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# Endologix, Inc. (ELGX)

Stephens Fall Investment Conference

# CORPORATE PARTICIPANTS

Chris Cooley
*Analyst, Stephens, Inc.*

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

# MANAGEMENT DISCUSSION SECTION

## Chris Cooley
*Analyst, Stephens, Inc.*

Well, good morning, everyone. Welcome to the Stephens Fall Investor Conference. I'm Chris Cooley. I'm the Senior Medical Device Analyst. We greatly appreciate you joining us here this morning. It's great to see you.

## Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

I'm happy to be here.

## Chris Cooley
*Analyst, Stephens, Inc.*

And if you wouldn't mind, just for everybody in the room, maybe just a quick overview of the company, kind of where you are here today and then we'll dive right into our standard Q&A format. I know we're on a tighter timeframe this year than in the past.

## Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

Sure. So good morning, everybody. Thanks for taking the time to listen to our story. I'm Vaseem Mahboob. I'm the CFO for Endologix. We are a company in transition and we have been here at this conference a few times in the past. And we've gone through a pretty significant change, but the bottom line is that it's still fundamentally a company that has highly differentiated products in a pretty big market, in the AAA market, which is about $2.8 billion. It's growing mid-single-digits; in the more mature markets are low to mid-single-digits. And then the high growth market's growing about 10%, especially in the complex space.

Typically, you're looking at in the U.S., 40,000 procedures in the traditional market or the AAA aneurysm market. And then you have another 12,000, 13,000 cases in the complex space. The traditional market is highly saturated with a lot of competition from Medtronic, Cook and Gore. And within the complex segment, there's really not a whole lot of penetration into that market because innovation really hasn't really addressed some of the anatomical challenges there.

So we are a company in transition, like I said. We went through a pretty massive change with the CEO transition early this year. And then back in August, we announced a strategic reset, where we are really positioning the company back for growth. We've had to deal with some challenges with some manufacturing and quality issues in

the past, sales force disruption here in the U.S. and we continue to work on data to try and get these products to market, primarily Nellix and Alto, which we think are really solving some of the defect modes in the AAA space today which are not addressed, and that gives us hope that we can try and grow this company from where it is today to a company that can grow double-digits top line and be EPS positive in the future. So that's really Endologix in a nutshell.

# QUESTION AND ANSWER SECTION

Chris Cooley
*Analyst, Stephens, Inc.*

Q

Great job. Let me maybe just start off here this morning, and let's start off big picture, and then kind of maybe work our way down, and let's talk a little bit about the data that's out there between open surgical repair and endovascular repair. And specifically, if we look at the data at eight years, I think it was about 5.4% of mortality statistics versus just a little over 1% for open surgical repair. Talk to me about why – well, first and foremost, are these statistics cause for alarm? Should we worry about the endovascular market? And if not, how does your portfolio square up versus that? Is there any unique opportunities for you to drive growth?

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Well, the bottom line is it's a market. The EVAR market has been around for about 20, 25 years. And the underlying principles on the technology are for aneurysmal disease, which is essentially the aorta which is the largest vessel in the body is expanding, is weakening. And we've taken self-expanding stents. We oversize them, we put them in the aorta and they're applying outward radial force.

Now, when you look at the physics or just a layman's term, you're applying pressure on a disease that's trying to expand the aorta, right? And what you're seeing in some data, especially the outlines coming out of NICE and other places in Europe, people are starting to realize that the failure [ph] modes (00:04:10) of EVAR are really causing some durability issues, right? It's the technology that is now starting to realize that – people thought that you would treat somebody for five years, and now these patients are living longer. They're coming in for re-interventions and realigning. So when you look at the data today, compared to open repair, it's five times the higher risk of rupture for people that are getting treated with EVAR.

And we've seen this trend start to happen a couple of years ago in Europe where certain physicians and certain centers had already started to move away from EVAR, and now NICE has come out and said that they're not going to reimburse it at the same level as they have in the past. So is it going to have a pretty significant impact on the market in the short term? The answer is no. I think it will be a gradual change, but it's something that's a pretty dark cloud on EVAR.

