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ELGX - Endologix Inc to Discuss an Update on the Nellix® Endovascular Aneurysm Sealing System U.S. Regulatory Status Conference Call

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PRESENTATION

Operator

Greetings, and welcome to the Endologix Incorporated Conference Call to discuss the company's update on the Nellix Endovascular Aneurysm Sealing System U.S. regulatory status. (Operator Instructions) As a reminder, this conference call is being recorded. This conference call is also being broadcast live over the Internet at the Investors section of the company's website, at www.endologix.com.

And a replay of the call will be available on the company's website for 1 year. Before we begin, I would like to caution listeners that this conference call will include statements that may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to enrollment in clinical trials, clinical outcomes with the new IFU and Nellix Gen2 device and the time line for regulatory actions, the accuracy of which are necessarily subject to risks and uncertainties all of which are difficult or impossible to predict accurately and many of which are beyond the control of Endologix.

Many factors may cause actual results to differ materially from anticipated results, including unanticipated clinical outcomes, the timing and results of clinical trials, uncertainties in regulatory actions and timing and additional regulatory requirements. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Endologix undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made or to reflect the occurrence of unanticipated events. Please refer to the Endologix annual report on Form 10-K for the year ended December 31, 2016, and Endologix subsequent filings with the Securities and Exchange Commission for more detailed information regarding these risks and other factors that may cause actual results to differ materially from those expressed or implied.

With that said, I would now like to turn the call over to John McDermott, Endologix Chief Executive Officer. Please go ahead.

John McDermott - *Endologix, Inc. - CEO and Director*

Thank you, operator, and good morning, everyone, and thank you for joining us on this morning's conference call to discuss the Nellix Endovascular Aneurysm Sealing System U.S. regulatory status.

With me on the call this morning is our Chief Financial Officer Vaseem Mahboob, and following my prepared remarks, we will open up the call to your questions. We have posted supplemental slides on the Investor Relations website, and as you will see, we have updated the new product pipeline chart to account for shifted time lines. I will discuss the major changes in my prepared remarks this morning.

Now I'd like to provide you with an update on our meeting with the FDA regarding the Nellix EVAS System, which occurred on Tuesday, May 16. First, let me start by saying that we are very encouraged by the level of collaboration with the FDA and that the agency seems supportive in helping us get the EVAS therapy to market. Based upon our discussions, both with the FDA and internally, we have determined that the best path forward to seek U.S. approval of the Nellix EVAS System is to conduct a confirmatory clinical study with the previously updated IFU and the Gen2 device. This is the same device in IFU, which we currently sell in Europe and other international markets and which is providing excellent patient outcomes.

We expect to collaborate with the FDA over the coming months on the confirmatory clinical study protocol and anticipate beginning patient enrollment in the fourth quarter of this year. Based upon our estimated time lines for enrollment, data collection, the submission and a panel meeting, we are forecasting a potential U.S. approval in the year 2020. Although, the timing for potential approval is later than our original plans, we feel the probability of success is higher. Essentially, while the FDA agreed that the 2-year results with refined IFU are encouraging, they still want prospective evidence and prefer the Gen2 device.

We certainly couldn't push for an advisory panel meeting with the Gen1 device, but the continued risk and uncertainty is not worth it in our review. Instead, we believe a confirmatory study with the Gen2 device has a higher likelihood of success and will provide further evidence that EVAS with Nellix provides excellent patient outcomes.

Additionally, FDA has encouraged us to add the ChEVAS indication to our IDE as soon as we have completed the necessary testing. We hope to amend our IDE to include ChEVAS by the end of 2017 and begin enrolling patients in 2018. This would put us on a time line to potentially gain U.S. approval for the ChEVAS indication in 2021. We believe that ChEVAS can expand the market and provide an endovascular solution for patients with complex anatomies, which represents 1/3 of the diagnosed aneurysms and a global market opportunity of over $1 billion.

Regarding EVAS, moving forward, we'll provide update as we gain approvals of the IDE supplements, begin enrollment, complete enrollment and of course, the anticipated approvals. We will also provide similar updates with all of our other product programs as they move towards commercialization in the key global markets.

To that end, we have decided to shift back the CE Mark time line for Ovation Alto, because the notified body has requested clinical data. Until we reach an agreement with the notified body about the amount of clinical data required, we will take a conservative approach and move the European time line back around the end of 2018.

