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Endologix, Inc. (ELGX)

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CORPORATE PARTICIPANTS

Vaseem Mahboob
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Jaime Lynn Morgan
Analyst, SVB Leerink LLC

MANAGEMENT DISCUSSION SECTION

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Okay. Hi everyone. We're going to get started here. My name is Jaime Morgan. I work with the medical device team here at SVB Leerink. Today, we have Endologix CFO, Vaseem Mahboob joining us. So welcome.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Thank you, Jaime.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

I'm going to let you give a short presentation and then, we can dive into some of the Q&A.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Great. Thank you. Okay. Hi. Good afternoon, everybody. My name is Vaseem Mahboob. I'm the CFO for Endologix and really appreciate the opportunity to present the Endologix story.

Our Safe Harbor and forward-looking statements and our disclosures and let's just right dive into the story. So this slide is a depiction of a lot of different aneurysms and I always like to tell people that no two aneurysms are the same. They're like fingerprints and to think that you have one graft that can treat all of these aneurysm is unthinkable even for a finance guy and the reason I say that is we are the only company that has multiple products in our bag relative to our competition which only has one product.

So the aortic aneurysm market, it's a large market, currently a $3.5 billion and growing to an expected $4.2 billion by 2024. It's divided into those two categories that you see on the slide, the traditional market and the complex market. The definition of the two markets is that traditional market are aneurysms that are below the renal arteries

and the complex are the ones that are above the renal arteries. The modest endo penetration in the complex is really why that segment growth is projected to be higher than the traditional segment.

We have now for a long time highlighted the challenges of EVAR as it relates to the durability of the repair. The following slide talks to those challenges as described last month in the Annals of Surgery publication authored by vascular surgeons from highly reputable centers. The study was funded partly by the FDA and also AHA among others. The primary outcome of studies was reintervention defined as any procedure related to EVAR after discharge from the index hospitalization. Almost 13,000 patients across 168 centers were studied from 2003 to 2015, 15% reintervention rate at 3-year and 33% at 10 years. The rate of rupture among all surviving patients was 5% at 10 years and patients who underwent reintervention had a rupture rate of 20% at 10 years. Two-thirds of the patients undergoing reintervention were associated with a hospital stay of three or more days. These hospital stays are often longer than the actual index procedure itself.

94.7% of the total devices used in the studied population were devices manufactured and sold by Medtronic, [ph] 58.9% Gore, 18.8% and Cook at 17% (00:03:01).

In commenting on the article Dr. Michael Conte, Chief of Vascular and Endovascular Surgery at UCSF stated that similar evidence of late failure one in three patients for a mechanical heart valve would likely constitute a front page story in the national media, yet the vascular community's response is largely muted; a clear call to action, one we are ready to respond to at Endologix.

At Endologix, we find ourselves well positioned at an exciting time in EVAR's evolution where significant improvements are required namely more durable outcomes and addressing the additional costs associated with the reintervention. We believe that we offer the only set of enabling solutions to meaningfully address durability in a consistent, reproducible manner across the heterogeneity of the disease.

On the far left, Endologix started with a conventional design that added anatomical fixation with AFX. In the center, with the Ovation platform, we introduced an entirely new and exclusive design where no outward radial force is being applied to achieve a seal unlike competitive endografts where oversizing each stent for each patient enables anchoring and ceiling. By eliminating outward radial force, we believe that we achieve a meaningful reduction in the rate of reintervention, as a result, realize a durability benefit.

With also the next version of Ovation, we're pursuing the broadest applicability in EVAR with an easier to size and an easier to use device.

Finally, on the right-hand side, you can see the EVAS or the Nellix platform. We have created a unique and exclusive design to actively manage the aneurysm sac. Through the EVAS1 propensity weighted subset analysis, we believe we may have a therapy in EVAS that potentially alters the patient's biological response to the therapy so as to catalyze a potential all-cause mortality benefit, demonstrating that benefit is the ultimate clinical development goal for the company.

We announced on Monday a major debt refinancing that we strongly believe eliminates the debt overhang and I would like to summarize the key terms of the deal for you. Our goals for this debt restructuring were to address four main issues. First, address the pending 2020 convertible stub notes of approximately $11 million. We have pushed the maturity of those to 2024 at par without any dilution in the near-term. Second, address the April 2021 Deerfield amortization payment of approximately $22 million. We've agreed to convert 50% of that payment into equity and pick the remaining 50% to the 2022 and 2023 payments.

We firmly believe that having managed through the reset and the restructuring of our business in the last 18 months, we have significant value creation opportunities ahead of us in the next 12 to 18 months starting with the Alto approval in the first quarter, completing enrollment in EVAS2 soon thereafter, submit our PMA application for Nellix, launching the Alto RCT, and then eventual clearance of Nellix by the end of 2021.

