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Endologix, Inc. (ELGX)

Q3 2019 Earnings Call

CORPORATE PARTICIPANTS

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Third Quarter 2019 Earnings Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions]

As a reminder, this conference is being recorded. This conference is also being broadcast live over the Internet at the Investors section of the company's website at www.endologix.com, and the webcast replay of the call will be available at the same site approximately one hour after the end of the call.

Before we begin, I would like to caution listeners that comments made by the management during this conference call will include forward-looking statements within the meaning of federal securities laws. These forward-looking statements reflect management's expectations about future events, milestones and results of operations, including anticipated regulatory approvals, clinical trial status, product portfolio updates and financial and operating projections and plans. These are known and unknown risks, uncertainties and other factors that may cause the company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

For a discussion of risk factors, the company encourages you to review its most recent annual report on Form 10-K, quarterly report on 10-Q and subsequent reports as filed by the company with the Securities and Exchange Commission.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, November 6, 2019. Endologix undertakes no obligation to revise [audio gap] (2:05 – 2:17) Sorry about that. Endologix undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

In addition today's discussion will include reference to adjusted EBITDA which is a non-GAAP financial measure. Adjusted EBITDA is a key measure used by the company to evaluate operating performance, generate future operating plans and make strategic decisions for the allocation of capital. Please refer to the company's press release issued earlier today for further information.

With that said, I'd now like to turn the conference over to John Onopchenko, Endologix's Chief Executive Officer. Please go ahead.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator and good afternoon everyone and welcome to our third quarter conference call. Today I'll provide a brief overview of our third quarter 2019 results and also provide an update on our product portfolio, including a comprehensive update on FDA status and the approval timeline for EVAS2, Alto and ChEVAS. I will then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our third quarter financial results and 2019 financial guidance in more detail. After that we'll open up the call for questions.

As a reminder we have posted an updated investor deck on our Investor Relations website directly below the webcast link. I am pleased with our solid performance in the third quarter as we achieved year over year revenue growth for the first time in more than two years while continuing to effectively manage our expenses and operating cash burn. Our proved performance across the business includes sequential growth of US AFX2 volume. We remain focused on the accountability and execution to drive sustained positive operational results across the board from sales to expenses to cash. We will now turn our attention to finishing the year strongly and positioning the company for sustained growth through strong execution in 2020. Looking forward, we are poised to achieve our 2019 financial targets and our team remains committed to building momentum through the end of the year.

I will now turn to our quarterly highlights. Total revenue for the third quarter was $35.8 million, representing a $2.9 million year-over-year increase. We achieved annualized growth for the first time in 10 consecutive quarters, which is attributed to the two enablers we referenced over a year ago. First, achieving AFX2 volume stability in the U.S. in Q3. And second, driving sequential growth of Ovation. Our o-U.S. commercial teams continue to deliver a solid performance and consistent with the teams in the U.S., continue to leverage our expanding body of clinical evidence to secure cases. We continue to rebuild credibility through transparency and evidence in the marketplace, while targeting high volume centers. We have a stable commercial team across the organization, which has continued to build stability and our return to year-over-year growth. We have achieved consistent and meaningful operational progress against our goals for OpEx and an earlier than expected achievement of our operating cash burn target completing the quarter under $5 million; a quarter earlier than we promised. We expect our expenses to be maintained at these levels through year end.

Now I'd like to give you an update on our current product portfolio including a comprehensive update on the status and timelines related to the EVAS2, Alto and ChEVAS, Nellix, and AFX2. I want to take some time to address the recent FDA safety communication regarding the AFX system. I want to be absolutely clear this is not a recall of the AFX product nor is it a correction to the product or product labeling. On October 28, 2019, the FDA issued a communication and press release in response to an abstract from the Kaiser Integrated Health System abstracted in the Journal of American College of Surgeons (sic) [Journal of The American College of Surgeons] (6:59) by [ph] Rothenberg, et al (7:02).

The FDA noted that the data may suggest a potentially higher than expected risk of type III endoleaks occurring with the use of AFX with Duraply and AFX2 endovascular grafts. The FDA also made clear specific to AFX2 the data only included a small number of patients with two-year follow-up. The FDA update restated that patients with the AFX system should continue with the existing recommended surveillance regimen.

