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MANAGEMENT DISCUSSION SECTION

Matt O'Brien
Analyst, Piper Jaffray

All right. Good afternoon and thank you so much for joining us. We're very pleased to have our – sorry, just real quick. I'm Matt O'Brien, I'm Med Device Analyst here at Piper. Very pleased to have the Endologix CEO here with us, John McDermott. I'm not going to steal too much of his thunder. There was a little miscommunication as far as what he should bring here – that's entirely on Piper, so my apologies. So there will be no slides, but John is going to run through the story and then we'll open it up for any kind of questions that you do have. Thanks so much.

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

Thanks Matt, and good afternoon everyone. As Matt pointed out, I'm John McDermott with Endologix, Irvine-based medtech company, with a primary focus on devices to treat abdominal aortic aneurysms. Our investor deck is online and available. There's a comprehensive overview of slides, so you can refer to that at your leisure. I'll just give you kind of a high-level overview of the company. Again, we focus on the treatment of abdominal aortic aneurysms; it's a couple of billion dollar market opportunity. We are one of the smaller players in the category, but the company with the most innovative new product pipeline. Most of the companies in our space, which are largely comprised of Cook, Medtronic and Gore, offer a single solution to treat these patients. We've adopted more of a portfolio approach and have accumulated three different unique systems to offer physicians the ability to treat each individual patient with the best potential device for that individual patient. And that's been our differentiating factor and we've been really viewed as the innovator in our space now for the past few years. That said, we have had some speed bumps in the road, particularly over the last couple of years with these products – these newer products as we bringing them to market. One in particular is a product called Nellix. So if you're familiar with the story, you may have heard this is a unique technology designed; it's the first and only device that seal the entire aneurysm sac. The benefit of that is the number one failure mode for these technologies are what we call endoleaks; or once you put in a device, there is the ability for blood to leak back into the aneurysm sac. So we acquired a technology several years ago and advanced it through development and into clinical trials to completely seal the aneurysm sac and really advance that to become a standard-of-care.

During our clinical study, we learned that there was a subset of patient anatomies that were not ideally suited for that. We've been through a process now of working with the FDA to narrow the indication for the initial design and we're hopeful that this summer that we'd be able to do that with the IDE dataset that we had already accumulated, but in fact the FDA wanted some confirmatory clinical data. It recently gave us IDE approval to run a confirmatory clinical study and we should enroll the first patient within the next several weeks for that study. That will be a trial of a total of 90 patients, of which 75 will be required with one-year follow-up.

So we expect to enroll that study over the course of 2018, follow those patients for a year in 2019, submit for and hopefully get approval by the end of 2020. So that's the Nellix product and if you've heard of some of the disruption related to Nellix and the timelines, that's what it is; as there's a subset of patients that are not ideally suited for this generation device. We have a future generation of that product that we think addresses that, but in the meantime we still see a lot of promise and value with the Nellix franchise. You also may hear about another indication for Nellix called 0 or which is an acronym that stands for chimney EVAS and that's using the Nellix device together with some branch devices to treat complex anatomies, which is about a third of the market opportunity and it's probably the most underserved segment of our market. That is also an area of great interest and some physicians are adopting that approach in Europe. We plan to start an IDE clinical trial to get that broader indication and start enrolling patients in the middle of 2018.

We're hopeful to get a CE mark for that indication sooner, but have recently updated the timeline to reflect 2021 for both the U.S. and European approval. However, we are pursuing an earlier path to approval using existing clinical data for CE mark and we'll provide updates on that over the course of the next 12 months.

So that's now Nellix, it's an exciting product. We're expecting to introduce some new and important clinical data on Nellix in the spring. Specifically, one of the big annual meetings for aortic care is a meeting called Charing Cross, it's in London. And there has been some growing evidence to suggest that possibly treating the entire aneurysm sac, which Nellix is the only device that does that, could offer a mortality benefit over the traditional EVAR devices.

We've seen signals of this in our one-year follow-up, our two-year follow-up and now our three-year follow-up, but if taken all of our data and given it to an independent research firm to do a propensity patient-matched evaluation comparing EVAS or Nellix to EVAR in a large dataset of the vascular quality-initiative patients in the United States. And that analysis is ongoing and the data will be presented in April and we remain hopeful that we'll be able to show actually a mortality benefit with the device. So stay tuned for April with that.