To enable a clear runway to achieving these milestones, we have negotiated two critical deal terms. One, we have negotiated with Deerfield that when we achieve $142.5 million in sales in 2020, we will push the amortization payments from 2022 and 2023 to 2023. To improve the liquidity profile of the company, Deerfield has agreed to receive the interest payments for the next 18 months in equity versus cash. And this allows us to keep approximately $13 million of cash in the business and strengthen our balance sheet.

Lastly, a key design principle for the deal is to de-lever our balance sheet over time and in a responsible manner by converting our debt to equity, we retain control of the equitization triggers. We have built in conversion features that allow for that de-levering to happen as we execute on the key milestones related to our Nellix PMA and other conversion rights to Deerfield and Endologix. I would refer you to the supplemental financial deck that's posted on our website.

Lastly, this is the chart that shows the pre and the post impact of this transaction on our debt maturities and the runway we now have to deliver on the key value creation milestones for our patients and our shareholders. Thank you.

QUESTION AND ANSWER SECTION

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

All right. So I was going to start somewhere else, but I guess maybe we could start here just because running the presentation with the recent debt restructuring. I think we have it on the slide, but just walk through kind of what the deal does for your pro forma debt balance and then talk about how this transaction allows for you to really deleverage the business a little bit more over the longer term.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So I think when you guys think about – we did a financing back in April of last year where we brought in about $52 million of new money into the company and we had created a mechanism to de-lever the balance sheet where as the certain triggers happened and the voluntary/mandatory conversions were supposed to happen, if the stock price was higher than $6.61. But as the Alto delay hit us in kind of the September timeframe, the stock started to decline, went below $6.61 and it kind of became a self-fulfilling prophecy where people started to do the math that I just walked you through where we had these pending maturities on the converts. We had the amortization payment and we did not have the cash to pay those or address those maturities.

So I think what the lesson we learned here and what we're trying to design into this process here is that the equitization triggers for the de-levering of the balance sheet is really tied to us hitting certain milestones. For example, I talked about $142.5 million sales number for 2020. Our guidance for the year is at least $145 million. So we feel very confident that we can hit that number and if that happens that pushes the debt stack out almost 12 to 18 months.

The second piece of it is the $11 million maturity is now converted into 2024 notes, a 5% coupon, so that that's still outstanding. So I think that there's elements of the deal that will happen over time. And as we kind of go through the rest of the year and the next 18 months, we should start to see those balances and you can see on the slide that I just presented here, you can see that there's really nothing outstanding through 2022 but the blue portion of the debt, that $74 million is really what will be left out of the Deerfield facility assuming all of the triggers happen and all the equitizations happen.

So I think – at this point, I think we can model out the minimum and the maximum dilution and what's coming and what's not coming. But I think for – what will be important for us to do is really track the milestones and those triggers that we have now established for the equitizations to happen.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Okay. And then just in the context of kind of – you guys have talked about cash flow breakeven by 2021. Do you think that the fact that you've done this just kind of how this in the perspective of your plans to breakeven by 2021, just like kind of put it into perspective for us.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So we are steadfast towards that goal of being breaking even in 2021 that has not changed. In fact, we wanted to have a clear runway to that number and to essentially have a little bit more flexibility. What we did was we agreed with Deerfield to convert some of the cash interest payments into equity or have the option to pay that in equity, so that significantly de-risks that so which means we don't have to go back into the capital markets and raise more money to get to breakeven in 2021. So again, with some – the acceleration in the top line towards the second half as we contemplate in the guidance that we've put out there and then having one full year of Alto sales baked into the number for 2020 and the top line number that's associated with that, we feel very confident that we can get to breakeven in the second half of 2021.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Okay. And then just kind of more from a housekeeping perspective, what – I mean we talked about debt but what's the pro forma share count that we should be thinking about now? Because I think you guys used some shares for the restructuring fee just to...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure, sure. So really what's going to happen right now is the only share issuance that has happened so far is the $2 million restructuring fee to Deerfield which is about 2.5 million shares.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Okay.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And then, condition precedent, Alto we think another 30 million shares will convert or will be handed over to Deerfield so that's the dilution that's tied to kind of us hitting the condition precedent for Alto having the deal in effect and then as we kind of go through, for example, the remainder of the year and as we execute on the Nellix milestones, there will be conversions that will happen over time, but right now immediately I think it will be the $2.5 million for the fee and then another $13 million for the amortization payment.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Okay. And then, just on interest expense, any – I think you guys are currently at about an 8% to 9% or $8 million to $9 million on a quarterly basis. Is it fair to think that that could potentially step up a little bit with kind of the higher interest rate converts that you guys have pushed out to the 2024 maturity or how should we be thinking about interest rate expense?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So I think our $8 million to $9 million of cash interest a quarter is really I think what will continue. I think it actually might improve because if we make that choice to pay Deerfield in equity versus cash, so that number will actually come down, but again we'll make that determination depending on how the stock is doing and at the levels it sit.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Okay. So kind of transitioning and kind of the first place that I wanted to start, but I think at a high level, you put out this business plan in October of 2018. Now that you've been through a year where you've executed on your expectations for the business, kind of just talk through what's gone better than expected? What areas still do you think present opportunity for improvement as you move into 2020 and then kind of what gets you excited about the business as you're transitioning into this next phase of growth?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So it's been quite an interesting 18 months for us. We put out a strategy in October at the Investor Day of 2018 and honestly, I'm happy to report that we have delivered on pretty much everything that we said we were going to do. And if you guys remember, what we have talked about as a pretty significant milestone for 2019 was that we had to stabilize our AFX business in the US, and then we had to grow Ovation sequentially and that was our path back to growth in the second half of the year.

