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MANAGEMENT DISCUSSION SECTION

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

All right. Good afternoon, everyone. I hope everyone is finding day one of the conference helpful and productive. Let me first introduce myself. My name Matt Blackman, I work on Rick Wise's medical device team here at Stifel. And it's my pleasure this afternoon to host a chat with Endologix's CEO, John McDermott, and CFO, Vaseem Mahboob. This will be a fireside chat, so please feel free to throw up your hands and join the conversation.

But, with that, why don't we just get started? So, John and Vaseem, I was just reflecting on the last time we sat down here about a year ago at the Stifel Healthcare Conference and a lot has happened since then. So, while we certainly want to discuss and dissect everything that's happened in the last 12 months, I think I'd also like this conversation to focus on why we think things will get better from here as well. So, John, if you could sort of maybe be helpful to sort of level set everybody and just give us a quick recap of the last 12 months, what's happened with the three brands, the AFX [ph] and Ovation (12:50). I know we can dive into what's going on today and how we should think about the next several years?

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

Sure. Yes. It's actually to the day we left the conference a year ago, walked back to the Hilton, which is where the VEITHsymposium occurs which is one of our biggest annual meetings. And as I was approaching our booth, I saw the look on the face of my Head of Regulatory and Clinical Affairs; I could tell something was wrong. Well, in fact, she had just gotten off the phone with the FDA and we've been working with the agency diligently on this Nellix approval. And she has just gotten off the phone and learned that the FDA, we'd seen the signal of migration in some patients and they requested two-year follow-up. So, that night, we worked through the night to get out a press release, first thing the next morning, to inform the world that there was going to be a pushback in the timeline and the clinical requirements. So, that was a bit of a tough week.

Followed, unfortunately, a couple of weeks later, we had our CE Mark spend it for the AFX product and that was a result of a legacy version of that device and some clinical complaints reported to the notified body. They didn't distinguish between the old version and the new version of the device, so they put the entire product line on hold. And then, to finish the year, we ran into a manufacturing challenge in our Irvine manufacturing plant and had to temporarily suspend the manufacturing of AFX, so that all happened in about 30-day period of time and then that was a pretty difficult situation.

Really to kind of round out 2017, just to flush out all the dirty laundry; in May, we got back together with the FDA, shared the two-year follow-up, and although there was a good signal that the new IFU for Nellix was positive, they still wanted some confirmatory data. So, that's kind of full circle of what I would say the disruption or the challenges faced in end of 2016 and 2017; and kind of fast-forwarding, if I go back, we were able to get the CE Mark reinstated relatively shortly thereafter.

We made all of the changes on the manufacturing line with AFX to get those issues addressed. We have, of course, subsequently met with the FDA now and recently have a confirmatory IDE approved, a smaller study about half the number of patients required to be submitted as the original IDE. So, we feel like we are on a good path there.

We've also brought in some new executive leadership. So, we've got a new Head of Quality and a new Chief Operating Officer, as well as during this past 12 months of debt refinancing, Vaseem led an effort to refinance some converts and get us a little bit more liquidity.

So, while it's been eventful. We've put a lot of the challenges behind us and feel much better looking forward.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Yes, that's a great recap. If we could start maybe on AFX and sort of where that business stands today, as you rebuild capacity. You know, the sense is that in the last couple of calls, that the trajectory of capturing or recapturing [indiscernible] (16:20). While share has not been as steep as you would have hoped. So, maybe, what's going on there, what's sort of the state of the AFX business and Vaseem if you're willing to get some contacts for people here, so the present-ish of sales that franchise represents since [indiscernible] (16:35) Endologix's might be helpful?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Yes. So, I can start. When we were going through the disruption that I just talked about. So, we had manufacturing on hold. We knew we were going to have limited availability of some codes of the product, and in some cases, no availability of AFX2 for the larger sizes. We were forecasting. We expected when we got back, going again, that we would see some level of recapture in the AFX2 business. And we've forecasted that to occur in the second half. And that doesn't happen and that's what let us to pull down our Q4 numbers is we thought we'd get more of a bounce back there. And what's effectively happened is, we look at the areas where we have not been successful at recapturing it. It's been the small accounts and what I would characterize is their infrequent users, people that were using AFX and AFX2 occasionally, we have been effectively countered detailed and those small accounts have been tough to get back.