One of our other key products in an area of some additional disruption over the past couple of years is AFX. It was kind of the company's flagship product. What's unique and different about that device is that it's the only system that sits on the patient's native bifurcations. So most of these devices are held in place with hooks or barbs or other fixation. AFX actually sits on the patients' anatomy and the clinical advantage of doing that is it preserves that distilled anatomy for future endovascular procedures.

So what I mean by that is if you have a peripheral lesion, for example, in your left femoral artery, you would access that through an incision or a puncture in your right groin over your bifurcation and treat it from above. That's how peripheral interventions are done. Once you have an endograft put in with all the other systems, you can't do that anymore. You actually have to do a different kind of an access. So AFX is the one and only device that preserves that bifurcation and that's been its clinical value proposition for many years and earned us about a 10% roughly market share position in the U.S. and similarly outside the U.S.

We had a manufacturing problem at the end of last year and some disruption with an earlier generation of that device, which created quite a headwind as we went into 2017 and we've been working through that over the past several months. The AFX business has been relatively flat over the past months, but we had expected a rebound from those manufacturing and clinical issues earlier in the year and haven't seen that. And that's what resulted in a more pessimistic outlook for Q4 that we guided on our Q3 call. So we've brought down expectations relative to that product.

So looking forward, we still think AFX is a very good product. There's still a good and loyal following for AFX, but we don't expect a lot of growth out of that franchise in the future. The big grower though in the product portfolio right now is our Ovation product line. Ovation is a technology that we acquired in a merger with another company called TriVascular back in February of 2016, and that product has been growing nicely, over 30% in the most recently announced quarter and what we've seen is continued adoption in the United States and outside the U.S. and growing clinical evidence leading up to and the planned introduction of a newer version of that system in the early part of 2019. So the cadence for Ovation is, we will have some new clinical data that we'll introduce in March of 2018 at one of the major meetings, followed by more good clinical data in June at the Society of Vascular Surgery (sic) [Society for Vascular Surgery] (08:22) meeting, and then leading to the introduction of the newest device which is called Alto, which we expect in the first part of 2019.

So Ovation's been growing nicely and we expect that to continue and there's a new product in the pipeline to support that growth. So that gives you kind of an overview of the pipeline, a little bit of a commentary on the disruption over the past couple of years. And with that, I'm happy to open it up for questions.

QUESTION AND ANSWER SECTION

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

A

Yeah?

Q

[indiscernible] (08:51) Let me start off with – I know that some of the patients are coming in with multiple comorbidities and just for people that are a bit [ph] newer (09:00) to the story or just any updates on sort of what the Ovation product is going to be a huge driver in 2018 as you've said in the last call, so what types of anatomy does that necessarily fits versus the AFX?

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

A

Yeah. One of the most differentiating features of Ovation is the profile, and what I mean by that is the size of the catheter, the diameter of the catheter that's inserted into the patient. So Ovation is the lowest profile endovascular device in the marketplace and to give you – to kind of calibrate the degree of that is, it's a 14-French OD system, outside diameter, compared to the next lowest is about 18, so it's a fairly material improvement in terms of profile. The clinical value of that is that smaller device is not only smaller, but it's more flexible, so it has the ability to treat small access vessels and tortuous tight anatomies, which is particularly prevalent in female anatomy. So for example, we ran a clinical study called the LUCY trial and presented those data at the SVS Meeting earlier this year. And for the first time, we're able to show that women could be treated as effectively as men. Historically, women have gotten worse outcomes and been undertreated than men over the past decade. So Ovation shows some promise at offering women the same kind of clinical advantage that men have with endovascular aneurysm repair. So that's one of the advantages of profile and that's unique to Ovation.

The other benefit to Ovation that separates it from the other traditional devices is all of the other devices, including AFX but excluding Nellix, work on a system of a stent that is attached to fabric and the device is implanted in a patient and applies continuous outward force on the aorta. Now, as you probably know, stents were designed

originally to treat occlusive disease, so where you have a narrowing in an artery, you use a stent to open it up, right? That technology was adopted to treat these aneurysms, which at that time made sense, but in retrospect as we move forward now two decades into the therapy, we're putting an expanding device adjacent to an expanding disease. It's not intuitive. So Ovation really was the first purpose-built system that doesn't do that. So instead of applying outward force to the neck or the proximal edge of the aneurysm, what it does is we have a polymer seal, which is like a gasket that is implanted and the seal is completed en vivo in the patient and the benefit of that is you get watertight seal, which is better than blood-tight seal as you would imagine. But more importantly, that polymer seal does not apply outward radial force to the aortic neck. And we've seen that absence of aortic neck dilation present itself now at years one, two, three and four and five, and it's proving to have a clinical benefit. And that's what's really helping drive the adoption. So, the growth innovation is coming from small torturous access patients and the benefit of this polymeric sealing ring in the aortic neck. As well as our sales team has now gained enough experience and confidence, it has enough patients under their belt to really be recommending the device more and more often. So, I think, it's got a good growth trajectory.

