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MANAGEMENT DISCUSSION SECTION

Rich S. Newitter
Analyst, Leerink Partners LLC

All right. I think we're going to get started here. I'm Rich Newitter, medical device analyst for Leerink Partners, and thanks for joining us this morning. We have the senior management team of Endologix, CEO, John McDermott; and CFO, Vaseem Mahboob. And I want to keep this as interactive as possible, so please feel free to raise your hands and we'll try to get a microphone over to you, and we'd love to hear your questions while we conduct this fireside chat.

So, John and Vaseem, thanks for joining us.

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

Happy to be here.

QUESTION AND ANSWER SECTION

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

I thought a kind of a good starting point, John, 2018 feels like a bit of a transition year for Endologix, a lot of catalysts out ahead, but it feels like kind of some of those are 2019- 2020. But there's a lot to talk about kind of from a teaser standpoint, some data in 2018 as well. So I want to spend most of our time talking on kind of what those key 2019-2020 catalysts are across the three businesses, or your three key products and then – and what the – what you see the kind of the trajectories for each of those, and if you can kind of give us a sense as to what we'll learn about each of those in 2018 moving to the year from the various kind of data pieces, that'd be great. But 2018 kind of a transition year, maybe tell us where do you see kind of Endologix right now? What do you – what were the biggest challenges coming off last year with AFX, the biggest opportunities and successes, Ovation, and how do we think about managing through this transition period till we get to that kind of inflection point year in 2019-2020?

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

A

Sure. So, yeah, to start with the 2017 disruption question, what I would say is we had – we started out the year. This time actually last year, we were unable to make our largest selling product, so we were – we're having some manufacturing issues with the quality issue discovered at the end of the year. We were working through that, but as we forecasted for the full year, we didn't have great visibility and when we'd have our primary product back and then when we got it back, what would be the uptick, and so that was a major headwind for us over the course of the year.

The good news is we did get it back, we got the product back, we got the quality issues addressed, we got the inventory levels restored, but we didn't see the rebound with the AFX business specifically that we'd hoped, and so that made for a challenging second half. That was further complicated by the decision the FDA to require a confirmatory trial with Nellix in May.

So we had a couple of headwinds, I'll call them, in 2017. And that's why when we stepped into 2018, we feel much better about having those things behind us. So we've got AFX now is from a quality perspective and from a product availability perspective, that's going well. And obviously, now with the Nellix new confirmatory IDE in place, we have a clear path forward for a Nellix approval. So, specifically, if we transition into the products and I go through each one of those products and how they're set up, maybe starting with AFX.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Yeah, that sounds great.

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

A

Okay. There isn't a lot of data readouts on AFX this year with one exception we have, continued to follow up in a trial called the LEOPARD study, which is the first and only head-to-head comparative clinical trial matching AFX against the Gore, Cook and Medtronic devices. We will have a preliminary update on that study here at the end of

this quarter. And then the full one year readout on the LEOPARD trial will occur in the fourth quarter of 2018. We think that should provide further evidence that AFX continues to be a safe and effective product.

Then transitioning to Nellix...

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Actually, can I just – so what do you think that will do for some of the account-specific trends that you've identified with what was kind of moving slower in the AFX recapture? What can that data specifically do for you?

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

I think it just provides stability. I wouldn't say it's going to spring that product back into growth, but also our sales force activity is more focused on innovation platform anyway. So, what I think it does is we saw some erosion in AFX in 2017 in our view in 2018 is that that product line should be stabilizing, although there are opportunities to upgrade some of that AFX business to Ovation. So, we might see a net decline with AFX over the year, but that would largely be driven by our internal sales activities, because when you convert a customer from AFX to Ovation, that's an upside, you can treat more patients with Ovation.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

It's a welcome to...

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

Yeah.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Yeah, converge.

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

It's not something you'd discourage.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

And should we think of kind of AFX declines or stabilization being a little bit more 2Q and beyond weighted, and so you get the data, the preliminary updates or it should kind of be under way?

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

We see internally signs that it's stabilizing. What I'm suggesting though is some decrease in AFX this year in favor of adoption of Ovation is okay. We do some cannibalization of AFX customers to Ovation, that actually sets you up for growth, not just this year but also next year and the year after.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Okay. So let's turn to Ovation because that's been a huge growth engine...

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

A

Yeah.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

... even in the face of some of these challenges.

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

A

Yeah. So Ovation has grown very nicely and we expected to continue to do that. In fact, if you look at the different milestones we have set up for 2018, it's very what I'll say Ovation focused. Specifically, we have a clinical study data readout that will occur at the end of this quarter, which is an amalgamation of all the prospective clinical studies that have been done over the past several years on Ovation. We think that data will be positive and well-received by the marketplace.