We view this as a worst-case scenario and are hopeful that will be sooner, but feel it's appropriate to be cautious until the requirements are well understood. Regarding the financial impact of this update, there is no change to our 2017 financial guidance. We don't expect the sales impact and believe we can balance the additional clinical investment within our current operating expense guidance of $170 million to $175 million. Our previous projection for cash flow positive in the second half of 2018 now shifts back to the second half of 2019. Between the cash we have in the bank and our unused revolving line of credit, we're confident that we have sufficient funds and do not expect to raise additional capital until refinancing the $125 million convertible bonds due in 2020.

And now I'd like to turn the call back to the operator for Q&A. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll take our first question from Michael Weinstein with JPMorgan.

Andrew Ronald Hanover - *JP Morgan Chase & Co, Research Division - Analyst*

This is actually Andrew in for Mike. Can you hear me?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes. Good morning, Andrew.

Andrew Ronald Hanover - *JP Morgan Chase & Co, Research Division - Analyst*

So John, I first want to understand time line. So do you mind sort of walking through what you're thinking so in terms of Nellix Gen2 starting in the fourth quarter of this year and 1 year follow-up probably put you out till August of 2019, so second -- third -- in the third quarter, mid-third quarter? And then for a P&A submission to the FDA that probably puts you more into mid-2020 versus, I think, the PowerPoint says first half 2020. Can you kind of help give some color as far as how you're sort of thinking about all this?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes. So as I pointed out, we estimate 2020 -- I'm looking at the PowerPoint here to see. I see what you're saying. It looks in the first half, that's really -- there is nothing specific about exactly where that dock lands on the chart. But I'll walk you through the time line. I think we just made room for also an anticipated Japanese approval. But nonetheless, we expect to start enrollment in the fourth quarter. I think, that takes us probably about 9 months into the middle of 2018, then we follow those patients for 1 year, which takes you to the middle of '19. And then to allow time for the data connection, the submission and a likely panel, roughly 1 year later gets you roughly in the middle of 2020. Obviously, this can vary by a quarter, but that's kind of the macro time line and the underlying assumptions.

Andrew Ronald Hanover - *JP Morgan Chase & Co, Research Division - Analyst*

All right. And then in terms of just your meeting with the FDA. I mean, is it fair to say that even though you're kind of saying you're having excellent discussion back and forth that there might be something with relationship plus there might have been something specific to the data that they called out and that you went back internally to review. I mean, is there any color you can give in terms of like what might have been the sticking point? And then just in terms of the balance sheet. I mean, I heard -- obviously, you're pushing out cash flow positive from -- into 2019, but how do we -- how should we actually think about this, given you do have a revolver or you just did a refinancing, you paid down some of the debt. But in terms of, may be, there is going to be incremental churn in the base business. So any incremental color in terms of balance sheet helps as well? I appreciate it.

John McDermott - *Endologix, Inc. - CEO and Director*

Sure. I'll let Vaseem answer the balance sheet question in a minute. In terms of the dialogue with the FDA, there weren't any new issues or any new concerns expressed. It's really as fundamental as they just have a strong preference for some prospective confirmatory data. They acknowledged the success that we have achieved with the new IFU and our efforts to validate that with these independent data sources and the work that's been done is clearly compelling. But at the end of the day, it was clear to us that not having any prospective data was just going to be a sticking point in that. In our view, it does not make sense to push forward with the Gen1 device and run the risk that we don't get approved and loose more time and resource. So after our discussions with them, yes?

Andrew Ronald Hanover - *JP Morgan Chase & Co, Research Division - Analyst*

Yes, just let me ask you the specifics, sorry to interrupt, but is the FDA looking at Endurant II as maybe the data point where they didn't have any significant issues on adverse events versus what you'll are looking at, you'll looked at more of the Endurant, the actual clinical trial. I mean, any incremental there as well?

John McDermott - *Endologix, Inc. - CEO and Director*

There was no discussion about Endurant in our meeting with FDA. So I can't tell you to what extent the failures with Endurant influenced the FDA's perspective, but that wasn't the topic in the meeting. It's really our -- based upon the discussion and our interaction with them, again, I think they were very collaborative. But at the end of the day, they're just bringing some level of prospective evidence despite what we think provided, which was very compelling. There is a point where we just got to step back and collaborate with them on a new confirmatory study and move forward. So that's what we're planning to do. And Vaseem, maybe you can address the cash and balance sheet.

