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ELGX - Q1 2016 Endologix Inc Earnings Call

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PRESENTATION

Operator

Greetings and welcome to the Endologix Incorporated first quarter 2016 earnings call. At this time all participants are in listen-only mode. A question-and-answer session will follow the formal presentation. (Operator Instructions). As reminder this conference is being recorded.

I would now like to turn the conference over to your host, Zach Kubow of The Ruth Group. Thank you. You may now begin.

Zack Kubow - *Endologix Inc. - IR, The Ruth Group*

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 website for one year.

Before we begin I would like to caution listeners that comments made by management during this conference call will include forward-looking statements within the meaning of Federal Securities Laws. These forward-looking statements involve material risk and uncertainties. For a discussion of Risk Factors I encourage you to review the Endologix's Annual Report on Form 10-K and subsequent report that's filed with the Securities and Exchange Commission.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, May 9, 2016. Endologix under takes 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 McDermott.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Thanks, Zach. And good afternoon, everyone, and thank you for joining us today for Endologix's first quarter 2016 conference call.

This afternoon I will provide a brief overview of our first quarter results followed by an update on the TriVascular integration and our key growth drivers. I will then turn the call over to Vaseem for a review of our first quarter financial results, 2016 financial guidance, and an update on our synergy plan from the merge. After Vaseem I will come back on to provide an overview of our top priorities and then we will open up the call for questions.

First quarter revenue was $42.4 million, which is significantly better than our original estimate. We attribute these results to the planning and effective execution of the merger integration. Our new combined team has worked hard to minimize disruption while focusing on customers and capturing the anticipated synergies.

While we are pleased with our progress in the first quarter we still have a lot of integration work to do and are anticipating considerable growth in the second half of the year. So we are maintaining our full year sales guidance in the range of $192 million to $202 million. Over the past few months we have made good progress with the TriVascular merger integration in all of our geographies.

In the US we consolidated our sales organizations, completed our territory realignments and conducted the initial product and clinical training on Ovation iX and AFX2. We're pleased with the early results of both products and believe national devices complement each other nicely to provide physicians with more clinical options for their patients. In Europe we completed our territory realignments and conducted our initial Ovation iX and Nellix sales and clinical training.

At the Charing Cross Meeting in London we provided additional training on the next-generation Nellix system, which received CE Mark on April 11th. Over the next few months we will transition to the new Nellix system in Europe and have received very good feedback from physicians so far. In particular, the additional new sizes should enable physicians to treat more patients with Nellix.

We have also already received CE Mark for AFX2 but are planning to launch that device in the third quarter because our European team already has their hands full with the Ovation iX and new Nellix systems. In our international distributor markets we have identified all of our long-term business partners and are working through contracts and transitions to minimize disruption and maximize market share gains. We are training our representatives, agents and physicians on the products available in each market and can see significant long-term growth potential, particularly in Asia and Latin America.

On the clinical front there continues to be a lot of activity, particularly with Nellix. At the recent Charing Cross Meeting in London there were several presentations including one by Dr. Jean-Paul de Vries from the Netherlands. He presented results from a multi-center study of patients with iliac artery aneurysms treated with Nellix.

The study included data from 72 patients with mean follow-up of 13 months. The investigators received 100% technical success in patients with common iliac artery diameters between 29 and 35 millimeter which are well beyond the indication for use of our EVAR devices. There was also a low 5.6% secondary intervention rate, which is outstanding considering the challenging anatomies of these patient.

At Charing Cross there was also an update on the Nellix global registry. The data now includes 300 patients with a mean follow-up of 20 months. Highlights from the presentation were freedom from persistent endoleaks of 98%, which continues to be the lowest level of overall endoleaks ever reported from an endovascular device to treat abdominal aortic aneurysms. We also had a low rate of secondary intervention in patients treated within the instructions for use and a very low overall mortality rate.

