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Endologix, Inc. (ELGX)

JP Morgan Health Care Conference - Q&A Session

CORPORATE PARTICIPANTS

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

OTHER PARTICIPANTS

Allen Gong
Analyst, JPMorgan Securities LLC

MANAGEMENT DISCUSSION SECTION

Allen Gong
Analyst, JPMorgan Securities LLC

Okay. So just kicking off the breakout session for Endologix. My name is Allen Gong with the Medical Supplies and Devices team. Just to kind of start us off, I thought I'd be appropriate to kind of take a look back.

Unverified Participant

Could you introduce them for the webcast?

Allen Gong
Analyst, JPMorgan Securities LLC

Sorry. I have the CEO, John Onopchenko, I have Matt Thompson, and I have Vaseem Mahboob with me on the desk.

QUESTION AND ANSWER SECTION

Allen Gong
Analyst, JPMorgan Securities LLC

Q

So I guess just to kick us off with kind of like a retrospective of 2018-2019, you guys have made some pretty sweeping changes at the company, completed a fairly comprehensive restructuring of your US and European businesses, exited some geographies as well. And this ultimately led you guys to grow sequentially over, I think, 4Q 2019 to Q2 2019 and then return to year-over-year growth in 3Q 2019. We haven't seen 4Q results yet, but just kind of with that as the backdrop, what has really, I guess, gone well for you guys in 2019? What has gone like to plan, better than expected and what are the things that you think you still need to work on as you head into 2020?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Well, I think the realization that a company of our size, in light of a growing regulatory standards environment, made the choices of exiting small, non-growing, either existing or potentially unprofitable markets, a relatively easy choice. It is not an easy decision to execute because you still have a requirement to support patients post implantation. I think what also I would give us a relatively high mark for is the recognition that our cash consumption relative to our value creation was out of balance and aligning that and closely coupling that I think was well done. I think that recognizing that when you're restructuring and when you're trying to optimize cash resources, the toughest challenge is what you say no to. I think we've done that well. The complement of that is we've actually preserved, if not, grown our level of resources for clinical development. Clinical development is in fact our basis for competing; it's the tip of our spear. We've preserved that in a way that enables us to realize the clinical milestones that I described in my presentation. What will always remain a works in progress is continuously improving the competitiveness of our operation, whether it's design, manufacturing, quality system or commercial execution. We are a company that, as a culture, has accountability at its center. And part of that mandate includes a willingness and ability and a commitment to continue to raise the bar across, again, all operating elements to include commercial execution.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Got it. So, as part of this kind of rebasing, one of the major overhauls that you guys did was kind of rationalization of your sales force. And when I looked at your presentation today in anticipation of the Alto launch and anticipation of Nellix, you guys actually kind of had a little piece in there about kind of – I think it was maybe like not investment specifically, but building out like the US channel in anticipation of those launches. So how should we think about that? Like what does building out the channel mean? Does it mean hiring more reps, does it mean like going more aggressively into newer hospitals? I know you guys are focusing on the higher volume ones right now. So I guess can you elaborate what building up the channel really means for you guys?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Yeah. I think what's been important first is to spend a moment talking about the things that we evaluated before we restructured beginning with the US. And what was important for us to understand is productivity. And what we realized was that we had a relatively high portion of our talent, both clinical specialists and our aortic account managers, frequently being both in the same procedure. And while there is certainly ample support for why you

would do that, whether it's supporting a clinical study or whether it's training someone who's recently come onboard, we started measuring that more purposefully and as a result, as we messaged previously, we focused our clinical specialists in supporting our traditional loyal base AFX2 business, which created capacity for our aortic account managers to start targeting new accounts or targeting accounts where we had relatively low penetration and that has started to yield fruit.