In addition to the small number of patients implanted with AFX2, that is 32 patients, the FDA noted additional limitations with the study design including the fact that the results are not stratified by Type IIIA and Type IIIB endoleaks and the lack of a comparison of these results to outcomes from other endovascular graft systems. In our view, the small number of patients with AFX2 at two years, that is 13 patients, prevents any clinically meaningful statistically significant interpretation of these findings. The objective of the [ph] Rothenberg, et al

(8:23) study was to provide crude mid-term post-operative outcomes with Endologix AFX, AFX2 devices. It is notable that differentiation of the type of endoleak was absent from the data as was the proportion of patients treated within the indications for use or any detailed patient anatomy or demographics.

We have spent time analyzing the data for [ph] Rothenberg, et al (8:53) and making direct comparisons to our own data in attempt to understand the findings. Endologix is a robust approach to monitoring the performance of our products through the use of multiple data sets that are benchmarked, compared against other commercially available endografts and analyzed for concordance. These data include the LEOPARD trial, the only randomized control trial of EVAR providing Level 1 evidence. Real world data from vascular registry, our own benchmark MDR complaint data and meta-analysis of current literature. All of the datasets we use are concordant and demonstrate through the prospective analysis of over 60,000 patients with the AFX system that our AFX Duraply and AFX2 systems currently achieve patient outcomes equivalent to other contemporarily commercialized endografts when accessed on an encompassing spectrum of clinical complications. These data also support our conclusions that changes to the ePTFE manufacturing process from Strata to Duraply, along with the AFX IFU updates, are associated with a reduction in the occurrence of Type III endoleaks for the AFX System.

With all of that said, let me outline the actions we have taken to-date. To start, we have provided our global sales force with customer-facing material in the form of a letter to health care providers, and a presentation on a Rothberg abstract and our clinical data. We have also requested an anonymized data set used in Kaiser's reported outcomes to ensure that we have exhausted our understanding of their results.

We have commissioned an independent analysis of both their data and our data to arrive at an impartial third-party appraisal of the clinical validity and significance of each. I want to be clear, that we believe we have a safe, effective and highly competitive product that is supported by a high degree of vigilance reporting and related assessments found within our quality system. We have subjected our findings and conclusions to independent sources that further reinforce our now stable products' justifiable place in the global market. We are committed to transparency in the data we use to assess the performance of our products.

We recently published our annual clinical update 2016 through 2019 for the AFX system, which is a 105-page document containing a detailed presentation of the clinical trial data, MDR complaint data and the LEOPARD Trial data that we have compared against the study from Rothenberg et al. It is worth noting that in the LEOPARD study which remains the only level 1 randomized controlled trial in EVAR, there have been no reported Type III endoleaks in 111 patients implanted with the AFX2 system and there is no difference in the primary endpoint of aneurism related complications between the AFX group and the comparator graphs from Medtronic, Cook and Gore

Due to the analysis of multiple data set including independent sources with data with active comparators we remain confident that the AFX2 device is a safe and effective product when used as indicated. We will continue to work to understand and place into appropriate context data that becomes publicly available but would stress that evidence must be placed in a hierarchy recognized by healthcare practitioners, payers and regulators globally. The level of evidence within that hierarchy including the sample size, data integrity and quality along with an active comparator are critical when assessing endograft performance as a holistic concept. Before I leave the topic of AFX2. I want to report that we've recently received FDA approval for a three year shelf life. This has a significant implication to us in managing our working capital going forward.

Turning now to progress we have made in EVAS2 IDE, we have 33 active sites and we have enrolled 80% of the study. We plan to present these one year data at the VEITHsymposium in 2020. In the early part of 2020 we anticipate completion of the full enrollment of 105 patients and we will begin submitting modules for the PMA. Our

evidence base to support EVAS continues to expand with two papers in publication. O'Donnell et al recently published a research report titled endovascular aneurysm sealing is associated with high or medium term survival than traditional EVAR in the Annals of Vascular Surgery. These data were previously presented at the Charing-Cross Symposium by Dr. Schermerhorn whilst the three-year results from EVAS1 have been provisionally accepted in the Journal of Vascular Surgery. This publication will emphasize the need for procedural adequacy in EVAS and contributes to furthering our knowledge about this new therapy. As we reached the end of enrollment for EVAS2, we will concurrently ramp up activities for ChEVAS, which we plan to begin enrolling in early 2020. There is considerable clinical excitement and engagement around this trial, which will offer a therapy in an anatomically area poorly served by endovascular therapy at present.