Professor Matt Thompson why St. George's Vascular Institute in London also give a presentation on the initial results from the ASCEND Registry, which is a student eave patient with complex aneurysms treated with the Nellix system and aortic branch devices. Dr. Thompson presented one year outcomes data from the first 154 patients, which included procedures with single, double, triple and quadruple branches. Highlights included target vessel patency of 98% to 100%, a low 1% rate of serious renal complications at 30 days, and zero persistent endoleaks.

These results are extremely encouraging and reflect the significant potential that Nellix has to offer physicians a solution for patients with complex abdominal aortic aneurysms. Today Nellix is not indicated for use with branch devices but we hope to expand indications in Europe in the second half of 2017.

As is a reminder the complex market is substantially under penetrated with less than a third of patients treated with endovascular technologies today. The market has the potential to reach $1.5 billion and represents a huge growth opportunity. Next months the Nellix one year follow-up clinical data from the US IDE study will be presented on Seattle, June 11th at the SBS meeting by principal investigator Dr. Jeffrey Carpenter.

We plan to issue a press release that Seattle with the key highlights from the study followed by a conference call with Dr. Carpenter to review the results in detail the clinical data from the IDE study was submitted to the FDA at the end of March which keeps us on track for potential PMA approval at the end of 2016 or early 2017. We also just received approval from the FDA to enroll another 100 patients in our Continued Access Protocol so we should be able to transition from the CAP into our commercial introduction based upon the current estimates and timelines.

In addition to the Nellix clinical studies we have several other important clinical initiatives to provide physicians with evidence and drive adoption of our products. First is the LIFE Registry which is a 250 patient study evaluating Ovation and a percutaneous fast track protocol. The results from this study are expected to be presented at a major medical meeting this fall. Next is the LUCY study which will enroll up to 225 patient to demonstrate the benefits of Ovation device in treating women.

LUCY should complete enrollment in 2017. And last is the LEOPARD study which is the first ever head-to-head clinical trial in EVAR comparing AFX against Gore, Medtronic and Cook. This 800 patient study is expected to complete enrollment in 2017. All of these studies are generating important clinical evidence while also providing opportunities to expand our relationships with more physicians.

In summary, we're very pleased with the results in the first quarter and the progress made with the TriVascular merger integration. Endologix is extremely well-positioned for sustainable growth which will be driven by our expanded global sales an clinical teams, our innovative new product pipeline, and growing clinical evidence.

I will now turn the call over to Vaseem for his financial review. Vaseem?

Vaseem Mahboob - *Endologix Inc. - CFO*

Thanks, John and good afternoon, everyone.

As John indicated, we had a solid start to the year as reflected in our Q1 financial performance. As a reminder, unless otherwise indicated, the comparisons made in my remarks to financial results for the first quarter 2015 will be on a pro forma basis to include the results of both Endologix and TriVascular in the quarterly period.

As indicated on the last earnings call, we have taken a position that we will limit the details of our financial performance and not risk putting our execution strategy and plans in the public domain. Starting with revenues, total revenue for the first quarter of 2016 was $42.4 million, a 5% decrease compared to pro forma revenue of $44.7 million in the first quarter of 2015. US sales were $29.9 million, down 3%, and non-US sales were $12.5 million, down 11%. We're down 9% on constant currency basis.

The out performance, relative to our expectation for the first quarter revenue to be down in the 10% to 15% range, was driven by three main factors. First, lower than anticipated instructions from the merger specifically in the US market. Continued strong growth of Nellix in Europe, and a good start to the AFX 2 control market release in the US.

As John indicated, while we are pleased with the early results of our integration efforts we still have a lot of work to do to position us for positive growth in the second half of the year. This is in-line with what was communicated in the quarterly guidance framework we put out back in February. US revenue was $29.9 million which represents 19% growth versus standalone Endologix and a 3% pro forma decrease versus Q1 last year. The decrease was due to the fact that our results exclude 2016 TriVascular sales prior to the February close date and the anticipated merger-related (inaudible).