And then we'll follow in June with more positive clinical evidence on the Ovation platform, specifically with the one-year clinical trial from the LUCY data, which is the first and only gender comparison clinical trial. We reported the 30-day data at last year's SVS Meeting, and this year we'll report the one-year follow-up which is going to be more impactful. So we think that those two clinical study readouts will provide continued support for the growth of the Ovation product line.

What will be happening also during that time is we'll be in the follow-up period for our ELEVATE trial, so we just announced recently the completion of a clinical trial called ELEVATE that is with our latest generation device called Alto. That's a new version of a device. It will treat a much broader range of patients than the currently available Ovation system. That requires six month follow-up for an FDA submission. So we'll make that submission to FDA and our notified bodies this year and are planning an approval for that device in 2019. So you've got good clinical readouts on the existing product to support growth, transitioning to a new version of the device to drive further growth with the platform in 2019.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

What kind of growth are we – so let's just think about 2018 for a minute without Alto. What kind of growth do you think is reasonable? Is this 30% level that you exited the year on sustainable and does it potentially accelerate from that level with Alto into 2019?

Vaseem Mahboob
Chief Financial Officer & Secretary, Endologix, Inc.

A

So let me take that, so when we look at the TriVascular business that we acquired, in the last report the number standalone is about $38 million, $39 million. And when you look at where we have been, we have almost doubled that business.

Now, when John mentioned the transition from AFX, this conscious transition from AFX to Ovation, the way to think about the U.S. business is that on a case volume basis, we still expect that business to grow, but we would expect to see some cannibalization on AFX that's going to lead to growth of Ovation. But at the same time, with that bigger base, we don't expect to be sustaining growth of 30%, 35% because the fundamental business with that core business on Ovation is a lot bigger than what it was. So while we continue to grow the case volumes in the U.S. and primarily Ovation, I think the expectation on where Ovation is going to be, we can clarify that on the guidance call when we talk about that next week.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Okay, that's helpful, but certainly solid, solid double-digit momentum is in the cards. And some form of acceleration off what we're really doing 2018 into 2019 once Alto is on the market.

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

A

Yeah, it's also an important product just in terms of kind of the evolution of the therapy. What I mean by that is all of the market today, with the exception of Ovation and Nellix, is served by what we call traditional devices, this older generation, the legacy systems. As we start to move the market and physicians up into polymer-based sealing devices, we really stand a bit unique from a competitive perspective. So, as we move our core business up into polymer, we're taking the whole market up with us ultimately leading to EVAS, which I know we'll talk about next, as what we think will be a superior long-term therapy.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

And just two more on Ovation, on Alto, maybe elaborate a little bit on how big of a market expansion situation is this for that portfolio? Can you quantify that at all? What's your addressable market now, where does Alto bring it?

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

A

Yeah, so the way to think about Alto is, first of all, it competes in the existing market very effectively. It does expand the market in terms of the neck length. So the length of the healthy tissue below the renal arteries, that's the part of the anatomy that we call the aortic neck. It can treat a shorter aortic neck than the other commercially available devices. So, it does expand the market, but I wouldn't think of its opportunity in terms of market expansion. It is a good what we call workhorse device, so it will have the broadest indication of all other infrarenal devices. So, if a physician wants to have a single device that they use to treat the vast majority of their aneurisms, it will be ideally suited for that. So you get some market expansion, but you also get a very well-designed kind of a workhorse system.

And it addresses some of the limitations with the currently available device. If you went out and did your doc checks, what you'd find is everybody has always agreed that the Ovation system gets very good clinical results, but it's a little bit more technically demanding procedurally. The Alto device addresses those limitations with the current system. That's why we're bullish on it being positioned as a workhorse system instead of just a device for women or other challenging anatomies. It's a much bigger product than that.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

That's helpful. And the second question, last one on Ovation, just on competition, there's been with Medtronic and Endurant II, can you talk a little bit about how you think of your position there?

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

Well, with specifically against Medtronic, they have introduced a system that's called Aptus EndoAnchors. So what they do basically is they take their legacy graph, which is I don't know eight years or nine years old now, and they have broadened the indication by using this little screw technology. So after they deploy their graph, they'll come in and they'll follow it up with a series of circumferential screws to anchor the device into the anatomy and in doing so have broadened their indication to treat shorter necks. So that's how they do it.

The reason I think we've got a better solution is they also have to charge I think their average selling price – I don't know what their selling price is, I know what their list price is, about $6,500 for that system in addition to their stent graft. There is no incremental reimbursement in the DRG to cover that. So there is a bit of an economic challenge for broadly adopting the EndoAnchors, we believe, compared to Ovation or Alto, where you don't have to use an accessory system for a broader indication. So in Alto, you'll have a broad indication without the need for additional procedural stuff and other accessory devices.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Got it. So reimbursement and...

