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Endologix, Inc. (ELGX)

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MANAGEMENT DISCUSSION SECTION

Robbie J. Marcus
Analyst, JPMorgan Securities LLC

Hello, everybody. I'm Robbie Marcus, the med-tech analyst at JPMorgan. I'm very happy to have Endologix with me. And today presenting will be the CEO, John Onopchenko. I'm sorry.

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

Thank you. Good afternoon. I want to walk through the customary safe harbor statement surrounding our forward-looking statements and then briefly our disclosures citing our product descriptions, our IFU references, study descriptions, and cautions about Alto and Nellix as investigational devices here in the U.S.

For those of you who are new to Endologix, we are a company dedicated to treating abdominal aortic aneurysms. They are, in fact, a leading cause of death. And the anatomical challenges of the anatomical heterogeneity that the disease state presents can make treatments quite difficult. This, in fact, is at the heart of our reason for existing and to be able to treat these anatomically anomalous conditions with anatomically adaptive products.

A bit about the market itself. It is a large and growing market expected to reach $3.3 billion from $2.8 billion currently by 2021. It's roughly parsed in two broad segments. The first is traditional AAA, and AAA that is, in fact, defined to be traditional is really the disease that presents itself beneath the renal arteries and complex disease that is treated at, around or above the renal arteries.

And as you can see below, the penetration of the traditional market is quite high. It's over 80% and slower growing at 4% than the complex segment of the market which is about 41% endo penetrated but growing at 9%. It is that complex market opportunity that is the subject of most of the market growth in this period through 2021.

Now, it is undeniable that endovascular aortic repair, or EVAR, is in fact, the standard of care. And while the traditional segment, as I pointed out in the earlier slide, is highly penetrated. Open surgical repair still produces a more effective and durable outcome to EVAR.

It is that unmet need that is at the heart of our mission. The left-hand chart shows the comparative probability of patients experiencing a rupture or re-intervention. Through eight years, you are five times more likely to experience a ruptured aneurysm if you are treated with EVAR versus open surgery. And the divergence begins after year or two.

The right handed side of this page shows aneurysm related mortality at four time intervals. From the time of intervention to six months, you are less likely to die from your aneurysm if treated by EVAR versus open, which reflects the differences in perioperative mortality. However, after six months and through eight years, again, an unfavorable to EVAR divergence occurs. You are five times more likely to die from your aneurysm after eight years if you were treated with EVAR versus open surgery.

Again, it's our mission to reverse each line's position with Ovation and then Alto, and to establish a third line labeled EVAS that ultimately demonstrates all-powered – an all-cause mortality benefit powered through that superiority through a randomized prospective controlled trial versus a contemporary endograft comparator.

Conventional EVAR, as the prior slide depicted, is really ripe for the introduction of innovation. As the evidence on the previous slide shows the continued outcome limitations of EVAR when compared to open surgical is no longer a defensible position.

This actually has been noted by public health authorities such as the UK and NICE where in its draft guidelines, it is categorically citing that endovascular aortic repair infrarenally and unruptured far favors open surgery to EVAR. The only place where an EVAR should be included is in a comparative trial when evaluating EVAR to open surgical repair in complex disease.

Now, at the same time over the past few years, there has been a number of 20-year paradigms that have been coming under challenge. For example, what are the predominant failure modes of EVAR and how effective is surveillance in treating patients post-implantation or more recently, it's been clearly demonstrated that aneurysm sac enlargement is now established as the dominant failure mode influencing long-term outcomes and specifically survival.

If you take a look at the Endologix portfolio, we believe it is highly differentiated from conventional EVAR. First, a consistency throughout our portfolio is that they are anatomically adaptive. If you remember my second slide that showed the substantial heterogeneity that the disease state presents. It is then therefore requirement that the products that you choose to treat those heterogeneous disorders need to be anatomically adaptive and the evidence that supports that use has to be of high quality.

Now, our current products achieved excellent outcomes and the most recent evidence that we've published in Charing Cross of last year was the ENCORE study which basically showed in a large cohort series, a five year look at that comparative evidence that shows an overwhelming favorability to outcomes attributed to Ovation versus contemporary endografts. And we still remain to be the only company that in the last 20 years has conducted a randomized controlled trial with direct competitive comparators using our AFX2 versus contemporary stent grafts. We believe that Alto and EVAS must be tested for superiority and we would intend to generate evidence to support this claim.

