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Endologix, Inc. (ELGX)

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MANAGEMENT DISCUSSION SECTION

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Okay. So, good morning, everyone. My name is Allen Gong. I'm a representative of the medical supplies and devices team here at JPMorgan. It's my pleasure this morning to introduce John Onopchenko, the CEO of Endologix. After the prepared remarks we'll be hosting a breakout session across the hall in the Sussex room.

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

Thank you, Allen. Good morning, everyone. Thanks for attending this morning. Our safe harbor statements surrounding forward-looking statements and our disclosures that cite product descriptions, IFU references, study descriptions and cautions about Alto and Nellix as investigational devices here in the United States. Abdominal aortic aneurysms are a leading cause of death globally. The disease presents a variety of anatomical challenges that requires devices to anatomically adopt in order to ensure an effective and a durable outcome. The market is large at $3.1 billion and it's expected to reach $3.9 billion by the end of 2023.

The market is parsed into two principal segments: the traditional AAA market which is disease that is found below the renal arteries and complex disorders that is treated at, around or above the renal arteries. There is high endovascular penetration in the traditional segment, roughly 75% of those procedures are endovascularly approached and a relatively low endovascular penetration in complex, roughly a 30%. That modest penetration in the complex segment represents the reason why growth rate in complex is 2 times higher than traditional, where it's still low-single digits in a highly endo penetrated segment of the business.

EVAR has clearly replaced open surgery as the standard-of-care for AAA. Endovascular aneurysm repair or EVAR has eliminated virtually all the peri-operative morbidity as a barrier to treatment, as shown in the hazard ratio that is halved when comparing EVAR to open surgery from time zero to six months post index procedure. Treatment options have expanded as did the patient pools that were treated. While endo-graft designs have evolved, those designs have yet to meaningfully address the unmet need of EVAR, that being the durability of repair. Regrettably, when compared to open surgical repair, EVAR has fallen short of achieving durable outcomes. Satisfying that unmet need is at the heart of our mission.

The comparative data of EVAR-1 shown on the left clearly illustrates, the divergence in the intervals beginning at six months and separating significantly thereafter. Through eight years, you are 5 times more likely to experience a ruptured aneurysm, if you were treated with EVAR versus open surgery. Durability concerns in the last two years and specifically late aneurysm related mortality culminated in a draft NICE guideline in 2018 that suggested that EVAR should not be offered to patients with AAA. We have clearly reached the limits of EVAR, the unmet needs and opportunities have never been clearer. So what are the causes of EVAR failures?

Those causes and their associated contributions are found on the right hand side of the screen; aneurysm enlargement, Type I endoleaks, proximal neck degeneration, Type 2 endoleaks, migration, Type III endoleaks, and limb occlusions. What we've learned in the last 20 years is that 50% of the patients are actually alive eight years after EVAR. Therein lies the durability challenge. EVAR confers no benefit in all-cause mortality or aneurysm-related mortality in the long term when compared to open repair. EVAR is associated with a higher rate of AAA rupture compared to open. EVAR results degenerate in the first year. EVAR is associated with higher rates of cancer and there is virtually little evidence that newer endographs based upon the same self-expanding stent wrapped in a fabric design have better long-term outcomes.

Compliance with surveillance is poor. Fewer than half the patients are followed and late aneurysm rupture may follow surveillance failures. Applicability is still relatively low with less than 60% and conventional low profile endographs have poorly performed in clinical trials. I say again that we've reached the limits of EVAR. The unmet needs have never been clear as is the opportunity. The state of EVAR and its related need for durable outcomes were described this month in the Annals of Surgery publication authored by vascular surgeons from Dartmouth-Hitchcock, The VA, Northwestern, UMass Medical Center, Beth Israel Deaconess and Weill Cornell Medicine Center.

The study was funded in part by Patient Centered Outcomes Initiative, the FDA, the National Institutes on Aging and AHA. The authors studied patients who underwent EVAR using the Vascular Quality Initiative Registry linked to Medicare claims, with 95% matching success. The primary outcome study was re-intervention, any procedure related to EVAR after discharge from the index hospitalization. 12,911 were studied across 168 centers between 2003 and 2015, a 15% re-intervention rate at three years and a 33% rate of re-intervention at 10 years. The rate of late aortic aneurysm rupture among all surviving patients was 5% at 10 years. This is a widely recognized underreported data point. Patients who underwent re-intervention had a rupture rate of 20% at 10 years, again widely recognized as underreported.