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

And just procedural simplicity. That's actually, you've got to do the core EVAR procedure and then you've got to follow on with a secondary procedure to fully utilize that indication expansion and with Alto you won't, it's one single procedure. That's actually easier than the current Ovation procedure.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Okay. But what about for Ovation today?

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

Yeah.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

[indiscernible] (14:22) still give you confidence that no real disruption, until Alto comes tomorrow?

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

Well, I think where Medtronic may be able to get a little bit of incremental share with the Endurant plus Aptus is going to be in the short necks, which we couldn't treat anyway.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Okay.

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

A

So with currently available Ovation, that product for them does expand their market opportunity of that, but it doesn't necessarily represent a threat to the Ovation growth because we're not competing in short necks today with Ovation.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

So maybe they get there a little early, and then once you get there, you hopefully...

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

A

We can show up with Alto and yeah...

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Maybe do better than...

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

A

Yeah. There is an indication difference. So to be very specific about it, they're indicated at 4 millimeters when they use Endurant plus the screws and will be indicated at around 7 millimeters. So we will still require a slightly longer neck. But as I pointed out, I don't think the value proposition with Alto is just in the indication. I think it's just a simpler-to-use device that can treat a broad, broad range of patients without any accessory procedures or devices or reimbursement challenges.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

That's really helpful context. So maybe turning to Nellix, you want to kind of update us on where you were exiting 4Q at a firm pathway for IDE and where are you in enrollment and talk to us a little bit about what's going on with your European experience there, which was a little challenging in the fourth quarter still, the refined IFU. Can you give us an update on that business and what data presentations we should be looking for?

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

A

Sure. So, keep in mind that over the course of 2017, we were going through a transition from the original IFU to the new IFU. So, for those of you who are new to the story, Nellix was introduced in Europe many years ago with a fairly board indication, we ran a U.S. IDE clinical trial and in the longer-term follow-up learned that there were some patients that weren't well-suited for the first generation device. So, we went through an effort to narrow that indication and announced that narrowed indication and have had the sales be impacted accordingly in Europe

over the past year. We see that Nellix business currently showing signs of stabilizing is how I would characterize that.

And in terms of the clinical trial, we have an approved IDE, so we went to FDA with the narrowed IDE request and they wanted us to run a confirmatory clinical study. We got an IDE approval to do and we'll enroll our first patient in the first quarter of this year and are anticipating that it will take a full year to enroll that trial, we'll have to follow those patients for one year, and then we've estimated about one year for the PMA approval process.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

What's the number of enrollment again?

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

A

90 patients.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

90 patients.

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

A

Of which 75 are required for the submission. So, we have – you enroll more than you need in case there's lots to follow up or any patient mortality.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Got it.

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

A

So that's the path right now for Nellix infrarenal with the new IFU and the Gen2 system. In terms of supporting data, you won't get any look at that data over the course of this year because we'll be enrolling that trial. Probably the most interesting data readout coming from the Nellix product will be we do expect a podium presentation at the Charing Cross meeting which is a large vascular meeting in Europe and London in April. There has been a signal over the past couple of years with Nellix that there might be a mortality benefit between EVAS which is Nellix Endovascular Aneurysm Sealing that compared to the traditional original EVAR devices.

And the hypothesis for that, just so everybody wants to know why, why would Nellix have a lower mortality rate? What we've seen is that when you put in a traditional EVAR device, you leave an open space, and that open space gets filled ultimately with thrombus. Thrombus formation is an inflammatory reaction. With Nellix, you occupy that space with polymer, so you're not allowing any open space for there to be thrombus or inflammatory response. So we've seen a market reduction in cardiac-related mortality with Nellix versus traditional devices which makes sense from the perspective of an inflammatory response.

So to rather than have these kind of anecdotal reports, what we did is we gave all of our prospective clinical data on Nellix to an independent research group in Boston and they're taking that data and doing the patient propensity matching with an EVAR cohort, a large cohort of EVAR patients so that the patients we matched in terms of comorbidities and risk factors and the results of that comparison will be presented in Charing Cross in April. So we'll be able to have more scientific rigor behind an evaluation comparing EVAR to EVAS.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

And you feel good that the data will fair out the hypothesis?

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

A

Yeah. We've seen preliminary when we compare it to other data sets, it looks encouraging. The only thing I don't know at this point is whether or not it will be statistically significant.

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

A

I guess what do you – so that data that get presented in April, what do you think realistically the tangible impact will be on the business in EU and how quickly? What's the best case and how significant is this?

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

A

I don't want to expect necessarily a lot of growth from it. I think it further provides stability, but most importantly probably validate that EVAS is the therapy of the future. So maybe we get some modest growth, too early to say. Let's get the data out, let's see what the final results are, and then we'll determine what impact it has on the business.