Our more stable long-time users came right back and that's been great and we are grateful for that. But we have struggled getting the others. So, if there is any good news there is that we have been basically flat over the three consecutive quarters in AFX. So, we don't see any erosion occurring there, but we haven't been able to get the growth that we had originally hoped for earlier in the year.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Let me just add to that a little bit. When you think about three captured discussion and we have said it consistently, you had Q1 when you had a massive disruption and you had physicians in the U.S. that

[indiscernible] (18:14) back to the AFX1 graft. We did about – the round numbers, we will take a few of it because we don't do product line reporting, about $20 million.

Second quarter, we got the approval from the FDA to ship the large diameter AFX2 a month earlier, but still a lot of disruption, again the base was about $20 million.

Third quarter, we had the hurricanes. You know, seasonality, we still had that $20 million. So, while we kind of look at the trend and say it's forming the base of that $20 million that John is talking about. We still kind of trying to get a read on Q4 to see what's that business going to do in Q4 where you don't have any disruptions, you don't have any seasonality, and it will be one clean quarter to kind of get a sense on that number for the whole year.

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

And to be clear that the disruption or the lack of recaptures most of the U.S. phenomenon.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Correct.

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

That $20 million of U.S. base of business.

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

Absolutely, so I'm talking the U.S. numbers only. So, [ph] 20 out of a $32 million (19:13), so that's the size of the AFX franchise. But, the great news is, that AFX that used to be about 120 or 130 cases a month business when we acquired TriVascular is now anywhere from 150 to 200 cases per month.

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

The combined company with Ovation is actually at a higher level.

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

Okay. That's helpful. And so, how do we think about obviously going to get through the fourth quarter, I'm not going to ask you for 2018 guidance, but how do we think about that franchise for the next several years? Is it sort of the best case scenarios you come out, you hold steady, and you know, maybe there's a little bit of growth. Could this become or recapture sort of a low-single digit market like type growth? What sort of the best case scenario when you think about how AFX plays out.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

I honestly think that we got to get a read on Q4 and get comfort. And then, we can have those conversations about that in the time we give out the guidance in February and March. And I know, people have mistaken that for lack of visibility, it's not about lack of visibility, it's not about not having the sense on which account sort of impacted. It's just us trying to get a read on our business and understanding that fundamentally what is the AFX business wanted to do here in Q4 like I mentioned earlier.

And then, how is Ovation do in Q4 and then give you a pretty good number. The last thing we want to do is put something out there and had to walk back from it, so it's more constructive to have that conversation at that time it's supposed to.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Fair enough. But, I think, I'm going to put words in your mouth, but, we should walk away from this AFX discussion again to sort of focus on the fact that it's been a tough few quarters. But, the businesses are not eroding. We should've found the – we hope we have found the base. It's not – the concern is not that there is degradation, it's just the question of what is and could this grow again?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Yes. If I wanted to be a pessimist, the worst case scenario today might be a lot of business is just kind of is what it is today?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

It's established a new baseline as the way we are thinking about it.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

And I just want to be clear and I don't know if [indiscernible] (21:15) maybe it is. But, you did sort of in the midst of all of this, there was some attrition on the sales force that you did not sort of backfill. And I just want to be clear that, that what we're seeing here is not – a function of a smaller footprint out there that the – now, this lost cases perhaps could be because we pulled people out of accounts, something like this – is there anything like that going on?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Well, yes. I would say that we adjusted the sales team from about 125 down 110 in round numbers.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Not a lot.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