Turning now to Alto, we continue to work collaboratively with the FDA and continue to have a line of sight to approval in the first quarter of 2020. We have submitted materials to the FDA in response to some of the issues that were raised at the 100-day meeting and we have completed all additional testing. We have some final outstanding questions, we are still working through that will be addressed in a face to face meeting with the FDA, which is scheduled to take place next week. We plan to submit our formal response to the deficiency letter shortly after this meeting. We have submitted our Alto data to the Society of Clinical Vascular Surgery and we will present our Alto data in March of 2020.

In the EU we recently met with NSAI in Dublin to discuss working practices going forward into the MDR. NSAI have our final clinical module for Alto and we believe we are still on track to receive Alto approval in Europe before the end of the year. Our execution this year has been solid and I am pleased that we've achieved stability in the business this quarter. However this is only the first step and we recognize there is still significant work to be done in order to return to sustainable long term growth. Our culture of accountability has been a key factor in driving progress against our goals and it will allow us to maintain our high level of commitment to on time, on budget, on target execution. We have a relentless focus on execution across functions and regions. As we close out the year we continue to generate clinical data that drive further adoption and growth of our products. We intend to compete on the basis of evidence that support superior outcomes of our current and next generation EVAR and EVAS products. We are well positioned to achieve our financial targets for 2019 as we advance our mission to transform aortic care by providing differentiated products that enable superior lifelong outcomes to patients suffering from both infrarenal and complex AAA.

And now, I'd like to turn the call over to Vaseem to discuss the third quarter financial results and provide you with details on our guidance.

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you John and good afternoon everyone. Our total revenue for the third quarter of 2019 increased 2.9% year-over-year to $35.8 million compared to $34.8 million in the third quarter of 2018. This is a significant milestone for Endologix as we return to growth after 10 consecutive quarters of year-over-year declines. And we are excited to report this year-over-year again.

U.S. revenue decreased 6.2% to $24.1 million in the third quarter of 2019, compared to $25.7 million a year ago as we continue to see the impact of previous commercial restructuring. Just a reminder of the executer on the commercial restructuring in August last year and as a result the third quarter represents the last quarter of tough comps due to that restructuring. We did see sequential growth in the third quarter on the heels of terrific performances from both AFX and Ovation, especially when considering the seasonality of the third quarter.

Third quarter international revenue of $11.7 million increased 28.7% compared to revenue of $9.1 million in the third quarter of 2018. This is largely driven by timing of distributor orders coupled with organic growth in Japan, where AFX2 continues to do well. Our European business continues to stabilize after the restructuring last year and the team has done a nice job converting some of our Nellix business to AFX2.

On a constant currency basis, our third quarter 2019 international revenue increased 31.5% year-over-year. On a product line basis, our global AFX system sales were up 18% year-over-year. Ovation was up 9% year-over-year and Nellix was down 84%. In the U.S. market both Ovation and AFX system sales grew sequentially. This is a huge accomplishment for the U.S. team and is a testament to the strength of our LEOPARD data and the resilience of our sales team. Third quarter gross profit was $23.1 million representing a 64.5% gross margin compared to 65.1% in the prior year period. The decline versus prior year is driven primarily by a smaller U.S. revenue number and lower absorption due to lower volumes, as we continue our efforts to drive better inventory turns and working capital improvements. We don't expect to see any favorable impact due to capitalized variances in the fourth quarter and we'll see sequential declines in our gross margins. We expect our gross margin to be approximately 62% for the total year.

We had another strong quarter of continued cost controls. Total operating expenses for the quarter were $33.9 million compared to $38.5 million a year ago which is a 12% reduction year over year. However, the third quarter of 2018 included $2.9 million in one-time items and on a comparable basis operating expenses declined 4.9% from the prior year period. Our improved expense management continues to drive operating costs lower, positioning us well to achieve our previously communicated 2019 OpEx guidance of $130 million to $140 million. Looking more closely at the third quarter operating expenses on a year over year basis, marketing and sales expenses were down 5.8%, research and development expenses decreased 7.8%, general and administrative spend decreased 7.6% and our clinical and regulatory expenses increased 13.2% as we continue to make investments in our pipeline and the evidence to bring new products to market.