International revenue was $12.5 million, which represents growth of 8% versus stand alone Endologix and down 9% on a constant currency pro forma basis. The international performance reflects continued strong growth from Nellix and some distributor disruption related to the merger. We have completed our distributor selection process and are currently working through contracts and transition programs.

Nellix continues to perform well, particularly in the direct channel where we continue to gain market share. As expected we saw a slowdown in Nellix with distributors de-stocking ahead of the CE Mark approval of the next-generation device. We expect this to rebound in the second half of 2016 and is already factored into our guidance. Gross margin in the first quarter 2016 was 66%, compared to a pro forma gross margin of 70.6% in the first quarter 2015.

Gross margin in the quarter was negatively affected by the purchase price accounting for TriVascular inventory, which we expect to continue to flow-through our margins for the next couple of quarters. Adjusting for the effect of purchase price accounting, the gross margins for the first quarter were at 72.6%. The improvement versus first quarter 2015 pro forma gross margin was driven by better pricing, a positive US regional mix and improved inventory management. Managing cost and capital allocation are extremely important for us as we strive to deliver our synergy targets and invest in the critical priorities for the business.

We are happy to report that we managed costs well and our operating expenses for the first quarter 2016 were $66.3 million compared to $54.8 million on a pro forma basis in the first quarter of 2015. First quarter 2016 operating expenses included approximately $12.1 million in one time acquisition-related expenses and a $4.7 million charged for the LIFE support legal costs centimeter cost of. Excluding these items operating expenses were $5.2 million or 9% lower than pro forma first quarter 2015.

The lower costs were derivative by cost action in-line with communicated synergy plans in bringing the two organization together. As reminder, for modeling purposes, this includes only a partial quarter of TriVascular operating expenses in 2016. Our GAAP net loss was $47.7 million or a loss of $0.62 per share in the first quarter 2016 compared to a pro forma net loss of $26.9 million for the first quarter of 2015.

Adjusted net loss for the first quarter of 2016 was $19.3 million or a loss of $0.25 per share compared to adjusted pro forma net loss for the first quarter 2015 of $23.1 million. Adjusted EBITDA for the first quarter 2016 was a loss of $14.1 million or $0.18 per share compared to adjusted EBITDA net loss of $18 million in the first quarter 2015. Since we use 13.6 million shares as part of the purchase of TriVascular we did not have enough authorized and unissued common shares available to cover all contract settlable.

As a result all or a portion of these contracts were reclassified from equity to liabilities. These liabilities were mark to market and a $5.1 million charge was recorded as a fair value adjustment of (inaudible) liabilities in the first quarter of 2016. We expect to continue marking these contracts to market until shareholders authorize additional common shares at our upcoming annual shareholder meeting in June 2016.

Moving on to the balance sheet we ended the first quarter 2016 with cash and cash equivalents and investments of $86.2 million compared to $177.3 million at the end of 2015. During the first quarter of 2016 the Company, as planned, used $84.6 million to repay our standing TriVascular deal and the cash consideration for the merger. We also paid $14.4 million for deal related expenses and $2.3 million as related to the first of the two cash payments for the LIFE [port] legal settlement. The second half of the settlement will be paid in 2018.

Now turning on to guidance, we are retrofitting our full year 2016 revenue guidance of $192 million to $202 million. As John mentioned, our strong first quarter results give us confidence in our ability to manage through the integration and drive positive growth in the second half with the launches of the next-generation Nellix in Europe and AFX2 in most markets. For the full year 2016 we anticipate a GAAP loss per share of $1.20 to $1.30 per share and an adjusted loss per share of $0.70 to $0.80 per share.

Our adjusted EPS guidance excludes purchase price accounting impacts related to the TriVascular merger. On our the expense side we continue to expect approximately $35 million in one time deal related expenses of which we have already recognized approximately $19 million between the two organizations in the first quarter of 2016. We anticipate the balance of approximately $16 million will be spent over the remainder of the year with the majority in the upcoming second quarter.