So we saw a top line growth in the third quarter. We saw top line growth in the fourth quarter. So we feel really good about that, especially with the FDA action in kind of late October, early November, we were still able to kind of hold that AFX franchise not only to grow sequentially, but also to kind of stabilize. Now, that came at a little bit of a cost of Ovation because we had to take time away from Ovation and spend time with our AFX customers. But net-net, it actually resulted in a pretty good [ph] case creation (00:14:31) for the fourth quarter. So we're really, really excited about that. And I think as we think about 2020 that continues to be the play to make sure that we have that certain level of AFX business for 2020 relatively flat to last year, but then on the heels of a Ovation product line that will grow alongside and approval with Alto gives us hope that we can continue to grow this business, as we highlighted at the fourth quarter earnings call and put out in the guidance. So really I mean, those are the big kind of takeaways from last year.

As we think about the next 18 months, we are really, really excited about the value creation opportunities ahead of us namely approval of Alto here in the first quarter, completing enrollment in EVAS2, enrolling our first patient in the CHEVAS IDE which is really, really exciting IDE for EVAS physicians and then presenting the one year data for the Nellix PMA at the biggest vascular conference in the country in November at VEITH. So it's all shaping up to be a very exciting 2020 for the company.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. So it sounds like you do have some impact from Ovation, Alto baked into the at least $140 million revenue guidance in 2020. I guess just remind us from a quarterly perspective, you put out kind of a cadence that you expect from a growth perspective over the year. So just walk us through kind of the puts and takes of that. You started to touch upon it but just remind us what sorts of factors are contemplated in the growth ramp from a decline starting in the first quarter to high-single digit growth ending the year.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So I want to kind of clarify. So we put out a guide for the first quarter of at least $30 million, and then we're talking about growing the business in the second quarter mid-single digits. Now, there's two aspects of it. There's the seasonality tied to our business. Second quarter is usually our biggest quarter. So, in the US, there's a pickup of anywhere to $2.5 million in the US just purely on the heels of seasonality. We have a little bit of Alto baked into our second quarter number in the US but not a whole lot because as you heard the company message time and again, we learnt our lessons with Nellix and we will not repeat those mistakes again. So we want to be very purposeful, very mindful on the launch cadence on how Alto gets rolled out. And again, our goal is to really take Alto to upmarket accounts and the academic centers to try and get into those accounts where there is a high usage and high volume relates to EVAR.

So then the outside of the US business, as I talked about on the earnings call, we do see a pickup about $4 million to $4.5 million purely because, one, our contract minimums with our distributors kind of kick-in; and two, the issue in Q1 was that we had no product available for Brazil for AFX2. We expect that approval to happen in the month of April. And once that happens, we'll catch up for that loss in Q1 and Q2, Q3 and Q4.

So we feel confident to kind of step up from the $30 million to the second quarter number of a mid-single digit growth, stay there for the third quarter because of the seasonality and then, fourth quarter when we launch Alto full scale in the US, we can see some acceleration in the top line to high-single digits.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. And do you guys feel like, I mean I think when you guys initially put out the plan, at first, I think it was to at least grow in line or possibly above the market rate in 2020. So, first, correct me if I'm wrong on that, but secondly, kind of what will it take? Is that on the table in 2020 potentially if things go better than expected and if not, kind of what are some of those factors in 2021 that are really going to help with carrying through that momentum and hopefully being able to grow at or above market rate?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So the guidance of at least $145 million and I try to do the walk for folks on the earnings call. When you look at the one-time unusuals or a normalized number for the first quarter, our OUS business on a headline basis

