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Endologix, Inc. (ELGX)

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CORPORATE PARTICIPANTS

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MANAGEMENT DISCUSSION SECTION

Unverified Participant

Okay. So, good afternoon everyone. Hope you guys all had a good lunch. Proud today to introduce the CEO of Endologix, John McDermott as well as the CFO, Mr. Vaseem Mahboob. After their presentation, we will be having prepared remarks or Q&A – after the prepared remarks, we have Q&A down the hall in the Sussex room.

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

Okay. Thanks, [ph] Alan (00:00:23). Good afternoon everyone. So here's our Safe Harbor statements and let me just jump right into it. So Endologix is a medical device company in Orange County. We develop devices to treat aortic disorders, primarily aneurysms, so that'll be the focus of the talk. Really what's unique and sets us aside is we've developed really the next generation therapies to treat these aneurysms, significant growth opportunities ahead, particularly coming from the new product portfolio as well as a clear path to positive cash flow.

So AAA disease is a leading cause of death. It's actually the 13th leading cause of death in the United States and what makes this disease so challenging to treat is, as you can see from this illustration, aneurysms are like fingerprints, they come in all different shapes and sizes and each patient has a unique anatomical challenges. And over the years, this therapy has evolved really to become a significant market opportunity. So as you can see here, the current market is about $4 billion of opportunity and it's into three different segments, traditional aneurysms, which are aneurysms that are pretty well-suited for treatment with the currently available devices that's the traditional segment. Complex aneurysms, which is about one-third of the diagnosed aneurysms which are actually not well treated today by currently available devices that's a growth opportunity that I'll talk about in a little bit and then thoracic aneurysms.

So the aorta is the main blood vessel in your body and this is an aneurysm is basically when we get a distention through a disease process and what we want to do is reline that artery before that artery ruptures and causes death, there's about a 70% mortality rate associated with a ruptured aneurysm.

And while there's been great progress over the past two decades in aneurysm therapy, and it has in fact become the standard of care particularly in traditional aneurysms. There's still a lot of unmet medical needs, in particular in the old days what they would do is if you had an aneurysm, they would do it invasive incision from just below your sternum down below your belly button. They will remove your abdominal organs, and so in a synthetic graft, and then put you back together and obviously that procedure came with a relatively high rate of mortality and morbidity. The endovascular approach was evolved over time, putting devices into catheters and guiding those catheters up into side the aorta and deploying a device to do that less invasively.

So the benefit was you got this reduction in perioperative mortality. But over time these patients need to be followed for the rest of their lives and as you can see from this chart, if you focus your attention is kind of the bottom right hand side is once you get out to about eight years there's a fivefold increase in mortality with EVAR patients over open surgery, and the two failure modes for EVAR today despite the fact that it's come a long way or endoleaks which is where you get a leak around the stent graft into the aneurysm or sac expansion, which is where this aneurysm has while we've put a tube in to take off the blood flow you can still get sac expansion. Those are really the two remaining unmet needs in the space, and have been actually for the past decade.

So here's where we want to take the market. Today, all of the devices that are currently in use are considered traditional EVAR, their self-expanding stents with fabric either sewn to or attached to these devices. This self-expanding stents are put in the aorta adjacent to aneurysmal disease. So you don't want to put an expanding technology next to an expanding disease. So the next step up in the evolution is polymer-based devices and I'll talk to you about that because that's the focus of our new product portfolio with our Ovation and Alto devices.

And then moving to EVAS. So for those of you who follow the story for a while, you've heard of a device called Nellix. Nellix is the first and only device that seals the entire aneurysm sac, that's the technology that will treat that second failure mode which is aneurysm sac expansion. So those – this is really how we see the market evolving over the next few years and we're the company with both polymer EVAR as well as EVAS.

So we've put together this portfolio of devices, AFX is our version of a traditional stent graft, as I showed you which is more akin to the other currently available devices from our competitors. Ovation is a very low profile system and the only device with a polymer seal in the aortic neck. We got the Ovation technology through a merger with TriVascular in February of 2016. So we're coming up on our two-year anniversary and I'll talk more about that device in a few minutes.

And then Nellix. Nellix as I've pointed out early on is the first and only device that treats the entire aneurysm sac, it really holds the promise of changing the therapy in the long-term. You can see that each one of these devices offers unique clinical value proposition for certain types of anatomies [ph] stents (00:05:46) most often physicians who use more than one device because today there isn't a single device that treats this wide range of anatomical considerations.

So if we take this portfolio these three devices. And by the way, we're the only company with a portfolio. So if you look at all the other companies, they've got one device to try to treat as many patients as they can. We've taken a different approach and have built a portfolio of devices to treat a broader range of patients. And you can see that here. So as you go across in the traditional and complex aneurysms, you can see the percentage applicability for the portfolio and the relative value or market opportunity for each one of these products. And as you work your way across, you can see that this Ovation Alto device has the potential really to treat the broadest range of patients within our portfolio, but also the broadest range of patients in the marketplace.

So this is exciting new product that candidly has been in the shadows of Nellix. Nellix has gotten a lot of attention over the past few years because it's probably the most disruptive and exciting product because it solves some of the problems that none of the other devices could solve. Meanwhile, Alto has been quietly going through the regulatory approval process. And this month, we will enroll the final patient in our U.S. IDE clinical study, in fact, the case is already scheduled and on the books. After that's done, we have a six month follow-up period of time and then we'll submit our PMA supplement and expect approval and commercial introduction of Alto in 2019. The benefit of Alto, in addition to treating the broadest range of patients, it will also be one of the lowest profile systems in the marketplace and offers this unique benefit of polymer that I talked about before.