Now, in preparation for Alto, I want to reinforce the fact that we've learned some very, very valuable lessons with the introduction of Nellix in Europe and we've learned some valuable lessons even with the introduction of Ovation in the US and that is introduction – an introduction of something entirely new requires a rigorous amount of training and it requires a rigorous amount of discipline around establishing proficient use first and also reinforcing at every turn the value of being on-label. And as a result, outcomes start to reflect the kinds of advantages that we envision and are purporting, you can't do that without adherence to the things that I just previously described. However, once that proficient use has been established and once we've converted Ovation customers to Alto customers, we can then start looking to potentially adding resources as we move up market because then we're supporting two platforms that we would expect to start growing, first AFX2, albeit very modestly. We're not making any predictions about their – its specific growth. Our intent is clearly to stabilize, but we are slowly seeing customers returning to that platform in light of the Alto, excuse me, the LEOPARD evidence and then obviously with the move with Ovation, we have a market expansion opportunity as I described in my prepared remarks.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Got it. So you touched on AFX2 there. So something that occurred before the end of the year was that the FDA came out with this new kind of like meta-analysis saying that there may be some issues with the AFX platform, even with the newer versions with respect to Endologix. And this is kind of the first time we've really heard this with the newer generations, there had been concern with older ones, but our impression was that these were issues isolated to those older generations. So I think you guys addressed that on the 3Q call basically saying that your own data doesn't support that. But could you provide us any updates on how like that's progressing when it comes to actual adoption in your sales base and how we should really think about that maybe concern or dynamic progressing into 2020?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Well, to be clear, the analysis that the FDA's notice was in response to was a presentation made by Kaiser at the American College of Surgeons in October and where regrettably there was only a few patients that had been followed with AFX2 out to two years. Now honestly, the FDA has a right and a mandate to ensure public safety. And whenever they see a signal coming from a product in the past, namely STRATA-based AFX, they believe they are well justified in obviously issuing that safety notice and we certainly support that. However, the evidence to the contrary is LEOPARD, where we have data out to three years with AFX2 that clearly shows a wide distinction between STRATA and a favorable comparison with other contemporary endografts. I don't know if Matt, you'd want to...

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Yeah, couple of things. I mean I think it's important, Allen, just to state it's not a meta-analysis. The FDA were looking at a small single center series with 13 patients out for two years. I think as John said, we have to be led by data and when we look at data sets for endografts, you really want to be looking at data sets that are valid, that

are verifiable, that are independent and are of high quality. So I guess what we end up doing is lining up the data sources that we have on AFX which, number one evidence with LEOPARD, a randomized controlled trial. But also, we look at the Vascular Quality Initiative data of our endografts versus all other comparative endografts. And we look at meta-analyses and also our complaint system and really all of our data sets and we have three data sets that we regularly update, are all concordant with the performance of AFX2 being at a level that is significantly different from STRATA and actually at a level that is either similar or slightly superior to the other endografts that are on the market. So I guess what we end up doing is looking at three verifiable, valid, some independent data sources against one single center series and why I don't at all wish to diminish what Kaiser presented, it's just not what we're seeing in our prospective analysis. So certainly at the moment, I think we can be very confident that our graph's performing at a level that is acceptable and certainly equivalent to everything else that's on the market.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Okay.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And just to add to that financially speaking, as I had messaged at the third quarter earnings call, we haven't seen any significant change to either case cancellations, case creation rates for AFX2. So, we still stand behind our initial thesis, which is that to stabilize US and AFX, we would have a AFX business that was going to be flat from Q2 to Q3 to Q4. So, no change to the guidance or for that matter our expectation of AFX for the fourth quarter.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Okay. Any question in the audience?

Q

John, can you speak to the Chinese improvement process of your products. Are you doing it at Endologix or is Boston Scientific doing that?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

A

Yeah. We're doing it in partnership with Boston and we've hired an independent firm who is expert in obviously such matters. And it's actually a multi-staged process where you gain clearance, but clearance then affords you an opportunity to be able to compete in local market tenders. And so that's an approval process. Obviously you win a tender, you don't win a tender. And then at the local level, obviously, there are preferences to create beyond an ability to compete based on a tender. So we're expecting clearances, as I said, next year for first AFX2. And then the agreement provides for expansion of that opportunity across our entire portfolio.

Q

Okay. Did you get Green Channel approval or no Green Channel expedited review, you know?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.
A

We've not publicly stated where exactly where we are on the approval process. We'll be updating that in the first quarter.