We continue to provide visibility to these costs on our quarterly earnings calls as we progress throughout the year. In terms of synergies we are on track to deliver the $17 million in merger synergies in 2016. Excluding the merger-related costs in the first quarter G&A spending was down 14%, sales and marketing down 5%, and R&D down 15%.

With that I will hand it back to John. John?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Thank you, Vaseem.

As you can see we're off to a very good start in 2016. We're on track with the merger integration, our new product pipeline, and our clinical studies. Our top priorities over the next 12 months are, number one, to get the Nellix PMA approved and initiate the US introduction, two, to drive growth from our three new product launches, Ovation iX in the US and Europe, AFX2 in the US and Europe, and our next-generation Nellix system in Europe.

Three, to continue advancing our Ovation, Alto and CHEVAS development and clinical programs for the treatment of complex aneurysms. Four, to leverage our post merger infrastructure and capture synergies to achieve profitability as soon as possible and, five, to continue building clinical and economic evidence with our LIFE, LUCY, LEOPARD and ASCEND clinical studies.

As we execute on these priorities we expect to deliver significant value to our customers and shareholders while providing patient with the best possible device for the individual treatment of their abdominal aortic aneurysm. We look forwards to meeting with many of you at the Bank of America and Jefferies conferences in May and June and announcing the Nellix IDE data on June 11th at SBS.

With that we will know open up the call for questions. Operator.

QUESTIONS AND ANSWERS

Operator

Thank you. At this time we will be conducting a Q&A session. (Operator Instructions). Thank you. Our first question comes from Rick Wise from Stifel. Please go ahead.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Hi, guys. It's actually Matt Blackman in for Rick. How are you?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Hi, Matt.

Vaseem Mahboob - *Endologix Inc. - CFO*

HI, Matt.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

So a couple questions. First of all, congratulations on the quarter. So, John for you first or Vaseem, I know it's it still early, but can any reads or sense of the cross-selling successes or opportunities whether it be Ovation into Endologix accounts or vice-versa just curious how is that shaping up now that the sales force in US is now cross trained.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. Matt. I would say it's very encouraging but still early. Keep in mind that the legacy Endologix's reps, the vast majority of them are still not certified on Ovation, while they have been through their initial training they're going through their case observation and certification process.

So I would say it's still too early to really appreciate the benefit of the cross-selling. That said we do get a lot of reports on a regular basis about positive feedback from physicians and what we call a power of choice where a doctor has the ability from one representative to pick the best device. So, it's clearly got a lot of potential, but we're still very early in unlocking that value.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. And any sense of when the legacy reps will be fully certified on the Ovation platform? Is that you a late 2016 event there just any color there.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes, later 2016. We already have had some so there's a handful of reps that are already certified. Part of it has to do with this case observation and so the territories with the more established base of Ovation business will tend to get certified faster and for those areas where there's less penetration those reps will have to travel some for their case observation requirements and/or it will just take them a little bit longer. Certainly by the end of year, but I would think we would have most of them done in Q3.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay. That's very helpful. And then I just wanted to touch on the iliac aneurysm data we saw at (inaudible). I was hoping you could actually, perhaps, size that opportunity for us. I know I've seen your presentation that the iliac aneurysms present anywhere between 20% and 30% of the time that someone presents with an aortic aneurysm.

Just give me a sense of how we should think about that opportunity and maybe also equally what that -- what iliac aneurysms are treated with today, what competitive (inaudible) and why now it's may be a better option. Thanks.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. So as you pointed out about a third of the patients diagnosed with an Infrarenal aneurysm also have iliac aneurysm disease. Most of the companies have devices with limbs that will go up to and accommodate an iliac diameter up to about 25 millimeters but that's typically the cutoff.