And we feel really confident that it plays right into Endologix' story because we are the only company that has this anatomically-adaptive portfolio that addresses some of these issues. For example, when you look at polymer-based Ovation, we don't apply outward radial force. We use polymer to get a seal. And you've heard physicians talk about neck dilatation, and the biggest defect mode in EVAR is Type 1A endoleaks or loss of proximal field.

But when you have polymer-based sealing on Ovation, and we saw that in the Ovation data set, which is a long-term ENCORE data that came out, we saw that the durability of repair with Ovation is the best in the industry. And this is comparing five-year data on Ovation to about 20-year worth of data in EVAR and we feel really confident

that with Ovation also coming and then also Nellix, which is essentially treating the aneurysm site, we're in a pretty good spot to address some of these failure modes with our anatomically adaptive portfolio.

Chris Cooley
*Analyst, Stephens, Inc.*

Q

So we've got the right portfolio. So you've laid out at the most recent Investor Day – and I'll paraphrase a little bit here but basically three key steps. So we think about it stage 1, you're basically building or strengthening the foundation; stage 2, returning to predictable growth; and then stage 3, just longer term obviously, innovation and accelerating off that base.

But I think what I'm getting the most questions on right now pertains to stage 1 and it's how you reorganize around rep capacity and, at the same time, you move upstream per se in terms of the number of centers. So if you can maybe just talk to us about the type of accounts you're going to target, how you're doing it with a smaller sales force, just the math there in terms of why we should have confidence [indiscernible] (00:07:01) accelerating growth, but profitable growth from those accounts?

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Yeah. So let me kind of take back the first question, which is we laid out on our Investor Day on October 2 a three-step process, and really Phase 1 was solidifying the foundation, right? The second one was to then try and start to grow the business. And step three was really bringing these disruptor technologies to the market at a high level to grow above market.

So on the Phase 1, what we talked about was – the plan here is really to build credibility and strengthen our footprint, and the biggest one is here in the U.S. So we did go through a pretty significant restructuring to take our sales force from 110 down to 92, which includes a mix of clinical specialists and field service reps.

But for those of you guys who haven't followed the story, back in 2015, we acquired TriVascular. And the genesis for the TriVascular deal was to create the capacity within the Endologix team so that we had enough feet on the ground here in the U.S. primarily to get ready for the launch of Nellix, which was going to be the end-all, be-all for solving every failure mode in EVAR.

And this was the time when Nellix was supposed to launch in Q1 of 2017. And now if you look at the revised timelines based on the data set which we'll talk about, we're talking about the Nellix launch in 2021. So we had built this excess capacity, so it's not that we are now trying to prune the team. We're trying to rightsize the team, and these were based on benchmarks that we got from a third party that looked at our productivity, that looked at our footprint, the way we were organized. And so really, from our perspective, rightsizing the team was to really rightsize for better productivity and performance, especially now that some of these products are delayed. So that's one.

The second piece of it is, yes, we want to kind of move to the high volume centers because that's really where the procedures are. So if you go back and look at the transcript, what we said was, today 70% of our business comes from these low volume centers and 30% of it comes from the high volume centers. Now these low volume centers was where the competition was not very significant. Our guys who had products could not complete with Medtronic, Cook, and Gore. They went downstream towards the low volume centers.

So our cost to serve in those segments is pretty significant. So what we're trying to do is, listen, when we look at the data that we have and the products that we have in our portfolio. And one of the examples that we heard at

the Investor Day was from Dr. Marc Schermerhorn and BIDMC, when you look at that data, it's very compelling data and gives us hope that we can convince some of these physicians to start to use our grafts and leverage that data set to move into these high volume centers.

So really from our perspective, we're not trying to suddenly say we're going to abandon our base today. It's a very small shift, and we put it out there. We said we want to go from 68% to 70% in Phase 1, which is in 2019. And then on the high volume centers, we want to go from 28% to 30%. So that represents about $10 million, which is essentially less than one case per rep a month for our field team.