That factors into not getting the recapture that you hoped. The good news is we have been able to keep it flat with 15% fewer territories filled. So, there are some leverage that goes along with that and you've seen that in our OpEx improvements. I still think even though with this slower number at 110, perhaps in clinical specialists again, we are talking about just the U.S. that there is still capacity there; there is growth potential within that size, sales organization, but I would not say that, that attrition adjustment down to 110 was a completely benign experience. Any time there is turn over in a relationship, intensive business, they will have some top-line impact.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. And so maybe close the FX conversation, Europe may just sort of state of affairs for the AFX franchise, they are smaller in Europe, but instead of any commentary there?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Growth rates in AFX in Europe is actually they're back to higher than where they were previously CE Mark. And I think that's -- what we think is the most impacted by the fact that the sales team in Europe is really looked at the progression with Nellix and realized that they got to get into the game with AFX. And also, the fact that we haven't launched AFX2 in most markets in Europe, and we are in the process of launching and relaunching AFX2 and most of its market, so that's really driven it.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

AFX, do you have a premium over AFX?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

No.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. What – it's user to use?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Price kind of a bottom line in terms of the adoption profile.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. Maybe we shift to Ovation which is a real feel story. I think. And maybe be helpful to give like a just 20-second sort of what is Ovation, how is it differentiate? So, the crowd understands then, you can walk into. I think the most important question is, is this 30% growth you are seeing the U.S. sustainable?

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

Yes. So, we completed the merger with TriVascular in February 2016, the attractiveness of that merger for us was this platform called Ovation is what we would characterize as polymer-enabled EVAR. So, we have traditional EVAR, which would be more like the AFX device.

And then, Ovation is really a next generation system that utilizes polymer to seal in the aortic neck and has been able to generate some very good clinical data over the past 5 years. It's also a very low profile device and has a broad indication. It was a perfect fit for us and broadened our portfolio in terms of patients we can treat within the portfolio.

And it took a while, after the merger, there was still our legacy reps had kind of biased and a preference toward AFX. But, when we ran into some of this disruption this year, they turned more of their attention to Ovation and you are starting now to see what that looks like. So, as you pointed out, we grew 30% through the third quarter. And I would say they're still gaining their confidence with that products.

So, I spend a time in the field, and as I'm interacting with reps, I can tell that they are gaining more and more confidence all the time in terms of -- when to use the device, when to recommend it, tips and trouble shooting and just all the clinical nuances of rolling out an implantable medical device. So, that looks good.

I would also say that it's a product that's well set-up for the next few years because we had good clinical data, but we have more good clinical data coming. So, there will be some good clinical data that comes in March, there will be more good clinical data on Ovation in June. And we will also complete enrollment in the Alto clinical study which is called Everest, around the end of this year and announced the six month follow-up for that device in the third quarter of next year.

So, you've got a nice cadence of clinical data for that product, leading to then the launch of the Alto device in 2019.

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

What part of the Ovation message do you think is starting to resonate with clinicians or is starting to resonate with your sales force they are actually selling? Is it we've talked a lot about – is it the low profile, meaning you got ability to access a lot of patients that perhaps were much more difficult. Is it, you don't get neck expansion because using a polymer not a radio stand, what's sort of [indiscernible] (26:32) or is it not that precise?

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

Well, no. It is that precise, but it's very individual for each physician. So, the device is gaining a reputation for being really the best product for female and individuals with small difficult and tortuous anatomy. So, when there is access, challenges and you need a low profile system, Ovation is clearly the lowest profile. I think there has been growing appreciation for neck dilation story. And what that means for those of you who aren't as familiar with the platform, all of the other devices except Nellix, the way they achieved seal in the aortic neck of a patient and that is that's the healthy tissue just below the renal arteries, between the renal arteries and where the top of the aneurysm starts. All of the traditional devices have a stent, which has got radial force, ongoing outward radial force which pushes the graph materially against the wall of the aorta and that's how it gets sealed.