Allen Gong
Analyst, JPMorgan Securities LLC
Q

Okay. So moving on like past AFX2, to I think the product launch that everyone's really paying attention to, Ovation Alto. You officially launched that in the fourth quarter in Europe, I believe are still on track to launch that in the first quarter in the US. [ph] You've always (00:12:34) consistently talk about kind of having a more measured launch. So I guess when we think about the kind of growth of your Ovation business in 2020, I think it's clearly going to stand out in your portfolio over the course of 2019. Should we think of Ovation Alto as kind of sustaining that kind of growth rate through 2020 or even though it is a more measured launch, could it lead to a little bit of an acceleration or a tick-up? And then once you do when, if you have, I don't know when you know, when you think you know you're going to transition to a full launch, but do you have an idea of when that would be and then what kind of the growth of the business could be after that?

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.
A

Well first, we have not yet received approval for Alto in the EU; we're expecting that in the first quarter. We have certainly an intent, as I mentioned earlier, job one is to displace Alto with our highest volume Alto users and establish use proficiency. As part of that, we also want to introduce Alto in large volume centers where Ovation has been used in a very narrow set of anatomic indications. A reason that's important is because we believe with the expanded applicability of Alto, there's a reason to have further conversations in those centers and then furthermore establishing use proficiency and expanded use with Alto in those centers also introduces the likelihood of including those centers obviously in our Alto RCT. But we want – I guess the best way to think about it, Allen, is that the first priority is to establish use proficiency in those highest volume centers and we do that at the expense of broadening its introduction to lower volume centers or to new users because again, it's the use proficiency which guides the expansion, not our desire to simply displace one product for another. We can live with a dual platform based on a polymer sealing ring technology. But what we will not experience is an introduction that fails to establish use proficiency because we are a company who is anxious to get it out as quickly as possible. So you can think about that throughout 2019.

Allen Gong
Analyst, JPMorgan Securities LLC
Q

Got it. 2020.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.
A

Excuse me.

Allen Gong
Analyst, JPMorgan Securities LLC
Q

Should we think of this as, on the pricing side, should this be an ASP uplift relative to Ovation or is the focus really going to just be on driving adoption with same or comparable ASP?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yes. So I think when you look at our product portfolio today, we do have a premium pricing or had a premium pricing when Nellix – when we were selling it in Europe so the market could support that and we do see a price premium on Ovation relative to AFX globally. So depending on, to John's point, the update curves and how we decide to go forward with it, we should expect to see a slight premium to the current products that we have in the marketplace.

Allen Gong
Analyst, JPMorgan Securities LLC
Q

Got it. And then moving on to the final product in your portfolio, Nellix, so you're planning to – you are on track to finish the EVAS II study at the start of this year or early in this year, submit in 3Q, which will be put you on track for maybe a 2021 approval and I think you guys had said a 2022 launch. So I guess – and you also contemplated re-launching that in Europe. So how should we think about the dynamics of a Nellix launch and re-launch given the concerns with off-label IFU use – of IFU use – and kind of the fact that you'll be launching with that like ChEVAS out at the same time? Should we really think of this as kind of like a slower introduction ahead of the next-generation device with Chimney or will this be kind of a more dedicated launch from you guys?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

I might pitch in there. So I think important for us when we launch in the US and relaunch in Europe is to learn the lessons of the past. So on-label use for Nellix is absolutely crucial if it performs – if it's going to perform as we want it to in the longer term. So we will be controlling that launch so that essentially all patients that receive that endograft are going to be on-label with regard to the anatomic indications for use and the surgeons are going to be trained so that they are able to replicate a reproducible and optimal procedure. So that'll be controlled by us in that sense. With regard to ChEVAS, ChEVAS is a system. So it's not Nellix and any peripheral stent, you like, it's a system of the chimney stents for that purpose in Nellix. And equally, we'll be launching that as a system preapproval of cases to make sure that on-label use is followed. So, you can think of that as a very deliberate launch in centers that have an appropriate patient population to support on-label use.

Allen Gong
Analyst, JPMorgan Securities LLC
Q

Okay.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

And let me just add to that a little bit here. So, Allen, I point everybody to the investor deck. And if you look at the Nellix opportunity, on-label that we have laid out, it's still a $700 million opportunity where that we can target that product globally. Now, if you look at – and obviously the biggest segment within that $700 million is here in the US, where we expect to launch the product in 2022. So – and again, very modest market shares in that $700 million segment, it's still a very significant opportunity for that product, albeit on a narrowed IFU.