So it's not a significant change, Chris. It was misunderstood when we kind of put it out there. But really, our goal here is to make sure that we can leverage the mix of clinical specialists, which we are going to target towards that low volume centers and give our field service reps the capacity to go into these high volume centers and sell really the value of the data that we have and convince these physicians to use our brands.

Chris Cooley
*Analyst, Stephens, Inc.*

Q

Right. Are there any questions for him? I don't want to monopolize the time here. If not, maybe we'll just keep going here. So when we think about the U.S. market, there has been some transition there as you've alluded to in the outset. How will you have confidence that when you look out at next year, 2019, company's guidance is at least $140 million because that's really the hard deck here in terms of [indiscernible] (00:11:15) of the business, and you can really scale from that. What are kind of the critical elements that have to happen for that $140 million to really see the base, and then really start to see an acceleration after 2019, hopefully next year? So please go ahead and grow next year.

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

So, listen, we have not given guidance and also there's a fundamental change on how we're trying to manage our numbers. And we don't want to kind of get into a point where we say, [indiscernible] (00:11:41) we got two months' worth of data in August and September after the reset. Is this too early? We had pretty good quarter. We came in much higher than the consensus. And I mentioned on the earnings call, that our October is kind of tracking to plan, but I think it's too early to tell.

So when we think about the disruption that was caused because of the restructuring in the U.S. and in Europe, which is pretty significant; the field safety notices that we put out for Ovation and AFX; and then some of the markets that we have exited as part of the reset, listen, we have done a lot of modeling and really looked at our average daily sales metrics in the U.S. But fundamentally, what it comes down to is the framework that we talked about, which is that the AFX business in the U.S. has to stabilize, right?

And Matt Thompson put out data, which looks at the implantation rates for the AFX Strata and the IIIb incidents associated with that product. And how they're kind of falling off and even from Investor Day to the earnings call, we talked about the four-year data for AFX, which gives us a lot of comfort that the AFX2 with Duraply has IIIb incidents, which are as good, if not better, than competition. And we're the only company that has done the first head-to-head trial, which compares AFX with some of the competitive grafts. And we have actually shown that data. So the data will be presented at VEITH as well. So we feel really confident that the AFX business will stabilize in 2019.

And then on the heels of an Alto launch in the second half or in 2019 next year, we can start to build the Ovation business. And then on the OUS side, listen, we have spent a lot of time in rightsizing that business. And what

gives us comfort is that every dollar of sale in OUS markets will be profitable. And otherwise, prior to that, we were essentially shipping cash overseas. So having that healthy mix of U.S., OUS growth, where we are scalable, we are durable and we are predictable gives us comfort that 2019, that $140 million is the base and we can kind of grow off of that.

Chris Cooley
*Analyst, Stephens, Inc.*

Q

Super.

Q

Okay. I've been away from this story for a couple of years, but I heard your comment on Nellix, how the [indiscernible] (00:14:09) multiple years now. What was the setback there? And then, I was just looking at your revenue number. Even more recently, they've fallen off. So what in your current portfolio has fallen on as well? And [indiscernible] (00:14:23) what was expected a year or two ago?

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Sure. So what's changed in the last couple of years from a revenue perspective? That's the question. So let me slide through different elements to that conversation. Step one is when we did the trial for Nellix, the one-year IDE data that we've presented was the best EVAR data that we had seen in IDE for the 25 years in EVAR. But one of the challenges in that data set at that time at the one-year mark was the migration number, which was 2.3%. So, as we follow those patients and as we submitted the PMA to the agency, we realized that at the two-year mark, we had a higher incidence of migration.

So, essentially, in certain anatomies where there's a high thrombus burden, the flow lumen was much narrow and you could not get enough polymer volume into that aneurysm sac. Over time, the stent was kinking in and migrating from the [ph] proximal size that's (00:15:18) causing a Type I endoleak. So we've been working with the agency, and when we realized that it was specific to certain anatomies, we agreed with the FDA to do a change in our label or narrow the indication on that market. And that's what we're now trying to validate through EVAS2, which is the current trial that we're doing here in the U.S.