The problem with that is that outward force continues until that graft reaches its nominal diameter. So, as an example, you would put a 34 mm device in an aortic neck that's 32 mm. Over time you will stretch out that aortic neck. You don't want to put an expanding thing in an expanding disease. The unique advantage of Ovation is that it doesn't have a stent that puts outward force on the aortic neck. So, we don't see that same kind of neck dilation.

That story is now starting to resonate more and more with physicians, there has been more articles published. And so, in addition to the low profile advantage, you see more and more traction with the neck dilation conversation. And of course the Alto device has that same benefit, but the sealing ring has been moved up near the top of the graph. So, we will be able to treat even more patients.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

And so, we walked about sort of the messaging that's starting to resonate, what are the – describe the – is there sort of a common thread in the accounts that are now becoming more sort of Ovation heavy, are these prior Endologix accounts or these – when we talked about this sort of back in the day, and I don't know if the right way to sort of parse things out. But, where is it gaining traction, and I assume some of it is cannibalizing your AFX business and I think that's obvious. But, you did say that that your total case volume is higher today. Is there a common theme among your accounts?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

No. There isn't a single common theme. No, there is – so, there is some just raw growth. So, new accounts where we have been successful at penetrating competitive accounts that typically done with low profile. So, most of those times, they'll have a difficult access case and they will try Ovation and they will go, "Geez, that wasn't as hard as my Medtronic rep told me."

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Right.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

And will start to get some traction there. Other situations is, in an existing account where we have a mix of AFX and other business where we'll introduce it and be able to pick up some share.

And then, in addition to that, there has been situations where we have lost AFX business in a disruption and we've been able to pivot to and get some traction with Ovation. So, it's – there isn't and we are not heavy in one of those segments over another. We have actually been able to get a little bit in all three of those buckets.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

And so, some of the beachhead, I can't get this into a 90-year-old woman. So, let me try Ovation that sort of the beachhead, can Ovation be a workforce? I mean, no, it can't. But is it possible with, you know, there is six other – another 10 grafts in the market. Can Ovation be a real workforce then?

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

I think it can, it has it when it was first introduced a few years ago, it had a bit of a stigma as a little bit more of a technically demanding graft, harder to put in. The next generation of the device which is the one we sell today called iX, had some design improvements to make it easier and also has more design improvements to make it even easier. So, I think what happens is, people have some – maybe they've heard stories of the early version or they had some experience with the early version, and there is a little bit of a headwind on adoption for iX until they try it. And then, typically, the story as, "Geez, that wasn't as bad as I remember or I thought and we get a little bit of traction."

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

Okay. And then, so that's the U.S., how is Ovation doing in Europe and sort of -- they sort of common...

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

It's the same clinical position. It tends to be used for these kind of special anatomy. It's a small base, but it's growing nicely, and they are excited about it and the introduction of Alto as well.

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

And that was sort of next question, Alto has been delayed, and so, is that tendering adoption there?

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

No, they didn't. There has been a lot of focus in Europe historically on Nellix. So, we originally the feedback from the notified body was, we wouldn't need clinical evidence to get Alto approved. Then, with the adoption of the new medical device regulations, there was a change in perspective on those requirements, that's what led to the push out. And now, we are needing to use the same data set for the U.S. approval as we are for Europe. But, it hasn't negatively impacted that product line, it's just postponed the growth opportunity.

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

Got it. Instead of closing the Ovation discussion, now, is that 30% growth? I mean, that's impressive, it's also small base. But it sounds like there are a lot of positive momentum behind it. There is more coming with more data. I mean why can't this be a 20% type franchise grower over the next several years. Is there something that I'm not thinking about or is it just blocking and tackling? Or Matt, you're asking for 2018 guidance, again, stop.

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

Yes. Well, what I will do is, we won't use the number, the growth range, but we will say that it does look like that growth is sustainable. There is a nice cadence of clinical articles. There is a new product already in the [indiscernible] (32:44). I mean, it's set up, you have a sales force that's gaining confidence and momentum with the product. So, it's got all the right ingredients to have a nice run here.