Vaseem Mahboob - *Endologix, Inc. - CFO and Corporate Secretary*

Sure. So Andrew, on the question on cash, as you can imagine, we have run multiple, multiple scenarios on the health of the business and the amount of cash liquidity that we have. And I got to tell you, in the worst-case scenario that we modeled out and again, I don't want that to be the guidance. The worst-case scenario that we modeled out, and again, I don't want that to be the guidance. The worst-case scenario that we modeled out, which is to grow the top line in this business at market, and we have proven that in past quarters that we have done a lot better than market without Nellix. We feel that we have adequate cash to see ourselves through to cash flow breakeven in 2019, and which would be kind of coinciding with the $125 million maturity. So we will look at that when that comes up. But at this point, based on our understanding of the incremental cost of this new study and our OpEx guidance, we don't see any pressure to either the 2017 number or the need for us to go into the market and raise more money.

Operator

And we'll go next to Ravi Misra with Leerink Partners.

Ravi Misra - *Leerink Partners LLC, Research Division - Associate*

Just wanted to follow up, I guess, on that last comment. You've been growing above the market, you're saying with that -- with the Nellix -- I'm sorry, with the AFX and Ovation products. Just now with Nellix pushed out now, what's your outlook on the company's ability to continue growing about the market with sort of the products on hand and this includes the delay in Ovation as well?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes Ravi, as Vaseem pointed out, as we -- in the second half of last year before we ran into this manufacturing challenge and the CE issue at the end of the year, we were starting to really grow in the high single digits. And there isn't any reason to think that we can't get back there. Obviously, we're coming out of some supply constraints and some issues in the first part of this year. But as we've pointed out in the past, we expect the business to perform incrementally and sequentially better each quarter for the rest of this year. So as Vaseem pointed out, we've modeled a variety of scenarios, forecasted cash with several different scenarios and are confident in our ability to grow the business, certainly at a minimum but above the market growth rate. And in doing so, we expect to have adequate cash to support the business in our continued investment programs. So keep in mind, AFX2 is going to be coming online without inventory constraints here in the second half. We are continuing to build momentum with the Ovation iX device in the U.S. We've got some rate data that we're going to launch at the SBS here in the June. And we're seeing some stability and expect some growth from Nellix in the international markets in the second half. So having this broad portfolio, we think gives us some unique competitive advantages, and we think we can grow the business. And then when Nellix comes in the U.S., it'll just accelerate the growth.

Ravi Misra - *Leerink Partners LLC, Research Division - Associate*

Okay. And then just maybe one question on what we can expect at SBS and your next update. On the call, you talked about that Dutch study. Was that presented to the FDA by any chance? Or sort of any update on the status of the data collection around that? And is that data even valid anymore now that you're going into the new sort of trial for the Gen2 product?

John McDermott - *Endologix, Inc. - CEO and Director*

The data -- the Dutch data was not presented to the FDA. We described what it was and the anticipated time frame from getting it. I don't think it would have changed the outcome. I think there is just still a fundamental desire to have some level of confirmatory prospective data. That said, we believe that the data, the Dutch data, further validates the strength and effectiveness of the new IFU. And we -- keep in mind, we have a core business of Nellix in the market right now. And all of these activities to validate and support this new IFU should be incrementally positive to that story. The other benefit to the Dutch data is that it gives us, together with the other data sources, tremendous confidence moving forward as we go to run this confirmatory study. And we feel there is a high probability of a successful outcome. So I think all of these activities that we have taken on over the past several months to try to move forward with the Gen1 device in the U.S. are still going to be very supportive and incrementally positive for the business in the long run. So that's our view.

Operator

The next question is from Steven Lichtman with Oppenheimer & Company.

Steven M. Lichtman - *Oppenheimer & Co. Inc., Research Division - MD and Senior Analyst*

John, any sense of how many patients you'll need in the Gen2 study? And what are the main parameters that you need to discuss with FDA in the coming months to get that study solidified?