So what's unique about the data that was presented by Dr. de Vries is that a significant number of those patients actually treated patients with iliac diameters beyond the indications for use of the other EVAR devices. So we're able to treat these patients who would otherwise need more complex procedures or branch technologies which are much more expensive and time consuming.

So we think that this ability to treat these oversized iliac arteries in about a third of the patients and be done faster and more cost-effectively with Nellix versus the other currently available technologies. It really should become kind of the go-to product for patient with iliac aneurysms.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

All right. That's very helpful. Thanks and congratulations again.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Thanks, Matt.

Vaseem Mahboob - *Endologix Inc. - CFO*

Thank you.

Operator

The next question comes from Brooks West from Piper Jaffray. Please go ahead.

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

Hi, guys. Can you hear me?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. Hi Brooks.

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

Hi. Thanks for taking the questions and congratulations on a good start to the year. So probably no surprise in the question I'm going to ask, but, Vaseem, I'm hoping you can give us a little feel for the underlying Nellix or I guess Nellix in the direct channel and maybe can you parse through just the components of OUS growth so we can get a little bit of feel of kind of what's disruption from the merger and, again, is Nellix kind of on the same trajectory that we have been seeing over the last couple of quarters.

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure, Brooks and, again as I said at the beginning of my commentary on the quarter, we did take that position at the last earnings call to limit our disclosure primarily because we didn't want to put our strategy out in the public domain, but having said that, as I mentioned in my comments Nellix continues to do a fantastic performance outside of the US.

You know, we had continued success in the direct channel and the one number that I know a lot of you guys care about, we can just give you some clarity, that the direct business is growing elderly north of 20% and, as we expected, the indirect side of the Nellix business was slow in Q1 and as expected because of the de-stocking that our distributors knew about, which was the impending CE Mark approval which hand in April, so they continue to work some of the SKU inventory for Nellix we should see a pretty nice uptick here either later in the second quarter or starting in the third quarter.

So I would say Nellix is doing as expected. No surprises. The direct business is doing really well and aligned with the communicated disruption in the indirect channel no real surprises, but there's a lot of work for us to kind of get done to get that channel humming again, which we expect to unlock in the third quarter and the fourth quarter.

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

Okay. That's helpful. I appreciate the additional color. And then, John, maybe just following up on the FDA process. So, getting the additional CAP I think is a good sign, but by the time we see the data in June should we also be in a position to know kind of where FDA is on panel, no panel? Obviously we should know if they have accepted the PMA. Just any update you can give us on that process. Thanks.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. Well, in terms of accepted the PMA I can affirm that that has hand so, actually, at the end of last week the agency gave us notification that they have everything they need to continue the review. So that's a good step forward. In terms of knowing panel, no panel by the SBS that's a little early, Brooks.

The 100 day meeting will occur in the middle of July so we're about a month ahead of when we would formally need to know if we were going to go to panel. At this point what I can tell you is the process is clicking ahead on schedule and the interaction has been constructive. So right now everything continues to look like a PMA approval, hopefully, by the end of this year or first part of next year.

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

Great. Thanks so much.

Operator

The next question comes from Chris Cooley from Stephens. Please go ahead.

Chris Cooley - *Stephens Inc. - Analyst*

Good afternoon and thanks for taking the questions. Hear okay?

Vaseem Mahboob - *Endologix Inc. - CFO*

Yes.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. Hi, Chris.

Chris Cooley - *Stephens Inc. - Analyst*

Hi, super. Thank you. I just want to follow up on Brooks' question and maybe address it a little bit differently. (Inaudible) we have heard of some fairly aggressive price discounting by some of your competitors. If we think about the European market in the direct channel, are those reps certified

on both product offerings and can you now maybe address that market a little bit more creative with Ovation, AFX, and, obviously, Nellix combined? Then I have just one quick follow-up.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes, Chris, the potential exists if we want to get more aggressive with price. We're not going to get into too much detail about pricing between the different products other than to say we do have that potential. At this point the legacy Endologix reps are not yet certified on Ovation iX. Some of them are on AFX.