The second challenge on why the numbers have come down is because we had a manufacturing issue with AFX, which is essentially two-third of our business. And we were able to resolve those manufacturing issues in the first half of 2017, and that actually cost us about $25 million to $30 million of revenue in the U.S. But those issues have now been resolved and AFX2 is back on the market without any manufacturing issues.

Q

Vaseem, can you talk a little bit about competitors, [ph] Nuances (00:16:18), Gore, Medtronic, [ph] how (00:16:19) you're selling maybe differently or if there's an opportunity there? And then [indiscernible] (00:16:27) for each company just to kind of understand it a little better?

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Sure. So there's – really, when you look at the competitive land, so there's Medtronic. Globally, they're number one and Gore is number two. Cook and Endologix were tied for a number three spot before we had some of these manufacturing issues with AFX. In the U.S., Gore has actually overtaken Medtronic as the number one. So we think they have about 37%, 38% market share. But that's really because Gore has been innovating, and they've probably been more innovative than Medtronic. And quite frankly, what Medtronic has launched through the Aptus device in the U.S., and there's really no reimbursement for it. They get a physician payment for it. But really, over time, Medtronic is losing market share here in the U.S. to Gore.

So, from our perspective, listen, I think it's a very traditional market. You compete on the same basis. It's a high touch, high relationship-based sales team. And when we look at our sales force, we have high tenure, very seasoned team. I think what we really struggle with is some of the challenges with Nellix but I think, more importantly, the manufacturing issue that we had with AFX.

So for us, as we look at where we're going and with the reset and the new CEO, our goal here is to really leverage the data that we have. And we feel that with ENCORE, which is the Ovation graft that's polymer-based, and some of the overhang with EVAR gives us the ability to really go into these high volume centers and sell our story around the data and the durability of the repair, which we feel will help us win in these segments. So really, in the past, we have been in a different segment and we're trying to move into a different approach to selling, but not significantly. Again, it's a very small impact to 2019, but 2021, we feel that we will be better equipped to make those changes.

Q

And just like for example with the high volume centers, they traditionally use one product or [indiscernible] (00:18:38) using Medtronic products and Gore products. How open are they to adding other solution [indiscernible] (00:18:48)?

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Well, the biggest in our share in the space is ease of use. So if you're a physician who's doing less than 10 cases a year, I think the switching costs for them is pretty significant. They don't really want to bother. But in the high volume academic centers, there it becomes a pretty big deal.

And typically, they would have one, maybe two grafts that they use and in some of the practices where we have had a good success with AFX, these are physicians that have built some practices around AFX because AFX with the anatomical fixation solves a certain clinical unmet need. So we were never really a primary graft in some of those accounts. We were probably a secondary graft in those accounts. So it all depends on the kind of treatment or the types of cases that you do.

I can tell you that some of the high volume centers in Europe, for example, were using Nellix really to treat cases that could not be treated with anything else. So it all comes to physician presence at the end of the day, but data is a big deal. And I think for us, as we think about the future, we want to engage in those high volume centers where they're trying to solve the defect modes that we talked about that open repair addresses today versus the EVAR, and who actually acknowledge that the outcomes have to change and going back to open is not an option. So really for us, we want to kind of engage with those and finding those 25 centers next year, we feel, is the first step to really demonstrate that we are making progress in that direction.

Chris Cooley
*Analyst, Stephens, Inc.*

Q

Vaseem, let's maybe switch gears a little bit here and think a little bit about the capital structure. [indiscernible] (00:20:31) kind of touch on that. You guys have laid out I think credible guidance to see year-over-year reduction of about $25 million to $30 million in OpEx when we think about going forward.

And you've also recently adjusted a little bit of the converts that are out there as well. So talk to us about kind of the key metrics for reducing overall OpEx. Part of that is the more efficient cost to serve, from all of that you've touched on at the outset. Let's go into there first and then after that, let's think a little bit about what kind of latitude you have now with the revisions in the covenants [indiscernible] (00:21:09) and be successfully positioned to address the next round of converts, which I believe has a 2020 maturity.