Net loss for the third quarter of 2019 was $7.8 million or $0.40 a share compared to a net loss of $10.1 million or $1.19 per share a year ago. This net loss reflects the structural changes we have made since the 2018 August reset and the strategy we laid out at the Investor Day last year. Adjusted net loss totaled $10.5 million compared to an adjusted net loss of $13 million for the third quarter of 2018. Adjusted EBITDA totaled a loss of $5.6 million for the third quarter of 2019 compared to an adjusted EBITDA loss of $9.3 million for the third quarter of 2018.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were $47.8 million as of September 30, 2019, compared to $24.7 million as of December 31, 2018. The availability on our revolver with Deerfield as of September was approximately [ph] $19 million (22:24), putting us at approximately $66 million of available liquidity. Our operating cash burn for the quarter was approximately $4 million, bringing our year-to-date operating cash burn to roughly $24.7 million. As previously communicated, we were targeting an operating cash burn of less than $5 million in the fourth quarter of 2019. We are happy to see us get to that number a quarter earlier than planned. We expect our operating cash burn to be less than $5 million in the fourth quarter as well.

As we discussed previously, our $20 million annual operating cash burn target was predicated on $30 million of total operating cash burn, offset by $10 million of working capital improvements. We remain on track to hit our $30 million operating cash burn target for the year, however the working capital improvements we had originally anticipated will start to accrue in the fourth quarter and into 2020, especially the impact of the three-year AFX2 shelf life extension project that John mentioned for which we received FDA approval in early October.

A quick update on the debt to equity conversion resulting from the financing deal announced in April of this year, as part of that deal, up to $50 million of our debt, $25 million with our 2024 convert holders and $25 million with

Deerfield was made subject to a mandatory conversion to our common stock. These mandatory conversions happen when certain conditions are met. We converted approximately $3.3 million of our debt in the third quarter that resulted in us issuing approximately 500,000 additional shares. These new share issuances are included in the 17.9 million shares outstanding at the end of the third quarter. We will continue to provide you updates every quarter if/and any of these conversions happen and lower our overall debt load.

Turning to guidance, we are [ph] retrading (24:19) our previously provided guidance; in 2019 we continue to expect revenue of at least $140 million while operating expenses are anticipated to be in the $130 million to $140 million range. For the fourth quarter of 2019 we expect revenue in the range of $32.5 million to $35.5 million. The low end of the range reflects the uncertainty surrounding the impact to our US business due to the recent FDA notice regarding AFX. This impact is based on historical trends we have seen following the issuance of a Field Safety Notice and similar regulatory actions.

We know that the FDA notice has created questions among our investor base on what the implications are. We are encouraged by the early signs on our US business where we have seen no material impact on either our case creation or our case cancellations thus far. Obviously it is still early, so we will continue to monitor the situation. And as noted in our guidance we have factored in the potential impact from this FDA action on our Q4 revenues while still maintaining our annual 2019 revenue guidance. Overall, our third quarter and year-to-date performance positions us to achieve our revenue and expense targets for 2019. We are pleased with our performance to-date as we continue to execute against our strategic initiatives and deliver value to our customers and patients.

With that let me turn the call back to John. John?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Vaseem. This marks the fifth consecutive quarter since our reset a year-ago, in which we delivered on our commitments for revenue, OpEx, reducing operating cash burn through both expense reduction and working capital improvements, while improving the balance sheet.

We are encouraged that our AFX2 system sales were stable this quarter as compared to the second quarter and we are aggressively pursuing to achieve overall sales growth in the fourth quarter. Our ability to secure new users and high volume centers continues to take hold with promising early results. We plan to present our updated LEOPARD data at VEITH and our [ph] elevate (26:32) clinical trial data at the [ph] SCBS (26:34) in March of 2020. Finally, we continue to make progress on ALTO EVAS2, Next Gen EVAS and ChEVAS in pursuit of realizing our mission of transforming aortic care for life.

With that we will now open the call for questions. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you. We will now be conducting a question-and-answer session. [Operator Instructions] [Operator Instructions] [audio gap] (27:18 – 28:07) Thank you. I would like to turn the floor to Mr. Onopchenko for closing remarks.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Operator, we've concluded closing remarks, if there aren't any questions, I will then call the third quarter call to an end.

Operator: This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation.