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Endologix, Inc. (ELGX)

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CORPORATE PARTICIPANTS

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MANAGEMENT DISCUSSION SECTION

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

[indiscernible] (00:00:00) and then part two, now that you've got six months into it, how would you say it's gone so far versus [indiscernible] (00:00:09).

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

A

Thanks, Robbie. So, the question is what did I see when I walked in and how do I feel about what we've done since. First, I will tell you that as I mentioned a moment ago during the presentation that the evaluation first in essence took the senior leadership team through those five – looking at the business through five lenses: culture, markets we serve, the products either in the marketplace or in development, the clinical evidence that supports them and then ultimately, the operating expenses of the company. I felt as though and we actually had some work done for us independently, that we just had an uncompetitive cause to serve in the U.S. So, part of the restructuring obviously included that.

The evaluation on markets basically said that if you look at what – let's begin with Europe, if you look at what competent authorities and were notified bodies in essence over the last seven years have introduced and that is a significantly higher burden in order to be in those markets. And as part of this reset, we needed to critically focus on those markets that had strong growth potential and that we could serve responsibly and profitably. So, we obviously made some choices there going from 23 to 10.

In terms of our clinical development, frankly, it was untouched. If anything we're actually growing in our clinical development expense year-over-year and that really is in support of the basis for competing and that is – it is on the back of that evidence that we intend to create preference and ultimately reestablish growth. So, those were the critical elements that we evaluated and took action on. Again, restructuring of the company was complete by the end of August of last year.

And in answering the second part of the question, how do I think it's going, that's really one of the charts that I presented that were color coded where it was intended to answer. Are they all green? No. Have we made substantial progress in each of those categories? We have. There are still plenty of wood to chop. We feel very good about improved performance as evidenced in both Q3 and Q4.

So, brought in and basically an entire new set of leaders into the company. Jeff Fecho is the Global Head of Quality; Jeff Brown, Chief Operations Officer; Elisa Hebb, new Head of Clinical Development and Regulatory Affairs. We just announced today a Head of – Global Chief Commercial Officer, [indiscernible] (00:03:06). And we also will be announcing [ph] Reyna Fernandez (00:03:10) who will be our Chief Human Resources Officer. So, new team, new processes, disciplined execution.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

The past week or so we got two pretty big [indiscernible] (00:03:22), one was Nellix discontinuing [ph] from the commercial setting (00:03:25) and today, really good fourth quarter pre-announcement. So, let's start with [indiscernible] (00:03:33) the quarter. Maybe just walk us through what was it that drove better results versus what you [indiscernible] (00:03:40).

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

A

Yeah. Again, we tried to depict that in the bridge and really, the three elements of uncertainty post reset were, what was going to be the disruption to the U.S. commercial team given the cost-to-serve mandate of becoming more competitive. Secondly, what was going to be the price of the disruption associated moving from 23 countries to 10 countries? And then, finally was, what was the impact of these two field safety notices that came out in the second half of the year? One for AFX2 which in essence was describing the re-intervention on or through AFX2, and in the case of Ovation, it was a field safety notice relative to [indiscernible] (00:04:31) when the product was used off IFU.

So, we've been able to manage the disruption of both U.S. and OUS lower than we previously had risk titrated to. Same thing with field safety notices. And then, obviously, that resulted in better-than-expected performance.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

And as you think about now it's gone forward, do you have now with the – moving out commercial, does that have a lower profitability [indiscernible] (00:05:11).

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

A

No, in fact, quite the contrary. The reason we took the action that we did was to first and foremost put patients first. Using the product – look, if you step way back from this, it is a very different design for an endograft, dramatically different design, and the potential of those design differences are significant. And frankly, post-CE Mark approval, I think that was far more aggressively used than anyone ever intended so soon in the history of that product's commercial experience. And I think, we responsibly issued field safety notices, three of them, since being commercial. But even with those field safety notices, we still saw regrettably a high amount of off-label use that had us take this action. So patients got put first and in turn, I think, we've preserved the potentially disruptive nature of the technology.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

Remind us of the timelines of what you're expecting [indiscernible] (00:06:28).

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

A

Well, EVAS2 is expected to complete its enrolment by the third quarter of 2019 and we're expecting EVAS and ultimately Nellix to be commercial in the U.S. by 2021. And then as part of that obviously, our next-generation EVAS product, again the milestone clearly is first demand by the end of 2019.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

Great. So we had a good fourth quarter. You said in the presentation that you held firm in terms of reps in the fourth quarter. What gives you confidence to hit your 2019 numbers? What is it that you saw maybe third quarter, fourth quarter after the restructuring that gives you the confidence to get to the 140?

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

A

Well, first, the process that we used in the second half of 2018 to arrive at a prediction for 2019 was very comprehensive and rigorous, and it included new, very seasoned leaders who each were responsible for obviously taking hold of their remit and the cost under which that remit was going to be effectively served. So, very rigorous process. Two, as we saw the risk getting mitigated around the field safety notices, as we saw the risk being mitigated around the disruption, OUS and U.S., and we saw obviously the results of that getting better than expected performance in Q3 and in Q4, we are still calling out that attrition is our number one risk. Whether it's commercially or non-commercial, folks come to work with a $0.60 stock price, it's a very daunting reality that we need to manage very carefully and is impossible for me to over-communicate at this time with our employees, so I do it frequently and I do it in earnest. And I think that's gone a long way, in essence, aligning and unifying the company. So, rigorous process, lot of risk getting mitigated in the last two quarters gives us confidence in 2019.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

Vaseem, I'll loop you in here. There's been a lot of moving parts in terms of the capital profile the company. But now with the changes in place, good performance in the fourth quarter, what are you thinking about in terms of the profitability of the company? How we'll see that progress over time?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. Listen, I think we have done what needed to get done in 2018 to really stabilize the company. From a capital structure perspective, we did the deal with Deerfield in August, which was a very different deal than what we had done in April the prior year. The risk premium adjusted, it was an expensive deal, but we got the short-term liquidity that we needed to run the business. We did the BTIG, bought deal, in November to pay for the 2018 stub that we had on the converts, we paid that off and it needed to be done.

So really, when we look at our cash balance that we announced this morning of $24 million organic, plus the revolver that we have with Deerfield and the fact that restructuring is already complete, and we have bent the cost

curve. We showed you in the end of third quarter that our run rate for OpEx was $35 million which is tracking to the 2019 estimate of $130 million to $140 million on the high side.

We're very confident that we have bent the curve on the expense side to manage through 2019. And really what it comes down to and it's not a surprise here, is we got to now go back in as we have publicly stated, refinance the 2020 converts that are out there. So, we'll address those here this year, but at the same time when you look at the sequential growth profile stabilizing the business, stabilizing the foundation, improving our credibility, we feel that with the full year of Alto in 2020 and a stable business and right data readouts on EVAS2 and ChEVAS, we can start to really think about a business that starts to grow again in the second half of 2019.

And as we return back to growth, we probably, with the lower cost-to-serve, have a path back to cash flow breakeven in 2020. So, we're very confident on how to get there. We just have to manage these intervals as we have managed in 2018, continue to do them in 2019.

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Q

You have the refinancing of this 2020 convert, do you feel like you have enough cash on hand plus the revolver to get you through to cash flow profitability?

A

Based on visibility that we have today and the assumptions that we're making for 2019 and the assumptions for 2020, we have a path to get to without really going back in and getting more cash. Now the question is how do we really finance? What's the structure and the mechanism [ph] door (00:11:42) exchanging the 2020 converts, I think that's where we need to spend some on. I think, there's a question in the back.

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

A

A question in the back.

Q

Absolutely. Given [indiscernible] (00:11:50-00:11:59)

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

A

With Nellix?

Q

With Nellix.

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

A

Yeah, in 2013.

Q

2013. Yeah, so you [indiscernible] (00:12:04-00:12:43).

A

So, only just to give you some color on that and as John said, you [indiscernible] (00:12:46) a look at the history of it. So, you're right, Nellix was commercialized 2013. And since that time, we've obviously seen some patients out to five or nearly six years now in Europe. And our knowledge of the therapy is exponentially increased to what it was in 2013, and we've learned some good stuff. As John said, when Nellix works and it's on its indicated label, you're seeing virtually no endoleaks, very low rate to total endoleaks, very low rate to sac growth, low rates of all cause of mortality. But what you're [indiscernible] (00:13:24) and actually is exactly the same as the EVAS1 trial and that if you're off the refined IFU, there's adverse events in terms of migration, principally some [indiscernible] (00:13:35) endoleaks and some sac enlargements. What we see now and they've been maybe five publications out of Europe in the last, let's say, six months, is really an affirmation of what we saw in the EVAS1 trial.

So, if you think about the cadence of peer reviewed publications, the publications that we're seeing at the moment, essentially reporting outcomes of Nellix in an unconstrained patient population between 2013-2015. What they're actually showing us is exactly what we saw in the EVAS1 trial, I mean, it's actually reaffirmed our root cause analysis.