Two-thirds of the patients undergoing re-intervention were associated with a hospital stay of three days or longer. These hospital stays are often longer than those witnessed at the index procedure. 94.7% of the total devices used in the studied population were devices manufactured and sold by Medtronic, Gore and Cook. 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 and their response is largely muted, a clear call to action one we are ready to respond to, while we respect and support the challenge and recognize the potential of rebalancing with open repair, our mission is to achieve lifelong durability using endovascular approaches and to meaningfully increase the applicability of EVAR. We have clearly reached the limits of EVAR. The unmet needs in opportunity have never been clearer".

At Endologix we find ourselves well positioned at this exciting time in EVAR's evolution where significant improvements are required and those improvements come with satisfying a reduction of associated costs associated with the high rates of re-intervention. EVAR's limitations are increasingly being characterized and

published across a broad constituent base, physicians, institutions, regulators, payers and policymakers. We are clearly not alone in our belief that EVAR has reached its limits and that meaningful improvements, both outcomes and cost, must be addressed. We believe we offer the only set of enabling solutions to meaningfully address durability in a consistent reproducible manner across the heterogeneity of the disorder.

On the far left Endologix started with a conventional design that anatomical fixation with AFX clearly and easy to use and deploy product and the only EVAR product supported by Level 1 comparative evidence via a randomized controlled study named LEOPARD. LEOPARD evidence supports the fact that AFX2 clearly and effectively competes with any market-leading EVAR product. In the center with Ovation we introduced an entirely new and exclusive design where no outward radial force is being applied to achieve a seal unlike competitive endographs where oversizing each stent with each patient enables anchoring and sealing. Furthermore, Ovation sealing is customized or patient specific, attributed to our conformable polymer ring.

By eliminating outward radial force in an already dilative disease we believe we will achieve a meaningful reduction in the rate of re-intervention and as a result realize a durability benefit with patients that we treat. With Alto, the next version of Ovation, we are pursuing the broadest applicability in EVAR with an easier to size and use device. Finally, on the far right with EVAS and our Nellix platform we've created a unique and exclusive design to actively manage the aneurysm sac by combining entire sac sealing with a dual stent conduit. Through EVAS1's propensity weighted subset analysis we believe we may have a therapy in EVAS that potentially alters the patient's biological response to the therapy.

That altered biological response serves to catalyze a potential all-cause mortality benefit. Demonstrating that benefit prospectively is our ultimate clinical development goal. Let's take a closer look at each platform. AFX2 actively seals while its unit-body construction preserves the aortic bifurcation. A design feature preferred by customers when treating patients who is present with a narrowing of the bifurcation. We announced last quarter AFX2 sales volume has stabilized in the US, in the second half of 2019, a critical milestone in our return to growth. That stability is attributed to two factors, its preference in specific aortic [ph] anatomies (00:12:29) and the evidence that supports its use namely LEOPARD, the only RCT in the last 20 years of EVAR.

A study that includes the three big contemporary competitive endografts, AFX2 shows a statistically significant advantage in ease of use, freedom from aneurysm-related complications at one year, freedom from limb thrombosis at three years, freedom from conversion to open repair at three years and freedom from Type III endoleaks are actually similar between AFX2 and our comparators. With the Ovation platform, again, we produce no [indiscernible] (00:13:16) force. The neck is sealed through a conformable polymer ring that mitigates aortic neck dilatation and favorably impacts durability. Through our ENCORE registry we've witnessed similar performance in large aortic body diameters when compared to smaller sizes.

In contrast with conventional self-expanding endografts where 12 peer reviewed publications over the last three years have each concluded that large aortic bodies are a predictor of eventual EVAR failure. With Alto it is intended to extend our custom ceiling benefits by expanding patient applicability attributed to raising the ceiling ring from 10 millimeters to 4 millimeters from the lowest renal artery. That difference we estimate increases patient applicability in traditional EVAR by now being able to treat a 7 millimeter neck versus a 13 millimeter neck; that's about an 11% greater applicability or an estimated increase of more than $200 million in product level market opportunity, globally.

We are anticipating FDA clearance in early 2020 and in a post-market setting intend to yet again create Level 1 evidence in evaluating Alto's superiority to traditional competitive endografts. Finally, with Nellix our platform introduces an entirely new design again resulting in a mechanism of action by actively managing the aneurysm

sac through complete endovascular aneurysm sealing. We are currently completing enrollment of our confirmatory IDE trial EVAS2 using modified anatomic indications for use and enhanced procedural training. We will complete the study in early 2020. The design intent is completely different from EVAR with an aim to reduce type 2 endoleaks alter the adverse biological response to EVAR and treat complex AAA in combination with adjunctive stenting namely through our ChEVAS IDE recently approved in the US.