None of them are on AFX2 yet so we've still got quite a bit of training work still to do, but I think importantly, as it relates to your question on pricing flexibility, we have it -- haven't exercised it much yet, but it represents a good strategic opportunity for us moving forward if we want to position a value product in the bag.

Chris Cooley - *Stephens Inc. - Analyst*

Understood. And then maybe just as a quick follow-up. Here could you maybe just characterize kind of where you are at this juncture in terms of the AFX2 launch here in the US just in terms of the metrics? I'm assuming there's some excess inventory that had to be switched out in the market, education, et cetera. Could you just maybe bring us up to speed with where you stands on that I will get back in queue. Thank you.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. We think we'll be fully transitioned in the US to AFX2 by the end of June, so we're in that transition process as we speak. The initial cases have gone great. The physician feedback has been extremely positive so that's -- that's all thumbs up at this point. We will be fully converted in the U.S. by the end of June and, as I mentioned in my comments, we won't take AFX2 into Europe until Q3 just because they're busy getting up to speed with Ovation iX and now rolling out the new version of Nellix. So they will get AFX2 in Q3. Thank you.

Operator

The next question comes from Glen Navarro from RBC Capital markets. Please go ahead.

Glenn Navarro - *RBC Capital Markets - Analyst*

Hi. Good afternoon. When I was out at Share and Cross I heard a lot from the implanters there that Nellix was predominantly being used in very complex cases. What do you think it takes for Nellix in Europe to become more of a workhorse graft? Thanks.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. We actually that's a great question, Glen. Initially when the product got introduced people could see that it could solve clinical problems that none of the other devices can solve. So that was the direction a lot of clinicians wanted to go to early, but what we have seen and what was presented at the registry update data, is that the results in standard anatomies are really exceptional and so clearly that's an area of interest for us moving forward.

We were a bit selective in our initial accounts to try to focus on higher volume users early, build some experience and clinical capabilities and really fine tune our training program. That's all done now. So I think we're in a position to start to roll the platform out more broadly to smaller users and the new version of the device sets us up nicely to do that. So we've refreshed the procedure and the device to take it out to the broader market segment and put a little bit more energy behind traditional anatomies.

Glenn Navarro - *RBC Capital Markets - Analyst*

And as you have broadened the user base, assuming in the model going forward that you can maintain the premium price for Nellix?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. Again, we're not going to talk too much about price. We will do what we can to hold it, but we'll balance share capture and price sensitivity.

Glenn Navarro - *RBC Capital Markets - Analyst*

Okay. Then just one quick follow-up. I know it's still a ways away but I was wondering if you can provide us a little bit of color on how the first 12 months of the US Nellix launch will go. In other words, you know, how many centers today have been trained and is there any specific goals as to how many centers you would like to train in year one and, you know, when the product does get launched does it just go on the shelf, do the centers have to buy?

The only reason I'm asking these questions is because in med tech we have seen some significant new product launches and as these product launches occur companies do give some sort of guidelines as to how many centers they would like to train within the first 12 months, they give you some updates on -- just something that gets sold directly or is it just put on the shelf for consignment. So any type of color you can provide for our modeling purposes. Thank you.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Sure. Well, initially, Glen, we'll have -- the US centers that participated and continue to participate in the IDE, there's 27 of them in the United States. So they will of course become commercial customers out of the gate. Several of them will also become training centers. So upon approval and well in advance of approval, obviously, we'll be working with those selected training centers to get them up to speed and ready to be able to train physicians.

We plan to start that out in a gradual way. I'm not going to give you the number of centers just yet. We might -- we get another quarter into the year and get a little closer we can get a little bit more detailed with the specific training plans, but as we communicated I think near the end of last year, our goal, when we're in a fully loaded capacity, would be to be training about 50 doctors a month once we have gone through the initial phase up and we have ramped up to kind of our full training capacity best case scenario gets us at 50 a month.