looks to be negative 4%, but it's actually up 8% when you factor in the impact of the product availabilities and the conscious choice that we made as a company to sunset, for example, Ovation Prime in Brazil or AFX1 in Brazil. When you factor in the Korea exit from Q1 of last year, so you address some of those one-time unusuals, the one-time inventory adjustment for Japan, the business is actually growing market plus 1%. So it's just that the timing of it is a little bit pushed out from Q2, Q3 and Q4.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Okay. That's helpful clarification. I guess in the 5 minutes we have left, I just wanted to transition a little bit. So Nellix, obviously an important product for you guys and one that's had a number of resets, so what sorts of things, kind of where you stand with the FDA now gives you confidence that you're going to be able to have that submission in the, I think the third quarter of this year and then be able to launch it according to plan. Said differently, I think what I'm trying to get at is kind of is there any risk to submitting this product in the third quarter of 2020 if the enrollment completes at the end of the second quarter?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, I mean, I've been at Endologix for four years and one thing I realized is when you're talking about a regulatory process there's always risk.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Yeah.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And the – but the question is what are we doing to manage that risk. And so I think we're having discussions with the FDA about the format of the submissions, right. And I think our assumption here is that we finish enrollment in early April. We get the submission to the FDA sometime towards the second half of the year. We'll present the one year data at VEITH. We'll submit the clinical module sometime next year, hopefully before the first or the second quarter, and then gives us the 180-day window to get the approval by the fourth quarter of 2021. And then, we would commercialize that product in 2022.

So I think we're very confident that we can finish the enrollment in the study here in early April. And I know that's been a little bit of a challenge because it's kept slipping. And honestly that's also a little bit of a testament to the fact that the rigor around that trial is pretty high and we wanted to make sure that the case review board looks at those cases and has a process to assess the cases. And I think we've done all the right things. If you remember, we had the voluntary Nellix recall back in the Q4 of 2018 where we took the product off the market in the Europe. That was to de-risk the US PMA.

So I think we've done all of the right things. But at the same time, I think it's an FDA-driven regulatory process, but we're very optimistic that one, the data, the process, and then the timeline supports that commercialization of 2022.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Just remind me, how many patients are currently enrolled in out of the total?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

So we have about 92 patients that are enrolled. We need to get to 105.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

105? Okay. Great.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Yeah. And we already have some cases scheduled, they're just not implanted. So we feel pretty good that it will happen in early second quarter.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Got it. And then are you guys preparing your sales force at all. I mean obviously, launch is still couple of years away but what sorts of initiatives are you doing in between now and when you anticipate launching this product to really rally up the sales force to be able to go to market and kind of what's your strategy when you are ready to go to market with this product?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yeah. So, I think, listen, it's 2022, honestly, we haven't done much in terms of commercialization of Nellix. I think the teams are focused on finishing enrollment. So there's a team of people that actually is different from the sales force because obviously our sales force can't be promoting an IDE product. So we have clinical specialists that have been working with physicians to kind of get the cases enrolled. We have now moved our attention to getting CHEVAS and getting the awareness on that, getting those sites up and running. I think where the team is focused on right now and should be is on the Alto launch. The US sales force met a couple of weeks ago in Nashville and it was all Alto and launching Alto that's where the focus and the energy is going to be to make sure it's a purposeful, it's a world-class launch so that we can start to see some benefits on the top line relatively quickly.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Got it. I guess I just like to finish off kind of bringing up a partnership that you guys had announced back in August with Boston Scientific in China. Just remind us what product approvals are you pursuing there first, how involved are both parties in the Alto approval process and then what should we – how should we be thinking about a launch into that market.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yeah, so we've spent a lot of time in the last six to eight months working with the Boston team to kind of get kind of through the process of what are the products, what's the timing. We have a cross-functional team on their side and a cross-functional team on our side. In fact, I happen to know the GM of Asia very well from my GE days. And one of the things they told me is they have taken one of their best people and actually put him on the launch of Endologix products in China.

So we're making a lot of progress. I think the plan is to launch AFX first in that market. And they're excited about the product and they're also using Japan as a proxy. And for those of you guys, Japan Lifeline, our distributor in Japan that markets AFX has gotten to almost a 20% market share in that market just with AFX. So they're really excited to use Japan as a proxy for a $250 million market, which is the second largest market as China after the US. So we're really excited about that. Now, in terms of sales question, I think it's too early to comment on the sales.

Jaime Lynn Morgan

Analyst, SVB Leerink LLC

All right. Well, I think that wraps it up. Thank you for attending our conference.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

No, thanks for having us here. Really appreciate and thanks for those of you who are in person.