the cost base the guidance of $170

million to $175 million, I think, is the right number for the year, so that's unchanged. And as part of our process here as we kind of get clarity on the top line assumptions and what we think the core business can grow as we start to see some recovery of the AFX 2 business in the U.S., we'll come back to you guys as part of the guidance towards the end of the year on what that cost base looks like. But at this point, we are running different scenarios and we feel very comfortable that that number of second half 2019 to be cash flow breakeven.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks.

Operator: [Operator Instructions] We'll go next to Mathew Blackman of Stifel.

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

Q

Good afternoon, John, Vaseem, Dr. Thompson. Do you hear me okay?

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

A

Yup. We got you, Matt.

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

Q

Okay. So first question, when would you expect to have definitive FDA sign off on the informatory and ChEVAS studies? And would it be safe to assume that those trials will be, I don't know, less than 100 patients?

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

A

Yeah. So there's a couple questions in there, Matt. We are targeting to have to have the IDE supplement approved in the third quarter and start enrollment in the fourth quarter for the infrarenal indication. As it relates to ChEVAS, our goal is to try to get IDE approval by the end of the year and then start enrollment in the first part of next year.

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

Q

Okay. That's helpful.

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

A

Yeah. Think of those two as separate. The good news is they're going to be a part of the same IDE, but they will be separate studies within that IDE. As it relates to the study size, we're still working with FDA to determine that final number. I don't really want to get a number out there yet, but I can tell you it will definitely be less than 150.

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

Q

Okay, got it. Next question, I'm not going to ask for an update on 2Q, though feel free to provide one. But I thought maybe John or even Dr. Thompson could share sort of the state of Endologix and business primarily outside the U.S., both Nellix but also AFX. I'm just curious how things are due to reaction to what's going on in the U.S. Is there any sort of collateral impact in Europe that you guys could see so far?

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

Well we have been inventory constrained with AFX outside the U.S. also, so this will be good news that we can open up supply to all markets so I think what we announced today is going to be viewed as positive. Globally, as it relates to Nellix, we feel like we've kind of bottomed out, if you will, on the adjustment to the new IFU and expect to start showing sequential growth with the Nellix product line outside the U.S. And then also for the Ovation product line outside the U.S., we have been growing nicely. So we're consistent with our guidance, we see good sequential quarterly growth globally over the next several quarters.

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

Okay. That's great. And then my last question. I've asked this before so I'll ask it again because we did see it again in the IDE study. This all cause mortality and cardiovascular event signal, when could we see – and I don't know if this is the right way to phrase it – but further confirmation of this? I suspect you don't have to run a full prospective trial. You could probably do some sort of meta-analysis or propensity-matched study. But just sort of is it possible, I guess, bottom line that we could see some sort of confirmation of this in the next, I don't know, 12, 24 months?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Matt, it's Matt, hi. Yeah, we're kind of bullish about this. So we saw this, really, as a signal at the year one results in the global registry, and then following on saw at two, three years in the global registry and see same kind of figures for the IDE. So, consistently, that signal has come up and I think now we need to take it seriously rather than an interesting observation. So we would have plans now to dig into this across our various databases, and I think a propensity-matched analysis with patient databases in different geographies is certainly on the cards now. So we're really going to be working towards designing that propensity-matched cohort study and I would certainly hope to be able to have something available within 12 months with regard to the results of those analyses.

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

Okay. That's all I had. Thank you so much.

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

Thanks, Matt.

Operator: We'll go next to Chris Cooley of Stephens.

Chris Cooley
Analyst, Stephens, Inc.
Q

Thank you. Can you hear me okay?

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

A

Hello. Yup. Hey, Chris.

Chris Cooley
Analyst, Stephens, Inc.

Q

Thanks, John [ph] , appreciate it (43:19). Just two quick follow-ups from me at this point. I wanted to clarify a comment made on one of the earlier questions. Is there a design change or an enhancement planned when you think about Nellix to counter the potential for migration in terms of adding another stent or did I maybe mishear that and that's actually the reintervention methodology there? I just was curious if that was maybe a little bit of signaling on a design change. And then one other quick follow-up after that.

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

A

Yeah. No, Chris, the gen-2 device that's going to be in the confirmatory study is the same device that will be used in ChEVAS, so the way to mitigate migration in the near term with the current Nellix device is through patient selection. Longer-term, we will introduce a newer-generation EVAS system that will embody a lot of the design elements within our portfolio that should be able to treat a very, very broad range of patient anatomies.

Chris Cooley
Analyst, Stephens, Inc.

Q

Understood, understood. And then if we just think back – I think this was kind of pressed on earlier I believe – I can't remember the slide number here but it's the IFU refinement and migration. 93.2% off the revised IFU and 97.7% at two years on the [ph] unrevised (44:56) indications for use. Maybe a little bit of a, I guess, look ahead. What would you expect to see or what type of data would you think the agency would expect to see to not have concern about migration? Either greater than 10 millimeter or a 5 millimeter range going forward? Maybe a look into what you would structure the trial design to be? Thank you so much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Chris, it's Matt. I think the agency were, when we presented to them, reasonably comfortable with the migration rates at 10 millimeters at the level that they are on the refined IFU, and they are almost certainly the figures that we'll be putting into some of the statistical analyses when we design our sample size for the trial.

Chris Cooley
Analyst, Stephens, Inc.

Q

Thank you.

Operator: At this time, we have no further questions. I would like to turn the call back over to our speakers for any additional or closing comments.

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

Okay. Well thank you, operator, and thanks, everyone, for joining us on the call today. We hope you have a great afternoon.

Operator: That does conclude our conference for today. We thank you for your participation. You may now disconnect.