Q

[indiscernible] (00:14:16)

A

It's confirmatory, but as John said, what those publications are reporting, if analyzed by the current label is a very high level of off-label use. And we know that the outcomes in these patients when they're substantially off label are suboptimal. And that's really the premise for making Nellix an on-label and the graft from now.

Q

Is there anything that you're able to read from, I guess, [indiscernible] (00:14:48-00:15:00)?

A

Yeah. There's not a tremendous amount there. I do know that we are working with a few physicians in Europe to actually get them to report specifically their re-intervention experience by using Nellix and secondary ChEVAS to re-intervene on Nellix. But I don't have enough color on the results of that to give you anything definitive. What I would say is that there are only very sporadic reports of re-intervention in the European papers today.

Q

Last question, [indiscernible] (00:15:32) was that in ChEVAS [indiscernible] (00:15:39) or was it in traditional [indiscernible] (00:15:42) maybe using Nellix when – even though you get – had disseminated the information [indiscernible] (00:15:49) etcetera, etcetera, they're still using Nellix.

A

Yeah. I can categorize it may be in full category. So, there was the off-label use infrarenal aneurysms where patients are outside the currently accepted indications for use, those used in the complex segment which would be off-label in terms of ChEVAS. And then there, if you like, even more off-label use was the use of Nellix to repair failing infrarenal EVAR and the use of Nellix to repair failing conventional grafts. So, it's like four categories of off-label use.

Q

[indiscernible] (00:16:29)

A

Sure.

Q

We use our prior thought process [indiscernible] (00:16:37) would be a very good tool, [ph] that this (00:16:43) problem with prior stent failures, have you learned something that tells you now that that is not a good use in that product?

A

I don't think we have enough information yet to answer that. But, I mean, I think, what is for certain is that if we are in the future going to use it for that indication, then it needs to be tested for that indication and studied.

Q

Yeah. So, I guess that in continuation what Robbie asked earlier [indiscernible] (00:17:14) the path to market in the U.S. And I don't think you really addressed it, but when it comes to, like, U.S. experience, right, obviously, you've just called it out in the OUS [indiscernible] (00:17:25) once you have the [indiscernible] (00:17:27) data and once you have [indiscernible] (00:17:29) and the next-generation device, what's kind of going to be your strategy to get that back in [indiscernible] (00:17:35) you had these series of setbacks, and actually calling off [indiscernible] (00:17:40)? What's [indiscernible] (00:17:41)?

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

A

Well, again, it will be evidence-driven. We will then have the evidence that EVAS2 is cleared against. We will be recruiting for ChEVAS at that point. And ultimately, it's again, continuing to train and educate physicians and more broadly customers on how to optimize performance by staying on-label.

I think with Nellix's decline and even in the presence of these field safety notices, this was the only responsible approach that we have in front of us in order to get that back and then continue to accrue evidence, and in the face of additional evidence, get back on the market with a product that is fully supportable.

Q

[indiscernible] (00:18:43-00:18:57)

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

A

Well, to be clear and to provide additional color, the decline of Nellix commercially for the last three years has been significant. So, it's not like we've got every customer that we ever started with in 2013 that has been consistently using the product off-label. It has been a declining customer base and that declining customer base is now down to regrettably not a lot that is now unfortunately continuing to use them off-label. I think, the U.S. is going to be a great bellwether and is physician practice surrounding on-label performance that I think will be the biggest – that peer-to-peer connection, I think, will be the biggest difference in reintroducing the product into Europe. Obviously, the European customers did not have that benefit with a U.S. contemporary, it will after EVAS2.

Q

Got it. And then, you mentioned like your guidance. Even with the pullback of Nellix off the market, you've obviously reiterated your [indiscernible] (00:20:11) of $140 million for 2019, [indiscernible] (00:20:14) quarter, 4Q and guided ahead of Street...

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

A

Yeah.

Q

...for the first quarter. So, I guess, on a constant kind of [indiscernible] (00:20:21), is that a function of just you guys have been very conservative to begin with, but your guidance really want to [indiscernible] (00:20:29) on the back of the restructuring or is Nellix really [indiscernible] (00:20:32) very incremental to your sales? I know [indiscernible] (00:20:35)?

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

A

Yeah, right. It's a bit of both. Nellix is not a significant revenue contributor in 2018. It wasn't predicted to be a significant revenue contributor in 2019. And that plus being very judicious in terms of what we are predicting, I mean, one of the [ph] tenets (00:20:58) of this company's recovery is to reestablish credibility, you reestablish credibility of, in essence, setting appropriate expectations and meeting or exceeding them. This is evidence of that being consistently applied.

Q

[indiscernible] (00:21:20).

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Okay. Great, thank you

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you.