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

Sure. So we entered the year with almost $260 million of debt and that's a pretty big chunk of debt for a company our size. We started discussions with a third party to secure an asset-based loan and sometime when the new CEO, John Onopchenko, came on board, we started to engage back with Deerfield because we had done the deal with Deerfield back in April of last year on $120 million term loan. And so the discussions are ongoing.

And honestly, with the reset that happened, we wanted to make sure that we did a deal that mitigated the risk of any other financial covenants that we had with Deerfield in the past, but at the same time, gave us the flexibility to go run the business and not have to worry about those covenants. So the idea behind doing the deal in August with Deerfield invited, they've been investors in the company for a long time. They owned a pretty significant chunk of the 2018 converts that we refinanced in April last year, and they wanted a bigger stake in the company even with the refinancing that we did.

So what we did was step one, we took $40.5 million off the convert for 2020, and we rolled it into the term loan $120 million we have with Deerfield. So Deerfield, that went from $120 million to $160.5 million. So that was step one. It was non-dilutive and it was a higher interest rate but we felt that, at these prices with equity, was very expensive. And we chose to roll it into the term because we know we can service debt at $150 million in sales. Step two was to secure an asset-based loan which we did with Deerfield. And again, they were interested in being first and second. And so we decided to do it with Deerfield. So we secured an asset-based loan, about $50 million with Deerfield in that same deal.

Step three, what we did was we also wanted to de-risk the company and the balance sheet of any risk of tripping these financial covenants as capital markets were going sideways, debt markets had started to see some pressure because we know that we got this highly differentiated set of products that we can bring to market, and we just didn't want to have something kind of take us off track there. So [ph] we sell (00:23:38) and at this point, equity's super expensive, but we did a $20 million stock sale, was to totally de-risk us from an execution perspective and not have to go back into the capital markets at conditions which might not be suitable for us. So we chose to do it at our time when we really did not need the money to give us some flexibility. So we will address that.

So, really from a – as a bridge, I think we have secured the cash we need to go from here to getting these products to the market. Now what's left out there is the $84.5 million of the 2020 maturities that we would look to refinance. But we strongly believe that by resetting the company and building that credibility that we talked about as Phase 1. And credibility starts with a [indiscernible] (00:24:26) and better accountability to our investors, to our

employees and our other regulatory stakeholders. We feel that we're in a better position and will be in a better position to refinance those $84.5 million when we do decide to go do that in the marketplace.

So the last bit was the restructuring of the business, right, from a capital structure perspective. For those of you guys who haven't followed the company, when we did the TriVascular merger in 2015, on a combined basis, the OpEx number was $228 million. And as you heard me talk about on the earnings call, we're expecting our OpEx number to go from $228 million in 2015 to $160 million. So we have taken a significant amount of cost out of the business.

And we have actually held our margins because we have taken multiple actions to make sure that we – ahead of these volume declines that we have managed our cost structure. So we know how to do that and when you looked at the third quarter actuals on OpEx, we finished on a – without the impact of the restructuring, at about $35 million and that puts us on a pretty good run rate to hit the high end of the range for next year, which is $140 million. So when you look at all of these things that we have done here in the last six to eight months, we feel very confident that we can kind of get this company to cash flow breakeven in 2020 and double-digit returns.

Chris Cooley
*Analyst, Stephens, Inc.*

Q

Great. A lot of progress, a lot of heavy lifting. Let's focus and look ahead and talk about the promise of the pipeline. And so if we think about the story, not only of Ovation but also of Nellix, we look at the EVAS FORWARD data, really impressive, just under 1% endoleak rate versus 9.8% for ENGAGE. I think that's even more impressive when we consider that about 37%, 40% of those patients were off-label, if you will, or outside the IFU. So help us think a little bit about what this means for active sac management with Nellix. And then also, let's tie that back to Ovation as well because of the polymer seal, how do we think about just the portfolio going forward? Maybe just walk us through the timelines.

Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

A

So the Ovation Alto product is going to launch in 2019. We finished enrollment in ELEVATE, which is a confirmatory study, in March this year. We're in the process and engaged with the FDA on the submissions. And so we feel very confident about that. Now Ovation Alto can treat 80% patients on-label. And there's study after study that's been done, which essentially tells you that when you treat patients on-label – in an industry, by the way, which is very notorious for off-label usage – the outcomes are better, right?

The other benefits are that when you look at the durability of data with ENCORE that I talked about earlier and having the next-gen product of Ovation, and the commentary that you heard from Dr. Marc Schermerhorn, listen, the data is absolutely fantastic, right? So we feel really good that Ovation Alto will be a pretty good product in the portfolio and has a lot of runway. But even iX, which is the current version of Ovation, in the marketplace is growing really nicely.

Now, we did see a little bit of a dip here in the second half of the year because of the field safety notices associated with polymer leaks, but it was procedural. We have put the FSN out and the feedback from that FSN has been really positive.

AFX2 with Duraply and there's a chart here in the deck which we updated. We will show at present data at VEITH, which we'll talk about the four-year complaint data for a pretty significant number of patients. And the data set that's going to be presented with LEOPARD, which is the head-to-head, randomized, controlled trial which

compares AFX to Medtronic, Cook, and Gore. And that data will be presented at VEITH. We feel very good about that data set.

And then the last one is Nellix. Listen, Nellix will get approved on this narrowed IFU. And the original applicability before the IFU change was about 55% and that has dropped to about 28% – sorry, it dropped to 40%, which is a 28% reduction in the market. But once you qualify here your own label, it's still the best outcome you can get on-label for that device.

When you look at the Kaplan-Meier curves for freedom from Type IA endoleaks, freedom from migration, from sac expansion, there's no data set out there two or three years out that compares as [indiscernible] (00:28:55) with Nellix. So we feel really confident that getting Nellix to market in 2021 followed by ChEVAS, which will be the product that can actually address some of the complex cases – and by the way, that is where there's a lot of interest in the U.S. with the physicians is their ability to treat patients in that complex space with ChEVAS versus [indiscernible] (00:29:17) with Nellix.

So we feel very good about the product portfolio. It's just a matter of time and I think with the reset and regaining credibility with the regulatory agencies, with investors, and with our employees, I think we'll be positioned well for the future.

### Chris Cooley
*Analyst, Stephens, Inc.*

Q

I agree. This is an exciting pipeline. Are there any questions in the room? We're going to come up till the top of the hour. Vaseem, I always want to give you the last word. So any thoughts that you want to leave us with for today?

### Vaseem Mahboob
*Chief Financial Officer, Endologix, Inc.*

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It's not loss on us on where the stock is today and what's happened in the past. But I do feel that the results that we put out for the third quarter are a reflection of the change that's happening within the company to rebuild our credibility, and I go back to the chart that John had in his Investor Day, which talked about the three-step process. I think it's a multiyear turnaround story. I think we've got great products and we feel really confident we can bring them to market.

We got to work through some of the short-term challenges, which we feel are transitory with the disruption because of the field safety notices and the restructuring that we've done. I think it's a risk that we are monitoring, but we're doing anything possible to make sure that we manage those risks better and set us up for a pretty good 2019. And then we'll put out the guidance for 2019 and JPMorgan will preannounce the results.

And then I think really the only open item that will be in 2019 and 2020 is the refinancing of the converts, which we will work pretty hard on and we feel confident that we can get these products to market. So really I appreciate you guys coming in and listening to the story and look forward to the one-on-ones later today.

### Chris Cooley
*Analyst, Stephens, Inc.*

Well, I think it's an exciting story and, Vaseem, on behalf of Stephens and myself, thank you so much for joining us again today.

[indiscernible] (00:31:09)

## Vaseem Mahboob

*Chief Financial Officer, Endologix, Inc.*

Thanks. Appreciate it, Chris.