08-Jan-2018

Endologix, Inc. (ELGX)

J.P. Morgan Health Care Conference - Q&A Session

CORPORATE PARTICIPANTS

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

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

QUESTION AND ANSWER SECTION

[Abrupt Start]

Q

So obviously Ovation was kind of, I would say, the standout performer of your company last year, a really good pickup on the TriVascular acquisition. What did that growth like really come from? Is it the deeper penetration of existing accounts, penetration of new accounts? And going forward, what kind of like mix do you see between those two different growth engines? Do you think it will switch more towards new accounts as you go forward now that you've kind of got some [indiscernible] (00:00:25)?

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

A

Yeah it was – it has been a mix and I expect it to continue to be a mix. So, we had, when we put the companies together, it took a while for the legacy reps of each organization to get familiar with the other products; that's really happened now. So, at the end of 2017, as we move into 2018 now, the reps, the legacy Endologix reps are trained and certified on Ovation and likewise, the legacy Ovation reps are trained and certified on AFX.

So what we saw was some growth in existing accounts for both account bases. So, where there were Ovation accounts, they started to use some AFX and where they were AFX accounts, they started to use some Ovation and we added new accounts on top of that.

So we still have a lot of growth potential in existing accounts. So, I'm not going to give you the details of our penetration levels across the U.S., but suffice to say that there's a lot of growth potential in the existing accounts.

We expect to get more of that growth as well as add new customers over the course of the next few years. So we're still 13%, 14% market shareholder in the U.S. So there's a bunch of runway for us and we're the only company with the new polymer technologies.

Q

And then kind of, I guess, talking a bit more about Ovation, just in terms of competition. So Medtronic, they just got approval for sort of a new iteration of their Endurant II graft, [indiscernible] (00:01:56) with the technology that they picked up from their recent Aptus acquisition. So that kind of got them into sort of this short-neck kind of market that Ovation has really been dominant in. So what kind of competition do you see that really posing in 2018 and how does that kind of factor into your expectations for how quickly Ovation [indiscernible] (00:02:15) grow going forward?

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

A

Yeah. I wouldn't think of Ovation as a short-neck device, first of all. So I'd probably start by resetting the perspective and the utilization of Ovation has historically been more on patients with difficult access in tortuous vessels. So, if you look at where Ovation has grown up, it's been based upon the fact that it's the lowest profile system in the marketplace. So, there are some physicians who use it to treat short-neck aneurysms, but that's not the majority. Really, the design attributes for the system are profile flexibility and the polymer seal ring.

That said, when you speak of the Endurant II device now with this expanded indication with Aptus, that indication really targets them more at the complex segment, not where Ovation has historically been used. And the uptick of that and the success of that, I guess we'll wait and see. The one headwind probably worth mentioning is that there is no reimbursement for the device. So if a hospital decides to use it, they have to pay for it out of the existing DRG.

Q

[Question Inaudible] (00:03:24) about the Medtronic device.

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

A

Yes, right. But in the context of that being a competitive threat, the things I would say is two things. One, it's really targeted at the complex market, which is where we don't have a product available today in the U.S. And two, there is no hospital reimbursement for the system. So, difficult to – you know, it doesn't look to us like a meaningful competitive issue moving into 2018. We'll get into it after we've had some more time experience competing with it.

Q

Got it. So before we move on to kind of Nellix, does anyone have any questions? Okay. So, obviously kind of like the big question and I'd say kind of one of the issues of 2017 was really Nellix with the [ph] weaker IFU (00:04:06) and then with the delays you had in the U.S. launch. So you just kind of got the CE Mark [indiscernible] (00:04:12) close to the end of 2017. So just kind of going forward or like whatever you heard since then in 4Q 2017 from your position from your users, what kind of impact do you think we should expect to see on Nellix as we move forward?

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

A

Yeah, once we introduced the revised IFUs at the end of last year or at the end of the prior year, it was a very gradual transition. So, physicians who were happy and generally getting good results didn't change their utilization behavior much. And it was only over the course of the year as we continue to reinforce it and then together with the FDA's decision to require a prospective confirmatory trial did the market really start to accept the fact that they

needed to narrow the utilization of Nellix and that has been happening. And I think that will continue to happen, you know, through the first part of 2018.

Our perspective is, is that if the mortality data for EVAS is favorable, that that can provide some support for the product line. I wouldn't suggest that it's going to give us meaningful upside, but it'll certainly be a validation of the therapy. And for those patients who can be treated on IFU, it could be a very, very good alternative.

That's one stabilization and growth opportunity there. The second one of course is ChEVAS. So when you – if you're out talking to physicians about Nellix, I think you'll find many people enthusiastic about using Nellix in a broader indication to treat these complex patients. So of course we have to run a clinical trial to get that indication. We've already been in discussions with FDA on that and hope to get an IDE approved in Q2 and our first patient enrolled in Q3.