Now, to Matt's point, what we have to make sure is to guarantee the outcomes that we continue to see not only with the old IDE patients, but also the data that we're seeing in the current EVAS2 study is that we have to make sure that those cases are on-label.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Got it. Any questions.

Q

Cash position of the company?

Q

Could you repeat the question?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So the question is about the cash position of the company. We haven't reported the fourth quarter, but at least at the end of the third quarter, we had about $47 million of cash on the balance sheet. We had $20 million of availability on the revolver that we have with Deerfield, that was not tapped at all. And then we've also said that we should expect to see a $5 million average cash burn going into the future. So if you do the math on that, we still have north of $40 million of cash at the end of the fourth quarter and then expect to see a burn of less than $20 million for next year.

Q

Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Got it. And then just like final question for me like going forward and something that you highlighted for the first time I think at the [ph] Spinal (00:19:50) Conference was also your plan to reach operating cash flow breakeven in 2021, so you guys have obviously done a very good job of stabilizing the top line, taking cost out of the system. But when I think about getting to cash flow breakeven, that's going to require obviously a fairly significant acceleration in the top line. So you guys have repeatedly highlighted your belief that the traditional market is growing around 5%, [ph] compound (00:20:15) is growing around 9%. So when we think about your growth in 2020 and 2021, you guys haven't given guidance yet. But directionally, how should we think about your growth relative to the market?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. So I think listen, we'll give the guidance at the earnings call middle of February. We'll have better visibility to this continued evolution or the impact of the AFX business which we feel has stabilized into January and gives us a good basis for kind of seeing what's coming in 2020. So as we have stated and as John stated in the investor

deck here, our goal here for 2020 is to grow at or slightly above market. And with that just assumption of that top line, we feel that we can get to cash flow breakeven in 2021.

Now that's in light of kind of sustaining the margin profile that we have today and the cost controls that we have put in place, so we feel confident that we can get to 2021 based on the cash position that we have and the sustained cash burn of $20 million in a year. Now having said that, I do also want to remind people that we do have some work ahead of us vis-à-vis the work that we started in April on the restructuring of the balance sheet and the [ph] $11 million (00:21:29) converts that we have that are due at the end of this year and then obviously the amortization payment that's due to Deerfield in 2021. So but again on an operating basis, we feel very confident that we have a company at a point where with an accelerating top line and the leverage and the cost profile that we have that we can get to breakeven in 2021, as stated previously.

Q

Okay. Any final questions? I think there's a question.

Q

Is the delay on Alto in Europe, is that specific to anything in particular around your notified bodies and everything [indiscernible] (00:21:57) would be attributed to that and should we worry at all about that approval, whether it's in Europe or US ultimately coming through, is there any indication there of particular issues that are being looked at?

[indiscernible] (00:22:13)

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Yeah, let me take that. So the question is around the Alto approval in the EU, the state of the notified bodies and the regulatory environment. So if I – if I kind of take that separately from an FDA perspective, we responded to our deficiency letter in December. We're back on the clock with the FDA and we're back in an iterative review process. And we remain confident in our ability to answer all the questions that are coming. In terms of EU, you are correct; it's a pretty changeable environment in there at the moment. Our notified bodies are going through the designation process in the MDR. That's also a focus of theirs. And as you know, they don't have a clock. So timelines are not as well stipulated as they are for FDA approval. But I will say that we are, again, in an iterative review process. The final module really, the NSAI, a notified body, is reviewing our – the clinical data. We remain confident in our clinical data and you guys will get to see it in March of this year where we're going to present the ELEVATE trial at the Society for Clinical Vascular Surgery, that's March 14 I think.

Allen Gong
Analyst, JPMorgan Securities LLC

Okay, thank you guys.

John Onopchenko
Chief Executive Officer & Director, Endologix, Inc.

Thank you.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you.

Matthew Thompson

Chief Medical Officer, Endologix, Inc.

Thanks.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thanks Allen. Good to see you again. Thank you.