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

And you're still getting a premium price on [indiscernible] (32:56)

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

I think the pricing is good.

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

Okay. So, let's shift to Nellix, and we will start in Europe. You – I think a month or two months ago was the official sort of sign-off change of the narrower label. We've also been digesting this for some time, and the investment community, I'm sure the [indiscernible] (33:18) as well. Has there been an incremental reaction since the actual physical change of label, and you sort of more intense pressure on utilization and there was a prior, let's call it 6 to 9 months, anything sort of the [indiscernible] (33:32)

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

I wouldn't say there has been a big increase or correspondingly a decrease in utilization because of the official IFU certification, but it has been a fairly gradual progression. Physicians once we sent out the first field safety notice in the fall, not everybody quickly adopted the new indication. So, that's kind of been a gradual process really over the full course of 2017 so far. So, what we've been doing is really reinforcing the importance of staying on the new IFU and the great clinical results that you get by doing that.

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

And the [indiscernible] (34:10) sort of back to the same theme, as the FX, have you reached sort of a stable level, have we bottomed out, is there a little bit more to go?

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

Like Vaseem said earlier, I think we will feel more confident in commentary around that as we give guidance for next year. I'd like to get through the fourth quarter and just see where that flushes out, but it feels that way. The other thing that we've done is, for given the revised IFU now, if you treat about 30% roughly in Europe of the patients, for small accounts that doesn't make as much sense. So, if a physician only does 10 aortas a year using Nellix 3 times a year, it's just – so, what we have done also is, we've kind of redirected a bit of our targeting efforts to the larger centers. And those centers that have an interesting complex because they will be perfect when ChEVAS is available to treat the more complex patients.

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

And that sort of the two part follow-up there. Do we have to wait till ChEVAS hits? And that's seemingly going to be a few years from now before it starts growing again. Nellix – or now can Nellix still grow on its own?

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

I think it can, but we want to set pretty modest expectations for that. We do expect some very encouraging new clinical results to be presented at Charing Cross Meeting in April.

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

So, you may be going to London again?

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

Well, that's your choice. So, we are – you know, there has been some – for those of you who have followed the story, you've heard maybe from the podium or seen in the articles some potential indication that Nellix might offer a mortality benefit. We have commissioned an independent evaluation of the EVAS data versus some contemporary EVAR databases. And the results of those investigations will be presented at Charing Cross.

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

Great.

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

So, that might – if that – if those data are positive, that might be supportive.

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

Yes. Now, to change the story a little bit. Yes.

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

Yes.

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

And I just want to be clear for ChEVAS, we initially thought end of the year European regulations and sort of the thresholds for approval have become more stringent. You took it off the timeline, did not sound like it was 100% off the table, I know I'm assuming it's off the table. Is there a point where we'll know definitely that it's a no go, it's not going to happen in the next – we do have to wait for the U.S. data to supplement it.

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

Yes. So, let me give you a little bit more color on that. We knew we have to move it out because it wasn't going to happen in the fourth quarter. So, at this last call, we had to move it. The decision was, do we move – do we make

an interim move without great clarity from the notified body or do we move it all the way back and work hard to see if we can get it done sooner. We choose that approach, right?

We should get a read from the notified body sometime I would say in the middle of 2018 on whether or not it's going to be sooner or if it's in fact going to be where we put it, which is in 2021.

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

Shifting to the U.S. clinical roadmap for Nellix, you may give us an update or reiterate the update you've given on timing. And you got the ID approved, we know that. We are still waiting for the first patient to be enrolled, maybe just help us understand what sort of has to happen between now and that first patient being enrolled, was sort of a blocking and tackling things that need to be done and I assume you're still on track for year-end?