Q

And [indiscernible] (00:06:06) on the issues you highlighted in 2017, as you mentioned, people who were getting good outcomes on Nellix [ph] stop (00:06:13) with it, but you said you were kind of having this issue with like small volumes [indiscernible] (00:06:18) a bit more like, I guess, uncertain, whether they would continue using Nellix. So as we've now moved through 2017, do you have a better updated view on kind of whether these – like what percentage of these small volume kind of centers have really come back, how many have decided that [indiscernible] (00:06:35) working with Nellix?

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

A

Yeah. So, just to clarify. We didn't have any issues with small accounts with Nellix. What we've been talking about was given the narrowing of the IFU and the fact that you can only treat a subset of patients, it really doesn't make sense to have Nellix used in small accounts because if they only do 10 a year, then now they're only going to be able to do three or four Nellix's, do you see what I'm saying. So, what we've done is shift our commercial emphasis to larger accounts; so, bigger centers that have larger volumes where it's worth the time and investment to become familiar and have best practices, procedures and training to get the best outcomes with Nellix. So, it wasn't so much an issue of small accounts opting out of Nellix as much as given the narrowed IFU, it just makes more sense for us to focus our commercial and clinical resources on the bigger accounts.

Q

Okay. You briefly mentioned the data set that you're going to be presenting at Charing Cross, comparing EVAS to EVAR. You mentioned it obviously in your presentation and you just kind of alluded to it there. You said it'd be kind of a more of a, I guess, minor impact on Nellix if it were to be positive. I was just wondering if you can elaborate on your own expectations for that data, what you are exactly going to be showing or open to show and whether you think you could maybe reverse some of the weakness in Nellix or if it will just be a better [indiscernible] (00:08:02) for ChEVAS [indiscernible] (00:08:06)?

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

A

Yeah. So, the data that's expected is a patient propensity-matched cohort. So basically what we're doing is taking prospectively enrolled patients from the Nellix clinical trials and matching those same patients in terms of their

comorbidity, their risk characteristics, their age, all of their medical conditions. You want to match these two populations. Since we don't have a comparative trial, it's the best way to get comparative evidence. We've given that to an independent research group in Boston. They've got a large data set of EVAR patients. They're going to mine through that and find a matched patient's population and then compare the mortality rates. And we'll see if what has been reported anecdotally, which is a mortality benefit for EVAS, is – proves out in the data.

So that's what will be presented in April. In terms of the impact, I just want to just manage expectations. So if that data is positive, well, I think we're all going to be enthusiastic about that and particularly patients and physicians should be enthusiastic because if we're able to actually reduce the mortality rate, that is the big problem with having an aneurysm. If you're a patient and you get diagnosed with an aneurysm, you're afraid of dying. So if we can actually provide an alternative that where fewer people die that's a meaningful advance. That said, we have to recognize that the narrowed indication isn't going to make it available to everybody. So I think we're – while we're cautiously optimistic, I don't want to create an expectation that if this data is positive that Nellix is going to go on a big run. I think it's a validation of the therapy which is really important. So that's how we see it in the context. It is also a very positive signal for then the future of ChEVAS as well.

Q

Okay. If no one else has any questions, I'll kind of just close with the final question [indiscernible] (00:10:09) the balance sheet and capital. Obviously you guys just released an announcement this morning that you guys had to back out of the Deerfield revolver, which was, I want to say, a $60 million, $50 million?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

$50 million.

Q

$50 million?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah.

Q

...revolver that you hadn't drawn upon yet. Does that kind of imply any risks to the $120 million loan that you guys already have with Deerfield? And then with respect to kind of your capital needs going forward, just how do you plan to kind of like meet those capital needs given that you're obviously still, have to spend a lot on to these clinical trials and [indiscernible] (00:10:41) invest back in the business to really get it back to where it should be growing.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So first of all, let me clarify. There was some confusion this morning about what actually happened. So we had a $120 million term loan with Deerfield that we signed in April this year and we also had a $50 million asset-based loan or revolver, as you called it, which we signed at the same time. So what we announced this morning on the 8-K was that we have terminated that facility with Deerfield because we did not meet our minimum net revenue test on a trailing 12-month basis. But at the same time, we also announced that we have signed our term sheet with another party, which will replace that revolver. So from a debt capacity perspective, there is no change to the company, the $120 million term loan is intact with Deerfield and they've been great partners. We tried to kind of work out a solution and were unable to. And we chose to place it with somebody else. We had a very competitive process. We had three term sheets and we went in with a partner that could kind of help us kind of take the business to a point where we don't have any liquidity issues and we continue to partner with Deerfield for the longer term and they've been the largest investor in the company for a while.

Q

So you think that you got another $50 million loan, you think that will be enough to kind of get you through the foreseeable future in terms of...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes, John mentioned on the presentation too, listen, based on the current projections on growth that we see over the next few years, some of the guidance that we're going to put out on the February call, we feel very confident that we still have [ph] path (00:12:19) to cash flow breakeven in the second half of 2019.

Q

Okay. Unfortunately we don't see [indiscernible] (00:12:23). Well, if no one has any other questions, I would like thank you guys very much for taking the time to [ph] be with us (00:12:30).

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Okay. Thank you.

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

A

Thank you.