Q

Could you talk a little bit about the [indiscernible] (12:38-12:47)?

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

A

Yeah. Sure. So, as I mentioned a little bit earlier in my remarks about Nellix, we went through this clinical trial and we learned through that effort that there were some anatomies that were not ideally suited for Nellix. And specifically, what those are the way that Nellix works is think of it as a stent and on the outside of the stent, there is a polyurethane bag. And in that bag, we're going to inject polymer. And that polymer is going to fill the aneurysm and conform to all the nooks and crannies in that open space and seal the sac. But it works on the premise that you need open space. There are some aneurysms that are actually filled with clot or thrombus, so you might have a bulge but the bulge could be filled with thrombus. Those anatomies we have learned are not ideally suited for Nellix, because there isn't enough space for the polymer to open up and seal. And when there isn't enough space for there to be polymer, what can happen is the devices can slip down a little bit – a clinical finding we call migration.

So when we started seeing, the one-year data was excellent. At two years, we started to see some signs and reports of this migration phenomenon, and we're able to go back and look at all the patients treated and associate that migration failure mode with this specific anatomy type. So what we've done is, we've gone back and revised the IFU to exclude those particular patients from the treatment. And we're hopeful that we could retrospectively apply that new IFU to the dataset and get approval, but the FDA wanted a confirmatory trial.

That's a little bit more of the history. As that relates to our experience in Europe, what's happened is when Nellix got introduced in Europe early on, because of this unique capability to treat and seal the entire aneurysm sac, not surprising there was widespread adoption. A lot of physicians used adopted Nellix very rapidly. In some cases, they were using it on the original IFU; in other cases, they were using it well off because they could treat patients that they wouldn't even attempt to treat with the earlier generation technologies.

So what we've seen in this adjustment from the original IFU to the new IFU has actually been more dramatic, because the device was being used with some degree of frequency off the original IFU and that's what we've seen. So we've seen this kind of gradual reduction in utilization of Nellix as physicians have embraced the new IFU. Now, the good news is that the results with the new IFU and the Gen2 device are exceptional. And we

expect to prove that in the confirmatory trial as well as the registry that we're running outside the United States. We'll start annualize those – that reduction probably in the middle of 2018, I would think. I also think that I mentioned that we have this potential mortality benefit. If that bears to be true and we don't know the final results yet, we've seen preliminary results which are encouraging. If that holds true, I think that provides some support for the product line in the second half of 2018 as well. Yeah.

Q

And how often does that happen with the anatomy? How do the [ph] feasibility (16:01) to adhere to the vessel [indiscernible] (16:03). What kind of reduction in patient population does that [ph] have (16:07)?

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

A

Yeah, we estimate that roughly 40% of the traditionally treated aneurysms are still candidates for Nellix. We have to get some more experience under our belt. Actually the prospective confirmatory trial will be a good test of that because we'll be prospectively screening patients and we'll have a better idea but it looks like it's about 40%.

The nice thing about Nellix, and you might say, well jeez, so this – it's encouraging, you've got this potential mortality benefit, but you've narrowed the IFU as there is still enough of an opportunity. And the answer is yes, and the reason is beyond the potential mortality benefit is this ChEVAS indication. So if we try to put dollar values on these market segments, we feel that the patient – the market opportunity for Nellix in the traditional aneurysms is about a $600 million opportunity compared to ChEVAS, which is these complex patients, that's another $600 million. So, on a combined basis, the Nellix product opportunity still represents over $1 billion worth of market opportunity. So running these two trials makes a lot of sense. And if we get the benefit of the mortality advantage, then clearly that's an exciting opportunity.

Q

[indiscernible] (17:30-17:34) what you originally...

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

A

Roughly. Yeah, yeah, that's right.

Matt O'Brien
Analyst, Piper Jaffray

Q

We only have 2 minutes left but there's another real quick one. [indiscernible] (17:41-17:46)

[Abrupt End]