I want to turn your attention to an announcement that we've made last Friday to voluntarily recall the Nellix product in the EU and globally. And this timeline, in essence, provides a bit of a contextual framework to give you better insight into the reasons that supported that decision. As many of you know, we had the CE Mark for Nellix cleared or obtained in 2013. And since that time, we've actually carefully monitored the commercial uptake of the product. And in response, we actually issued three field safety notices improving the performance of the product through obviously providing use experience that, in essence, drove the refined IFU, as well as describing how to enable an adequate procedure.

The last of those field safety notices took place this past summer. And in essence, it described while – with a reduced IFU, how we were realizing terrific outcomes. And then finally, we defined the criteria by which you would anatomically landmark inadequate procedure. Through the summer and into early fall, there were papers being presented and published in peer reviewed journals that, in essence, reinforced things that were the subject of our field safety notices. And that is, if you use Nellix off IFU, you were regrettably going to be confronted with poor outcomes. These papers, in essence, reinforced our prior findings.

And then finally, this past month the European Society for Vascular Surgery had published its 2019 practice guidelines for EVAR. And they clearly cited Nellix and EVAS as a product and a procedure that was best used under protocol to ensure on-label performance and durable outcomes. So in concert with this confluence of evidence, we took decisive action and really that action was to putting patients first by, in essence, withdrawing the product and putting the product under protocol where we would ensure ourselves as well as our investigators and customers that optimal outcomes could be achieved.

There were five key messages that were associated with our withdrawal. First, that it was in fact a voluntary recall and it was to remove all existing global Nellix systems inventory. Two, that new cases would be conducted under clinical protocol, again to ensure on-label good outcome performance. And at three, we would have patient inclusion pre-approved by an independent physician panel to ensure again on-label performance. Four, we issued a field safety notice in concert with this action that we issued in the United Kingdom. And then five, as I mentioned previously, this decision is entirely in alignment with the new European Society for Vascular Surgery Practice Guidelines. The take away again, we put patients first and we preserve the transformational potential of the Nellix system.

If we then turn our attention to the clinical work that we are undertaking, first and foremost, EVAS 2 which is the confirmatory trial for Nellix in the U.S. is underway and we're predicting to finish enrollment by Q3 of 2019. ChEVAS which is a label and a product that we intend using the Nellix platform to treat complex disorders. We are tracking to get an IDE approved by the first half of 2019. And it is our goal by the end of 2019 to have a successful first-in-human experience with Next Generation EVAS. And then finally in the U.S., we're expecting to get clearance with Nellix 3.5 by 2021.

One of the exciting parts of 2019 for us is getting the clearance and introducing Alto which is the next version of the Ovation platform. It will have at that time, the broadest patient applicability in the category, able to treat 80% of infrarenal cases and 26% of complex cases all on label.

It addresses critical physician feedback of Ovation iX by moving the sealing collar within 4 millimeters of the renal arteries. That's designed specifically to increase patient applicability. In addition, there's an integrated balloon. That integrated balloon is allowing for a reduced amount of time pressure that currently physicians occasionally experience in cannulating and ultimately allowing polymer to cure. We will provide for easier sizing and the U.S. approval for Alto is expected in the second half of 2019. And as I mentioned earlier, we aim to prove superiority of Alto versus a contemporary stent graft active comparator in a randomized controlled trial in the near future.

This chart in essence, describes our strategies to capture value. First, with AFX2, we see a platform that is, A, anatomically adaptive. It's probably the easiest stent graft in the market to use and to deploy. And again, we have contemporary direct comparative evidence from LEOPARD which shows that it is not only a competitive product but a superior product especially when considering obviously proximal or distal narrowing of the aorta.

With Alto Innovation, obviously, we have Alto clearance that we're expecting in the second half and the ENCORE data which we published as part of Charing Cross this past spring, shows against five key industries really best-

in-class performance. Freedom from all-cause mortality at 99%; freedom from conversion to open repair at 99%; freedom from rupture at 99%; freedom from the re-intervention for Type 1A endoleaks at 98%; and freedom from device-related re-intervention at 93%.

With Nellix, we've pioneered the concept of active sac management. And through a subset analysis of EVAS 1, our IDE trial in the U.S., we were able to show at the level of statistical significance with a patient matched cohort showing a high with an all-cause mortality benefit that was again statistically significant. And then, finally, in our next generation version of Nellix or Next Gen EVAS, we have made a design choice of including a polymer cuff at the proximal end of the endograft, and that enables the separation of fixation and sealing from sac management.

If you put our product portfolio into the context of the hierarchy of unmet needs within EVAR. At the base really is where competitive comparisons after 25 years the majority of them find themselves. And that is debating ease of use amongst and between competitive products all on the basis predominantly of marketing studies or registries.