The propensity weighted study I referenced earlier using VQI comparisons of contemporary competitive endografts presented at VEITH observed that patients undergoing EVAS with Nellix were associated with a statistically significant all-cause mortality benefit when compared to patients undergoing traditional EVAR. As I mentioned in my first slide, we compete in a large market estimated to be $3.1 billion globally where our ability to address this global market across our three platforms is estimated to be $2.3 billion. That breaks down to 80% applicability in the traditional segment and an estimated 63% applicability in complex. A summary of our clinical and regulatory milestones include completing enrollment of Nellix EVAS2 IDE subsequently initiating the PMA submission in Q3, receiving a determination on our Alto submission which we believe will result in an approval in early 2020, starting ChEVAS our complex aneurysm IDE study around mid-year and then toward year's end defining and initiating an Alto-led RCT.

Finally, we will continue to follow patients with our AFX2 LEOPARD RCT throughout the year with data readouts at VEITH. We're very excited about the next two years in Endologix. We've lined up some very important value drivers across three dimensions of our business. First being the evidence we intend to create, the approvals that evidence supports and the commercial execution fueled by evidence and clearances. In the evidence category, I've reviewed our EVAS2, ChEVAS, Nellix and our ALTO RCT timing in my previous slide. I would now add in 2022, post clearance of Nellix, we intend to design and execute Nellix RCT in evaluating all-cause mortality that will be prospectively derived.

Turning to product approvals with Alto this year in the US and EU, next year in Latin America and Japan, and then Nellix approval expected late next year, early 2022 where we would then restart sales of Nellix in the EU. Finally, our commercial execution mandate is to introduce Alto thoughtfully by establishing proficient use first with on-target patient selection. We will move and expand our presence in higher volume centers where engagement requires disciplined use of our clinical data, excellent training experiences, patients and meaningful partnerships as we initiate our Alto RCT. We're excited to introduce AFX2 in China next year through our partnership with Boston Scientific and finally launching Nellix in 2022 post FDA clearance.

Our value drivers and objectives are clear over the next two years, achieve double-digit topline growth, achieve cash flow positive by the end of 2021, all through consistent evidence-based execution that advances the most competitive AAA product portfolio in the world. I'm very proud of our team and our 2019 accomplishments. We've clearly strengthened our quality and compliance foundation. We've managed attrition responsibly and stabilized our organization post restructuring and most importantly we've established and are continuingly nurturing a culture of accountability. In 2019 as of November 6th we pledged revenue of at least $140 million, a $107.6 million year-to-date as of the third quarter.

Fourth quarter 2019 revenue is anticipated to be in the range of $32.5 million to $34.5 million as previously messaged. Operating expenses in the range of $130 million to $140 million where $101.9 million has had been realized in year-to-date as of the third quarter. Cash burn is expected to be less than $5 million per quarter in the second half of the year, and our third quarter year-over-year revenue growth of 2.9%. We stabilized the US AFX2 business as we predicted back in 2018. We've completed a major debt refinancing and raised $52 million in equity. We signed a China distribution partnership with Boston Scientific starting with AFX2.

We've enrolled 88 of a required 105 patients EVAS2 in Nellix IDE, confirmatory IDE, and we've restarted the clock for the Alto PMA clearance with early 2020 approval decision expected. In October of 2018 I first presented our phased transformation journey as a contextual backdrop for following our progress. We started by strengthening our foundation with achievements I described in the prior slide for 2019. The next two years we define as re-establishing durable predictable growth, I shared in my earlier catalyst slide. The third phase, accelerating innovation and profitable growth from 2022 to 2023, we're operating EPS positive, we've completed ChEVAS enrolment, we have Nellix cleared in the US and are targeting a first in man for a Next-Gen EVAS system.

The fourth phase, transforming Aortic Care, we've completed and intend to demonstrate Alto superiority in the RCT. We've launched ChEVAS in the US, in the EU and in Japan. The yardstick of our success in each and every phase is our commitment to achieve superior lifelong patient outcomes in a single procedure across the platform. Our return to growth occurred this year with a commitment to making that growth durable and conveying that growth predictably. We are a company hitting stride, we've completed a US and EU restructuring. We've returned to growth after 11 quarters of decline. We've reduced our cash burn from $12 million a quarter to less than $5 million a quarter by year end 2019.

We are on a path to being cash flow positive by year end 2021. We've managed attrition effectively. We've strengthen our quality system and we've established the distribution partnership with Boston Scientific in China. Our 2022 priorities are clear. Continue to support AFX2, secure Alto clearances in the US and in the EU, complete EVAS2 enrollment and initiate PMA submission. Initiate ChEVAS enrollment, continued prudent expense and cash management and maintain a cash burn of $20 million annually and advance our Next-Gen EVAS design. Finally, we intend to purposely rebuild our reputation by continuing to demonstrate accountability, transparency and ensuring patients remain first in all we do.

Thank you.