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

Yes, we are. So, with all of the clinical study sites have been identified. So, we are done with the site identification process and now we are going through IRB approvals and contracts. Once that gets completed, then they will start screening patients and will get those – we'll start the enrollment process, not all of the sites come up at one-time. so, you will focus on 10, get them through their process, then we will focus on another 10 and that's – so, we will – what will happen is, we'll get a few sites up and running by the end of the year, hopefully get our first patient by the end of the year, or first part of January. And then, more sites will come online over the course of – really the first half, you'd be surprised, some centers take a long time.

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

Right.

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

With contracts and IRBs and stuff. So – that's why we currently estimate that it will take about a full year to enroll the trial.

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

Yes. I wanted to delve into that a little bit, I appreciate that a lot of things have to happen. You have to see all the enrollment phases, but I think the first point is, how much overlap is there in – in the clinical sites through Nellix 2.0 versus the original trial. So, how much familiarity is there with it and sort of the [indiscernible] (39:08)

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

It's about half. But, we will have a little more than half of the study sites that are in, EVAS2 or in EVAS1.

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

And does that help? I got to think it at least helps.

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

It certainly helps on the training side. We are – this study is with the Gen2 device, so there are some subtle differences, but procedurally it's very, very similar. So, there is familiarity with the procedure and how the device works.

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

And then, how do we think about sort of the – I think I don't if they offset, but there – someone's a plus and sort of ones are minus, when I think about sort of the rate that you can enroll and I think the most obvious one is the smaller trial then, and I'm comparing this on a relative basis to your original trial. It's a much smaller trial, it's about half the size. So, that and on of itself should make it roll a little bit faster. But, you are now looking at a more sort of restrictive label?

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

Right.

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

So, are you those patients had to find? I guess is the question.

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

Yes. We'll we've been enrolling in a limited way patients under the new IFU in the global EVAS registry outside, we don't have a lot of centers up and running yet, so we don't have a really good read on that. But, I feel like the one-year estimates are reasonable estimate at this point. We will just update it after we get -- you get have to 10, 15 centers actively screening before we can build a reliable trajectory on that total enrollment time.

And then, the other thing that will happen is we are in the middle right now of a pre-submission process with FDA for ChEVAS. So, for those of you who aren't familiar with it, Nellix EVAS2 is just confirmatory trial. To further broaden the indication for the Nellix device, we will do another study, which will be called ASCEND 2, and that's for this ChEVAS indication, which uses the Nellix device together with branched stent grafts in the visceral vessels. We hope the current timeline has us getting approval for the IDE around the middle of 18 and starting to enroll that study after that.

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

Can you use that as an incentive? Obviously, not that Nellix isn't of itself exciting, but I think the potential to use it in this really complex cases, I think is a real differentiator for Nellix, and I just wonder is there going to be similar sites that are going to be in ChEVAS as they [ph] undergo (41:34) the 2.0 trial and you can somehow use that as incentive to get them to enroll one faster.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Well, you'd like to think that there would be a lot of motivation to be enrolling rapidly anyway, right? Most of these institutions who want to participate in clinical research and they have to meet certain enrollment targets to actually get their name on the final publication. So, that tends to be a motivating factor. Some, but not all of the EVAS2 centers will be participating in ChEVAS. The ChEVAS centers will be more targeted centers at complex aortic repair. So, there are some overlaps, but not a 100%.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. That makes sense. We're going to shift, and give you a two second break, let's catch breath. Once you talk about sort of all the work on the balance sheet, I think it's been impressive what you've been able to do in the last 6 to 9 months. But, I think also on the OpEx side of the equation as well, sort of the – one of the overhangs has been – are we going to run out of money before Nellix comes? And I think you have done a good job shoring up on local fronts, the company's cash position, and so, maybe give us a little update of where you are in terms of, sort of OpEx leverage and rationalizing costs and what sort of -- shape the balance sheet is in and how you are thinking about that margin to profitability?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Sure. So, I think that there is two parts to the – as we kind of came into the year, we had the 2018 converts to retire, and then, also some context for you guys, when we did the TriVascular deal combined basis, we were at $228 million of OpEx. Last year, we did $197 million. This year's guidance was $170 million to $175 million, and at the last call, we said we're probably going to be in the $165 million to $170 million range. So, we have taken a significant amount of cost out of the business. And when you are talking about cost out of these levels, this doesn't come by tweaking or just careful cost management, right? I mean, this is a broader look at what we do, what we do well and what we stop doing.