The other part that it positively influences is ChEVAS. So the other thing we haven't talked yet about is taking Nellix and expanding the indication to treat complex anatomies which is about a third of the diagnosed aneurysms that's an underserved segment of our marketplace. So if we have a mortality benefit with infrarenal Nellix, then the expectation is that when physicians can use it there, though, they should. Also for this other third of the market, that mortality benefit bodes well for the use of ChEVAS in complex patients as well.

Rich S. Newitter
Analyst, Leerink Partners LLC

Q

Got it. And on ChEVAS, you're looking for kind of a U.S. 2021 timeline...

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

A

That's right. Yeah.

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

A

...and I think you had – you're hoping for something earlier on CE Mark, but just to be conservative or safe, you told the Street to think about a 2021 timeline for both. I guess, what's the earliest you think in a best case scenario the CE Mark could come?

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

As tempting as it is to give you a date, I'm going to resist.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Okay.

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

And just let us do the work. We do think there's opportunity to pull it in sooner, but I just want to be careful to manage expectation. So we'll be involved in a more interactive regulatory process later this year. And so, if we get some color that we think can be instructive on narrowing that timeframe, we'll do that then, but probably better to sit tight right now.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Okay. That's fair enough. Tough to predict regulatory bodies.

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

Well, every time I try to crystal ball that, we get it wrong. So we'd rather surprise to the upside instead of giving dates and maybe missing them.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Got it. Did we miss any other clinical items to keep an eye throughout 2018? There's a bunch out there that we don't have enough already, but I mean it sounds like you have – in the first quarter, you have ELEVATE, you have another Ovation study.

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

Yeah, what we'd call [ph] OnCoRe. (22:56)

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

[ph] OnCoRe? (22:57)

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

Yeah.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

You have LUCY...

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

That's in June.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

...in the second quarter.

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

Yes.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

And then you've got – for AFX, you've got LEOPARD both at the end of the first quarter and then the full-year readout in the fourth quarter.

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

That's right.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Continued progress on enrollment for Nellix, which I'm sure you'll continue to keep us updated on for the U.S. IDE trial, and then the – and then you have also kind of this EVAS mortality...

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

Right.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

...study, which is in April. So are those the main ones? Did I miss anything?

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

Yeah. No, that's it. The only other thing I'd add to that, the other activity that will be going on, while we're enrolling the infrarenal trial with Nellix, EVAS 2 as we call, we will start enrollment in the ChEVAS study also in the U.S. So that will be another important milestone and the first off-the-shelf device to treat complex aneurysms that's ever been done. So there's a lot of enthusiasm for that indication for Nellix also.

Rich S. Newitter
Analyst, Leerink Partners LLC
Q

Got it. So, a lot of the exciting things to kind of look at in 2019 and 2020, 2018 a bit of a transition year, but we have some stuff to tide us over on the clinical data front. I guess, Vaseem, the next question's for you, how are

you thinking about managing the P&L in the expense side of the equation in this transition period? Do you still feel confident in your cash position that it gives you a clear pathway to cash flow breakeven by the second half of 2019?

Vaseem Mahboob
Chief Financial Officer & Secretary, Endologix, Inc.

A

So I think it's a question we get a lot, and I think the way to answer it is very consistent with what we have said in the past, which is when you look at the numbers for the company in the last couple of years have come down significantly and kind of created this concern around the liquidity of – and then the cash needed to run the company.

What I got to highlight is the fact that on the combined basis on TriVascular and Endologix, we used to spend about $228 million of OpEx and that number was down a bit, $197 million. The guidance for 2017 is in the $165 million to $170 million range, and we really feel that $165 million is the right number to kind of run this business without cutting into growth.

So having said that, we still have plenty of cash. We ended the third quarter and we'll give you the fourth quarter numbers on the earnings call at about $90 million of liquidity at the end of third quarter. The cash burn projected in the future is consistently in the $30 million to $40 million range. So no change to what we have said in terms of how we can run the company. That gives us a lot of comfort that with some growth on top line, we can still hold on to our second half 2019 cash flow breakeven number.

So, again, it all comes down to – for us to manage your cash, which we have done and have a track record of doing and, second, start to build the business again. So, as we stabilize the business and we kind of come out into a growth profile, we feel very confident that we have enough liquidity to run the business to that milestone. And also, we have the opportunity to look at our 2020 maturities and look at it if we have to do something at that time. But at this point, we're holding on to the second half 2019 cash flow breakeven.

Rich S. Newitter
Analyst, Leerink Partners LLC

That's great. We're out of time. Thank you, both John and Vaseem. We really appreciate it.

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

Yeah. Thank you for having us.