That will take many months to reach that level and it will also be really determined based upon the quality of the training, experiencing the feedback we get from the physicians. This is really begun to be more about quality than quantity. We want everybody to have a great experience and get excellent outcomes with the device. So if we have to pull back on that a little bit to make sure that happens, we will, but that's our internal target to get up to 50 several months post introduction.

Glenn Navarro - *RBC Capital Markets - Analyst*

Okay. Great. Thanks, John.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes.

Operator

(Operator Instructions). Our next question comes from Steven Lichtman from Oppenheimer. Please go ahead.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Thank you. Hi, guys.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Hi, Steve.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

John, can you walk through the benefits again of the next-gen Nellix and the potential for more patients to be treated? What are the type of patients it can expand into now?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. There's several enhancements to the device, but the two biggest that I would call out would be, one, the longer lengths. So the prior version only went up to 180 millimeters and so if you had longer aortas than that, that was a challenge. So we've added 190s and 200s. So those longer lengths are useful additional sizes. I can't give you a specific number to how many more patients that represents, but we have already had good feedback.

In fact, we -- the demand for the 190s and 200s has been high right out of the gate so we've got to make more. So that's a good sign. And then the second major improvement is as it relate to these patients with iliac aneurysms the former device the distal edge of the endobag was not attached to provide flexibility. The good news is we had flexibility.

The bad news is, is that you couldn't get as precise of a distal seal with that version of the system. So we have changed that. We now have the endobag attached to the distal end of the stint and preserve the flexibility and the benefit of that is the physicians can very precisely land the distal end of the device and get great seal. So up to and including adjacent to the hypo gastric artery, which is really key for treating these patients.

So, as I said earlier, our view is that the device really should be the go to product for patients with iliac aneurysms and now with the longer lengths we think we can pick up some additional patients that we weren't getting before. So those are the two primary benefits from the new system.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Okay. Great. And then on ASCEND, you know, after the solid start with the Beta presentation what are the next data points, what we will see out of that registry over the next say 12 months and is that data that should allow for potential label expansion in Europe next year?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

I'll answer the last question first. The hope is yes, that is a good bit of rigor going into the collection of this data. We hope to use this data to expand the indication and get a CE Mark in the second half of next year and the next look at the data will be at the (inaudible) symposium in November, at which time I would expect enrollment to be our complete and we'll have some initial results on the full cohort.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Okay. Great thanks, John.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

You bet.

Operator

The next question comes from Jason Mills from Canaccord Genuity. Please go ahead.

Unidentified Participant - *Canaccord Genuity - Analyst*

Hi. Good afternoon. This is actually Jeff filling in for Jason. John, you certainly have a unique advantage in terms of your product breadth and treatment capabilities with your portfolio. I'm certain this has not gone un noticed by your competitors. Just curious what you are seeing in terms of the competitive response. I guess, asked another way, are you seeing any change in ASP trends in the US?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

We have not seen a change in ASP trends from the competitors at this point. So it's early. Maybe that will become a reaction but so far we haven't seen anything like that.

Unidentified Participant - *Canaccord Genuity - Analyst*

Okay. Great. And coming out of Charing Cross we have heard that there's some concern about cannulation with Ovation in some cases and with the iX introduction and addressing some of these concerns I'm wondering if the Ovation uptake post iX is driving this fewer revenue to synergies and should we be thinking go Ovation iX workhorse system over the next few years, notwithstanding the Nellix approval?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Well, the Ovation iX design certainly address the gate cannulation question. So if there was a -- if you spoke with a physician that used Ovation Prime they wouldn't -- and not Ovation iX they wouldn't have yet had the opportunity to appreciate the new design. So the feedback we have received on the new design is very positive and physicians they can attempt to cannulate if they -- if it's a challenging anatomy in any way there's a design around that makes that part of the procedure very effective.