AFX2 again is the subject of the first randomized controlled trial in the last 20 years that shows not only the ease of use, but durability benefits associated with its use. If you move up the hierarchy, the next strata of performance is in therapy-related complications. And here Ovation and Alto, on the back of the ENCORE data has shown clear superiority as well as aneurysm-related mortalities, the next step-up in the hierarchy. And then ultimately it is our intent to prove through a randomized controlled trial that EVAS and Nellix show a statistically significant comparative all-cause mortality benefit.

If we then turn our attention to 2018 and financial performance, we began the year at a midpoint of consensus at $175 million in revenues. We announced our strategic reset on August 9 during our Q2 earnings call. We then changed our guidance to between $145 million and $155 million. We announced a significant change in terms of the markets we served. We went from serving 23 countries in Europe to 10.

We announced, obviously, the Field Safety Notices, one for AFX2 and one for Ovation, which we had predicted would cause some disruption in revenue performance as well as we took a decisive step in lowering our cost to serve, that's CTS, by taking $10 million out of our U.S. expense in order to become far more competitive from a productivity standpoint in that business.

We then obviously executed through Q3 and more recently Q4 and in Q4, we preannounced yesterday revenues of about $34 million as well as the full year at $155.8 million. The Field Safety Notices we had initially predicted had less than the high-end of the impact prediction that we made in Q2, which obviously led to the higher-than-expected performance. And the U.S. and EU cost to serve disruption was less impactful than previously expected and we've been able to manage our attrition related to those changes quite effectively. And then, within the OUS as well as the U.S., those restructurings were complete by the end of August of this past year.

If we then look at 2019, as we messaged during the Q3 call and we consistently released yesterday in our pre-release of earnings as well as our 2019 guidance, we are in essence predicting a floor of $140 million in revenues for 2019. We delivered fourth quarter of $35 million. We intend to drive sequential growth in 2019 beginning in the first quarter, obviously going from Q4 of $34 million to Q1 of $35 million.

As part of the reset that took place in August, we announced our prediction of the U.S. and AFX2 specifically stabilizing in the second half of 2019 and again with the introduction of Alto in the second half of 2019 as well as the growth of the existing Ovation franchise all leading to that sequential growth. And we continue to manage attrition quite effectively. I'm pleased to say that in Q4, we did not have a single regrettable loss in U.S. aortic account managers as part of the evidence that supports that management process.

During our investor event in October of last year, I described the kind of the three steps or phases of our transformation. And ultimately, it began with a critical assessment of our culture, the markets that we serve, the products that we have in the marketplace as well as under development, the clinical development that underpins the commercialization of those products and then finally our expenses.

That led to the three phases that I've described previously. The first phase through 2019 is strengthening our foundation. That is optimizing our global presence and restoring credibility. It's to be able to effectively prioritize, resource and plan and execute our work predictably. It is a world-class introduction of Alto in the U.S. and in the EU. And then, as I showed two slides ago, it's the successful first-in-man experience of our Next Generation EVAS platform.

Phase 2 is re-establishing durable, predictable growth. The first tenet or objective is to grow above market. That infers taking share. We will generate evidence to demonstrate the superiority of Alto through a randomized controlled trial. We will launch Nellix 3.5 in the U.S. We would initiate the Next Gen EVAS Global IDE. We would have completed enrollment for ChEVAS IDE. And we, by the end of 2020, intend to be cash-independent or achieve cash flow breakeven.

Third phase of the journey is accelerating innovation and profitable growth. Again, growing above market. We would have Next Gen EVAS Global IDE would have met its endpoints. We would have demonstrated the superiority of Alto in that randomized controlled trial. We would be consistently achieving category-leading compliance. We would have launched Next Gen EVAS in the U.S. and in the EU and we would be earnings per share positive.

All of this is enabled by a strong culture of accountability. The key tenets of our culture beyond accountability, first and foremost, is putting our patients first. We prioritize our patients above [ph] all else (00:23:04). Second is accountability. That is consistently expecting high performance of ourselves and each other. Third, it's operational excellence. It's ensuring compliant high-quality execution. And then finally, One Endologix. We behave and align our actions toward achieving our results as one company, independent of where we find ourselves functionally or geographically.

As part of the transformation, we've created a scorecard. It, in essence, gives investors a clear understanding of how we are doing in this journey. And you can see from the three quarters since the reset beginning in Q2 and ending most recently in December, Q4 of 2018, we've basically bracketed three broad categories, financial; clinical; and commercial.