So, I think the team is actually rallied really well and come together and kind of help us on the cost side, so, I feel really proud of that work that we have done, so essentially burning, reducing the cash burn.

The second piece of it was on the refinancing of the debt, we did in the term-loan with Deerfield and it was very important to have an investor versus just a lending arm. They were investors in the company. They had $52 million of the convert. They have $40 million of the 2020 converts. So, they would always lawn the story, so they came into the transaction with $120 million of debt at a very attractive coupon. The cost of capital between the revolver and the coupon was less than 10%, which was fantastic, and by the way, that was part of a very competitive process where we had five term sheets and they were the lowest.

So, I think from a risk mitigation perspective, as risk managers we did that ahead of the Nellix data. And we have the money in the bank. And we feel very confident that with the new levels of OpEx and the cash burn that we can still get to that second half of 2019 cash flow breakeven goal with the [ph] promise (45:12) that we got a start to see some good top-line growth. And 2019, will be very important as John mentioned with the launch of Alto and some of the positive read outs on the data that's going to come out in 2018, a year that we have to stabilize the business. I think we are set-up nicely for achieving that goal and also gives us a pretty good flexibility on how we handle some of our future debt maturities.

So, I feel very confident that the work that we have done, we are really short of the balance sheet, we have bend the curve on our cash burn and we got the OpEx levels to the right. And I keep telling people too, I think 165 is a good number to be thinking about, you know, what we think is the safe level to run this business because you don't want everyone to compromise – exactly, so it becomes a – it could get to a bad outcome. So, we think 165 is a pretty good number and we've got a pretty good chance to [ph] paint around (46:12) that business at that level.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. And our last couple of minutes, these are telescoped out, and maybe talk about your new COO and sort of what role that John 2.0 will play? And then, maybe just kind of wrap up as you do often on your calls, so how you're thinking about the priorities in the next 12 months? You know, what's top of mind and top of your list to get done?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Yes. Well, John Onopchenko has a very successful great career in medical devices, spent time at General Electric Healthcare and then a good bit of time also at Johnson & Johnson. Then, was on the board at Volcano and then moved into an operating role as Chief Operating Officer there. So, he has got a lot of great experience in his responsibility is going to be really focused on the products. So, operations, quality and supply chain. After having this hiccup that we had at the end of last year, obviously, that can happen again. So, we wanted to bring in a very seasoned executive to help manage that side of the business and provide additional debt and leadership and give me the capability to free up some capacity and focus those efforts on the commercial side. So, like Vaseem said, we've got the P&L now structured very nicely that growth will provide some very nice leverage.

So, John, will really lead our efforts on the product side, I will lead our efforts with the commercial sales and marketing folks, we will get the top-line going again and that's kind of everybody's role and responsibility.

In terms of how to think about the next 12 months. In the very near term, we will complete enrollment in the ELEVATE study and we will file the PMA supplement in the third quarter. That sets us up for a first half 2019 approval. So, that's an important kind of one-year objective. Obviously, getting this first patient enrolled and getting the EVAS2 clinical trial enrolled and also getting the ChEVAS IDE, so the Nellix franchise has got a strong pipeline and clear direction there, that's another key objective, and then, the last thing is to continue stabilizing the AFX business with the focus on growth innovation.

Mathew Blackman

Analyst, Stifel, Nicolaus & Co., Inc.

Okay. Any questions? No hands? I think we've covered a lot. Okay, great. Thank you.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

As always, appreciated it.

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Thank you. Thanks, Matt.