Why is that important? All the other devices have the self-expanding stents that expand the aortic neck as a part of their way they work. Polymer doesn't expand. So when we put these devices into a patient's aortic neck and we make this polymer seal in vivo, the polymer hardens and doesn't apply ongoing outward force to the aortic neck causing late aortic neck dilation. So it's not an expanding device adjacent to an expanding disease, it makes more intuitive sense and we will announce some clinical data in the first quarter that shows that we get great long-term durability with this device. So this is really the next generation of that system and it'll be the next meaningful new product launch in our space that's scheduled for 2019. So this is an exciting new opportunity for us.

Here's our guidance for this year. So no news here, this is the guidance that we gave on our last call and it's unchanged as of today. We plan to report our Q4 results as well as give our 2018 guidance on our Q4 call, which will be the third week in February. This is probably an important slide and for those of you want to monitor the company and kind of keep score with us throughout the course of 2018. I'll buzz through these milestones and catalysts here quickly. ELEVATE enrollment complete, that's for the Alto device. So the ELEVATE is the name of that IDE clinical study. We expect to enroll the last patient in that trial at the end of this month and again approval for that device in 2019 is expected.

EVAS2. So with the Nellix device this technology to treat and seal the entire aneurysm, we ran a clinical trial, we got very encouraging one year results, but at two years we started to see a signal that there were some anatomies that weren't ideally suited for that device. So we are now having to do a confirmatory trial to prove that a narrowed IFU is highly effective. We've got very good clinical evidence that it is, but the FDA wanted a prospective confirmatory trial that is EVAS2. The first patient for that program should start by the end of this month.

We expect that to be a one-year enrollment, a one-year follow-up in a PMA process which gets us to an approval by the end of 2020. So EVAS2 first patient enrolled, again that should start this month.

At the SCVS ENCORE data, what's that? That is an amalgamation of all the prospective clinical evidence with this ovation polymer-based system, so it will be over a 1,000 patients and we expect it to provide evidence that that device provides long-term durability and a reduction in overall endoleaks, which is the shortcoming for the currently available devices. So those data will be available at the SCVS in March.

Then turning to the second quarter 2018, you can see that we have this CX that stands for Charing Cross that is one of the big annual vascular meetings in London, EVAS versus EVAR. So one of the interesting observations over the past few years is we've been working on the Nellix system and this idea of endovascular aneurysm sealing, is we've seen this a reduction in overall mortality, in particular cardiac-related mortality.

And while up to now it's been really an anecdote, but as we follow the patients out one year, two years and three years, we're starting to see this signal become more pronounced. So what we did is we commissioned an independent research group to do a patient propensity match evaluation comparing EVAR to EVAS and that comparative data will be presented at this meeting in April. And we hope and expect that it will provide evidence that in fact EVAS does provide a mortality benefit over EVAR and that that puts us on that track that I've shared with you earlier in terms of the evolution of the therapy.

Then at the SVS meeting in June, the LUCY one-year data, LUCY is the first and only clinical trial comparing EVAR outcomes between men and women. Historically, women have been under-treated under-diagnosed and got worse outcomes than men. And we did a clinical trial, we announced the 30-day data last year in June and prove that for the first time women could be treated as effectively as men. This year, we'll announce those one-

year data. So while the 30-day data were very encouraging the one-year data are going to be frankly more important and that information gets presented at the SVS in June.

Then ChEVAS IDE approval. So utilizing Nellix, although, we've had to narrow the indication for the infrarenal use of Nellix. One of the most exciting applications for that technology is to treat more complex anatomies. And as I pointed out early on about one third one-third of the aneurysms are complex and not well treated with other currently available devices. This IDE will be to treat those complex patients for which today there isn't a good off the shelf solution. So that will be the beginning of a new clinical trial to broaden that indication and include complex aortic aneurysms.

Then turning to Q3 elevate the six months results. So this is that Alto that new device that we're hopeful to introduce in 2019. The six-month follow up is the data that's required by the FDA to get that approval, so we'll launch and introduce that data at one of the medical vascular meetings in the third quarter and then we also expect to enroll our first patient in the ChEVAS study in the third quarter and then finishing out the year. Another one of the big annual meetings is the VEITH Symposium, LEOPARD is a clinical trial, it's the first and only head-to-head comparative clinical trial evaluating our AFX devices and the competitive devices, the one-year follow up from that study will be presented at that time as well as we expect to complete enrollment by the end of the year in the EVAS2 clinical trial.

So there is a lot of activities here. There's both a combination of new data readouts as well as progressing our pipeline closer to marketplace. So this will be a good year to track our progress leading to what we expect to be some nice uptick in growth in 2019.

Here's just the product pipeline laid out in terms of years. I won't spend time on this now, but we can dig into this in the closed session. And then just to wrap it up. So innovation leader in $4 billion current market opportunity, we've clearly got the new technologies in the categories. Our competitors have been doing it the same way for many, many years with very incremental improvements. We think we've got the innovations required to really change the therapy and solve these unmet clinical needs and today have and in the future expect to have the broadest portfolio of devices. Here's the growth drivers.

So as I pointed out, 2018 will be focused on leveraging these new positive clinical results as well as the existing portfolio. In 2019, we plan to introduce the Ovation Alto device, in 2020 Nellix for the infrarenal indication and then in 2021, get a broadened indication to treat complex aneurysms with the ChEVAS indication. And then lastly through the growth and expected launch of Alto in 2019, we believe we've got a clear path to cash flow positive.

So that's what I've got for now and we'll meet for questions in the Sussex room. Thank you.