Under financial, revenues; margins; OpEx; and guidance. And you see, we've been able to achieve since the reset fairly consistent improvement in the performance. The small pluses within the green bars is exceeding the expectations that we've set. And the yellow bar under margins is that we did, in fact, have a onetime change relative to inventory as it relates to AFX2 innovation.

In the clinical category, really three elements that define the metrics. First, it is the enrollment and execution of EVAS2. Second, it is the initiation and execution of ChEVAS IDE. And then, finally, it is the initiation and commercialization of Alto. I'm pleased to say that we've taken, obviously, two reds and a green [ph] through (00:25:00) predominantly greens with still work to do in improving the enrolment of EVAS2, albeit it has been progressing nicely since the second quarter.

And then finally, commercially, first is the stability of AFX2, then the growth of Ovation in the U.S. It's being able to effectively manage attrition by eliminating any regrettable losses. And then, finally, it's the expectations that we have outside of U.S. commercially.

Pleased to say that certainly Ovation through the Field Safety Notice is improving, but still in yellow. Attrition, we've been able to manage quite effectively. As I mentioned, no regrettable losses in the third or fourth quarter moving us from yellow to green. And then, finally, OUS expectations have dramatically improved since our [ph] reset (00:25:57).

The final block to improve is obviously AFX2 stability, which I mentioned previously we're expecting AFX2 to be stable in the U.S. by the second to third quarter of 2019. Four principal underpinnings to 2019 in terms of strengthening our foundation is, first and foremost, stabilizing and growing AFX2 sales; secondly, growing Ovation and then Alto sales, it's increasing the commercial productivity of our U.S. team and concurrently overall lowering our cost to serve.; and then finally, a targeted and purposeful march upmarket to higher volume accounts with Ovation and then Alto.

We continue to make progress on these foundational goals, reflected ultimately in better-than-expected performance in Q3 and in Q4.

This chart, in essence, describes the four segments in the U.S. that we are measuring and managing. There are 45,000 EVAR procedures performed in the U.S. at 1,600 hospitals. The four categories are innovative; performance; value; and local. Innovative hospitals are predominantly academic medical centers. There are 75 hospitals that fall into that category that produce 5,625 EVAR procedures. That's 5% of the hospitals driving 13% of the volume.

In performance hospitals, these are large volume hospitals that have no interest in teaching anyone anything. They are interested in volume in their local markets and demographies. There are 125 of those institutions in the U.S., producing 13,125 EVAR procedures. It's 8% of the hospitals, 29% of the volume. Now, those first two categories alone, that's 200 hospitals, roughly 13% of the institutions that are driving 42% of the EVAR volume.

As you move left to right, in the value segment, that's 760 hospitals generating 21,392 procedures or roughly 48% of the hospitals, roughly 48% of the procedures and then local hospitals, small municipal hospitals typically 640 hospitals driving 4,600 procedures, 40% of the hospitals, only 10% of the volume.

And then, if you look at average implanters, it goes from four or five in each institution down to two or one in smaller institutions and then the volume per implanter from roughly 17 to 21 down to 11 or 5. That's less than one case per month in the value or local segment of the hospitals.

Our current position is roughly 30% of our volume in top two segments, 70% of our volume in the bottom two segments. Our intention is to move upmarket by literally shifting 2%. Segment-wise, that will generate roughly $10 million in revenues.

And then, again, strategy in the U.S. is simple. We've changed the sales model. We're more effectively leveraging our clinical evidence. We're shifting the basis of competition from niche anatomies to more broad-scaled adoption and then finally, deploying our clinical specialist to support the majority of our base business sales, particularly within AFX2. We are aligning with customers who have four foundational beliefs that we share, outcomes must improve; we were not going to go back to open surgical repair; the evidence that we create has to be more rigorous; and then finally that rigorous evidence has to produce more clinically impactful claims.

Our financing and liquidity plans. In 2018, we refinanced our ABL, the bridge to cash flow positive in 2020. The second step was we [ph] rightsized (00:30:03) the business and went through a restructuring that was completed by the end of August in addition to lowering our cost to serve in the U.S.

And then step three, in 2019 and 2020, it's to refinance the $84.5 million of the 2020 converts that are due in 2020, of course. And then as part of the restructuring of the Deerfield deal, we took $40 billion (sic) [$40 million] (00:30:26) of the $125 million and converted it into a term loan. And ultimately our reduced cash burn going into 2019, in essence, has us burning a total of $20 million of cash through 2019.

Again, our value drivers, in conclusion, strengthening our foundation, reestablishing growth and ultimately accelerating innovation and profitable growth.

I thank you very much.