So we think that Ovation for physicians who want a Proximal Fixation modular device could definitely be a workhorse. The good news is so can AFX2 and so can Nellix. So it's really going to come down to patient selection, the right device forthright patient and physician preference, but we're pretty uniquely positioned on all three front.

Unidentified Participant - *Canaccord Genuity - Analyst*

All right. Thanks for the color and thanks for taking the questions.

Operator

The next question comes from Joanne Wuensch from BMO Capital Market. Please go ahead.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Good afternoon. And thank you for taking the questions. Very nice quarter. Can we talk a little bit about how this rollout in the United States may or may not be similar to Europe. And I'm thinking in terms of simplistically days in training, number of patients that need to be lined up, how early the physicians need to, sort of, get in queue. How should we think about that?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Well, Joanne, I think the biggest difference, if we want to compare and contrast Europe to the US, is just the size and the experience level of the sales and clinical team in the US. You know, we have got a very seasoned highly capable sales and clinical team already on the ground in the US. We were building it from scratch in Europe while we were in a limited launch so we have got a much more experienced and larger, better integrated team. We were also learning still a bit.

You know, if you think back to the last few years when we first started with Nellix the procedure, technique and the steps and training program those were all evolving. That's all done. So now the procedure is very well refined, the training program is also very well developed. We have simulators now. We didn't have those before. I mean the whole thing has evolved a lot. So bigger, better team with bigger -- with better tools and more knowledge.

So those are the primary differences between Europe and the US. That said there will be training requirements that are not that different from what we have done more recently in Europe. They have to go to a dedicated training, they have got to do hands-on work and then their first several cases have to be proctored. So we will put them through a rigorous training program, but it's not uncharacteristic for what they're used to for other implantable aortic devices.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Very helpful. Thank you very much.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

You bet.

Operator

The next question comes from Chris Pasquale from Guggenheim. Please go ahead.

Chris Pasquale - *JPMorgan - Analyst*

Thanks. John, I understand the desire not to get ahead of ourselves with guidance this early in the year, but is there any reason to think that the strength that you saw in the quarter was just a delay in some of the dissynergies showing up?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

No. Not in particular, Chris. We just -- as we look at the full year, though we know we have got some distributor work still to do and we have got come good growth that we have forecasted for the second half and we think that the original guidance is the right place to be for the end of this quarter.

Chris Pasquale - *JPMorgan - Analyst*

Okay. And then I want to circle back on the ASCEND data and I know this is going to be putting the cart before the horse a little bit, but do you have any visibility at this point on what the regulatory pathway for a suprarenal indication could look like in the US? Is the expectation you need to do something else in addition to this ASCEND data set?

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes. I think we'll probably have to do some amount of prospective clinical work, Chris. We don't know wet yet. We have intentionally not gone to the FDA yet because we really want to get through the infrarenal indication first. Once we get that achieved, then we'll be having those conversations. The nice thing about ASCEND is that it provides some fantastic feasibility data.

So we certainly shouldn't have to do any feasibility clinical work. It will just be a question of if we have got to do prospective work how much and then also if there's going to be requirement for a post market how much. So I think we'll be able to advance those discussions pretty quickly with the agency after we get the infrarenal indication.

Chris Pasquale - *JPMorgan - Analyst*

Yes. First things first. Understood. Thanks.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

Yes.

Operator

There are no more questions at this time. I would l now turn the conference back over to management for any closing remarks.

John McDermott - *Endologix Inc. - Chairman of the Board, CEO*

All right. Well, thanks everyone for joining us on the call this good afternoon and your interest in Endologix. We look forward to seeing you at the upcoming conferences and we'll provide regular updates on our progress. Have a great evening.

Operator

This concludes today's conference. Thank you for your participation. You may now disconnect your lines at this time. Thank you and have a pleasant day.