John McDermott - *Endologix, Inc. - CEO and Director*

There are not specific -- there's not a specific protocol or endpoints. At this point, I would say that they've left it pretty open for us to propose a new design. They did express some willingness to allow us to leverage the existing data, but that we need to provide some element of prospective validation for the new IFU and the Gen2 device. So we had started previously some contingency planning and had some different ideas for a few different designs, if we needed to go down that path. And the feedback from the meeting was very helpful in terms of finalizing our proposal. So I don't want to get into the details of the design options right now. But what I can tell you is that we would expect the new study to be smaller in terms of the number of patients enrolled than the original IDE study. And as soon as we get it all sorted out with FDA over the next few months, we'll provide you with those details and be able to reaffirm the time line.

Steven M. Lichtman - *Oppenheimer & Co. Inc., Research Division - MD and Senior Analyst*

Your base assumption internally depending -- based on how many patients approximately you think is about a 9-month enrollment time, is what you're indicating?

John McDermott - *Endologix, Inc. - CEO and Director*

That's -- yes, that's correct. That's our current working estimate. Yes.

Steven M. Lichtman - *Oppenheimer & Co. Inc., Research Division - MD and Senior Analyst*

Okay. And then Vaseem, understanding the comments about 2017 absorbing any incremental spend. But all else equal, certainly we should assume some additional R&D expense in our '18 models for both this as well as for Alto? And -- or do you foresee being able to offset most of that next year?

Vaseem Mahboob - *Endologix, Inc. - CFO and Corporate Secretary*

So Steve, on the expense side, to John's point, there is still some things that we got to learn and understand, how big the study is going to be and kind of the time line and the associated expenses. But what we did was we went back and looked at the current IDE that we have ongoing, where we're tracking about 330 patients. That is anywhere in the $2.5 million to $3 million a year as an expense item. So if the study is a lot smaller than that cohort of patients, I'm just trying to give you a magnitude on how much more many we're talking about here. So in the grand scheme of things, on an OpEx of $170 million to $175 million, we feel very comfortable that we can absorb the cost of this incremental study. Now for future quarters, listen, we've already done a lot of synergy work and reset the cost base for the business. And I feel pretty comfortable that we don't have to do any major cost changes, if you will, to kind of protect that cash that we've been talking about. So that worst-case scenario going at or better than market and a normalized run rate on cost, which is the $170 million to $175 million, I feel comfortable at this point that we can navigate this higher cost burden and should not be materially different than what we have said in the past.

Operator

And we'll go next to Joanne Wuensch with BMO Capital Markets.

Matthew Henriksson

Yes. This is Matt Henriksson in for Joanne. With regards to the U.S. continued access programs, did you guys have any discussions with the FDA regarding that?

John McDermott - *Endologix, Inc. - CEO and Director*

We did not. No, once it became clear to us from that discussion that some level of confirmatory Gen2 data was going to be required, we didn't really pick up the CAP. There wouldn't be much reason to do that at this point. Unless the CAP was going to be a vehicle in which to collect this confirmatory data. But in fact, we think we can amend the existing IDE to gather the data. So the CAP really doesn't come into play under the new plan.

Matthew Henriksson

Okay. But just to clarify then that the CAP program is remaining as is, it's not eliminated?

John McDermott - *Endologix, Inc. - CEO and Director*

That's correct. There is no reason to eliminate it, but we don't expect to enroll in it. At least during the time we're running the confirmatory, we'll see if we need it for something in the future. But in the near term, we're going to pivot to the new confirmatory study and work on getting that approved and enrolling.

Matthew Henriksson

Okay. Got that. And then just for Nellix outside the U.S., is there any change to your outlook there? And is there any change in the kind of marketing or the messaging that you're bringing across to those physicians in Europe?

John McDermott - *Endologix, Inc. - CEO and Director*

No. In fact, I think, as I mentioned a little bit earlier, all of the work that we have done in the effort to validate the new IFU, we believe is supportive for the business outside the U.S. And we've got great evidence, and we expect to have more once we have the Dutch data next month that the

new IFU is effective. 3SQ, as we call it internally or what we refer to externally is the Gen1 device, really represents a very small amount of our sales in Europe in the international markets. And that's actually the device we have all the confirmatory data on. So we know Gen2 is even better. So we don't see any softness or risk anticipated in the Nellix business outside the U.S. And, in fact, think that these -- these IFU validation efforts should be incrementally positive to the story moving forward.

Operator

(Operator Instructions) And we'll go next to Mathew Blackman with Stifel.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

I'd like to start just back on FDA and on this confirmatory trial time line. Do you have a definitive go ahead from FDA for a 1-year follow-up trial rather than 2 years? And I'm asking, obviously, because the migration issues didn't really avail themselves until year 2. So any color on the sort of the duration of this confirmatory study?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes. FDA did reiterate the fact that these EVAR and EVAS studies should be designed for 1-year endpoints. And to your point, Matt, while we did see some signals primarily at the 2-year, we think there are also signals in the 1-year data. We can look at migration, for example, with 5 millimeters and detect that at the 1-year level. So we don't believe we have to have 2-year follow-up for the confirmatory study.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay. All right. And then just shifting to the base business, you've talked about sort of, at worst, may be growing at market. So remind me again, I think you've talked about you think the market's growing sort of low to mid single digits, is that sort of the base line we should be thinking about as you (inaudible)?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes, we estimate globally around 4%.

Vaseem Mahboob - *Endologix, Inc. - CFO and Corporate Secretary*

4% to 5%.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay. And do you have anything or do you need to do anything to ensure that there is significant U.S. sales force attrition? Obviously, reps are excited about Nellix, it's pushed out again. Is there a risk that you may have a higher rate of churn in the sales force and is there anything that you can do to prevent that?

John McDermott - *Endologix, Inc. - CEO and Director*

Yes, I guess, there is some level of risk. Although, we've been like we have with you and the rest of the investment community, pretty transparent about the risks going into this meeting. So we have programs in place to provide income stability for reps as we work through the AFX2 issues.

And I think, we've got good capability and a good sales leadership team to minimize turnover, plus we've got really the only company with 2 EVAR devices and a third one on the way. So I still think there is a lot of growth opportunities and I'm bullish about the quality and capability of the team, and I think that we can retain the -- our top performers.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay. That's helpful. And then Vaseem for you, just the balance sheet again, can you maybe -- if you can, sort of update us sort of today where you are? With accessing the Deerfield financing, how much is left of -- on the balance sheet and you have access to, after you refi the convert? And may be the easiest way to answer is just what you expect to sort of have as a cash position at year-end?

Vaseem Mahboob - *Endologix, Inc. - CFO and Corporate Secretary*

Sure. So what we forecast at this point, Matt, based on the redemptions that we've already had, which is about $68 million, we think there is another $18 million that we have to either carry or if we get approached on more redemptions, we'll obviously do them. So with the $18 million still outstanding, we expect that we end the year at about $60 million of cash in the bank and then we have another $30 million of the revolver. And then we have still a -- anywhere from $10 million to $20 million cash burn next year and then we kind of start to stabilize and get into low single digits and get to a breakeven in the second half of '19. So again, that's where I'd expect to be at this point. And again, that's assuming that we're going at or slightly above the market, which is the worst-case scenario.

C. Chu - *Canaccord Genuity Limited, Research Division - Associate*

Got it. And then that $10 million to $12 million cash burn you just called out for 2018, is that an annual number or a quarterly number?

Vaseem Mahboob - *Endologix, Inc. - CFO and Corporate Secretary*

No. The annual number for the whole year.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Okay. And then you burned -- I don't remember what it it was, maybe roughly $10 million here. In the first quarter, is that sort of the right proxy to think about as a burn rate for the rest of the year? Or will that dissipate throughout the course of the year?

John McDermott - *Endologix, Inc. - CEO and Director*

No I think, it will -- so Q1 typically is our biggest cash burn quarter because of all the bonuses and some of the payments that we have to make and the seasonality of the spend. But that actually gets a lot better towards the second half of the year.

Operator

So with no questions left in queue, I'll turn the call back to Mr. McDermott for any additional remarks.

John McDermott - *Endologix, Inc. - CEO and Director*

Okay. Thank you, operator, and thank you everyone for joining us on the call this morning. Also, I want to remind investors that we have an update call scheduled on Saturday, June 3, at -- excuse me, 3:00 p.m. Eastern Time to discuss the Nellix 2-year IDE data that's being presented earlier that day at the Vascular Annual Meeting. And with that, we'll close the call, and have a good day. Thank you.

Operator

This concludes today's call. Thank you for your participation. You may now disconnect.
