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Endologix, Inc. (ELGX)

Q4 2019 Earnings Call

CORPORATE PARTICIPANTS

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

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

OTHER PARTICIPANTS

Allen Gong
Analyst, JPMorgan Securities LLC

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Chris Cooley
Analyst, Stephens, Inc.

Chris Pasquale
Analyst, Guggenheim Securities LLC

MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to Endologix Fourth Quarter and Full Year 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 call 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 time – same site approximately one hour after the end of the call.

Before we begin, I would like to caution listeners that comments made by management during this conference call will include forward-looking statements within the meaning of federal security 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. There 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, performances or achievements expressed or implied by the forward-looking statements.

For a discussion of risk factors, the company encourages you to review the most recent Annual Report on Form 10-K, Quarterly Reports on Form 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, February 19, 2020. 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 references 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 call over to John Onopchenko, Endologix's Chief Executive Officer. Mr. Onopchenko, please go ahead.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon, everyone, and welcome to our fourth quarter conference call. Today, I'll provide a brief overview of our fourth quarter and full year 2019 results and also provide an update on our product portfolio. I will then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our fourth quarter and full year financial results and 2020 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'm pleased with our performance in 2019 as we achieved our revenue and operating expense goals for the year and we believe we are well positioned to sustain this momentum through 2020. We exceeded our full year financial guidance while effectively managing expenses and cash burn and have achieved stability in several key areas of our product portfolio. Additionally, we've made significant progress on the regulatory front and are preparing for the launch of Alto in the first half of 2020.

I'll now turn to our quarterly and annual highlights. Total revenue for the fourth quarter was $35.8 million, representing a 3% year-over-year increase. We achieved annualized growth for the second consecutive quarter with solid sales of both AFX2 and Ovation. Total revenue for the full year was $143.4 million, an 8.4% year-over-year decrease, but above our guidance of at least $140 million. Our commercial teams continue to execute by leveraging our expanded body of clinical evidence to secure cases. Quarter-by-quarter, we've rebuild credibility from transparency and evidence in the marketplace, while building our presence in high-volume centers.

Additionally, we continue to manage attrition risk. With change comes opportunity. So, as we've been managing through attrition risk, we also have been very purposeful in recruiting some terrific folks who recognize our recovery, believe in our strategy and our call to action on behalf of patients, and are ultimately inspired to join the fight. For example, during the quarter, we recruited back two highly productive sales reps that had previously left Endologix to join a competitor.

This is not only a clear positive for our organization, but it also means further credence to the market opportunity in front of us. We continue to achieve consistent and meaningful progress against our operating expense targets and the fourth quarter marked our second consecutive quarter of operating cash burn of $5 million or less. We expect our expenses to be maintained at these levels in 2020, subject to seasonality, as we drive toward our goal of achieving operating cash flow breakeven in 2021.

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 EVAS2, Alto, ChEVAS, Nellix and AFX2. Turning first to AFX2, as I've mentioned before, I'm pleased with the performance of our AFX2 business despite the challenges that we faced throughout the year. Our team worked diligently to drive the business forward in 2019 and I'm proud to say that AFX2 procedure volume in the US have stabilized and we achieved year-over-year growth in the fourth quarter of the year.

The most recent data cut of our LEOPARD trial reported comparable performance between AFX DuraPly and AFX2, and the control arm, which was composed of subjects receiving endografts from Medtronic, Cook and Gore. The LEOPARD data on the AFX platform reported statistically significant superiority in some outcome measures such as aneurysm-related complications at one year and was not inferior in any parameters. Most relevantly, there was no statistical or clinical difference in Type III endoleaks. These data continue to support the performance of AFX when directly compared to other commercially available endografts.

Now, turning to Ovation, as we've outlined before, some of our AFX2 growth in 2019 came at the expense of Ovation, as it is necessary for us to shift sales attention to AFX in the US in order to respond to the FDA's safety communication issued in late-October. We intend to rebalance sales attention with Ovation and remain confident in its ability to grow by leveraging the outcomes data supported by ENCORE as well as the dissemination of positive use experience.

Turning to the EVAS2 IDE study, we continue to make progress and currently have 92 patients enrolled and two cases scheduled. At this kind of enrollment, we anticipate that the last patient will be implanted in the IDE study in early Q2. As we near the end of the clinical study, we have concurrently started preparation of the PMA. We will be working with the FDA to determine the final schedule. However, we anticipate initial submission activities in the latter part of 2020. We plan to present the first view of the primary endpoints of the EVAS2 IDE clinical study – clinical results at the VEITHsymposium in November of this year.

Additionally, the mid- and long-term EVAS1 results continue to demonstrate good outcomes within the revised indications and have just been published in the Journal of Vascular Surgery. It is noteworthy that the signal from EVAS1 of the association between EVAS and a reduced all-cause mortality in comparison to EVAR continues as recently published in the Annals of Vascular Surgery. As we reach the end of enrollment for EVAS2, we will concurrently ramp up activities for ChEVAS, which we plan to begin enrolling midway through the year. We have our four principal investigators and the first 15 sites identified and are progressing from site activation and training.

Regarding Alto, we submitted our formal response to the FDA's deficiency letter on December 16 to reinitiate the review process. We continue to work interactively with the FDA and our anticipated approval timeline remain Q1 of this year. We expect EU approval in a similar timeframe. We executed well in 2019, and as a result, have achieved the stability that now enables us to focus on short- and long-term growth. We recognize that there is still a significant amount of work to be done in order to achieve our clinical, regulatory and financial goals, but we believe that our commitment to execution backed by the culture of accountability have put us on the path to profitable growth.

I'm very proud of the resiliency displayed by the entire team here at Endologix as we faced more than our fair share of challenges on the road to stability. We will carry this mentality forward as we continue to improve the business and work to generate growth in 2020. We look forward to continuing to leverage our ever-growing outcomes data as well as the launch of Alto this year in order to deliver value to patients and physicians through differentiated products that enable superior outcomes for patients with AAA.

And now, I'd like to turn the call over to Vaseem to discuss the fourth quarter and full year 2019 financial results and provide you with details on our 2020 guidance. Vaseem?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon, everyone. Our total revenue for the fourth quarter of 2019 increased 3% year-over-year to $35.8 million compared to $34.7 million in the fourth quarter of 2018. This is the second consecutive quarter of growth after nine consecutive quarters of year-over-year declines and we're excited to be growing again. US revenue increased 1.5% to $24.4 million in the fourth quarter of 2019 compared to $24 million a year ago, which represents the first time the US business has grown in 10 quarters. For the full year, our total revenue decreased 8.4% to $143.4 million. US revenue for the full year decreased 12.6%, primarily due to the headwinds we faced related to our commercial restructuring and the negative impact of the field safety notices for both Ovation and AFX, mostly in the first half of the year.

Fourth quarter international revenue of $11.4 million increased 6.5% compared to revenue of $10.7 million in the fourth quarter of 2018. This increase was largely driven by the strong performance of AFX in Europe and Japan and of Ovation in our capital markets. Full year international revenue of $48.1 million increased 1.4% compared to $47.4 million in 2018, where growth in our Japan business offset declines due to commercial restructuring in Europe and in Asia. On a product line basis, in the fourth quarter, our global AFX System sales were up 13% year-over-year, Ovation was up 10% year-over-year, and Nellix was down 18% year-over-year.

In the US market, AFX System sales grew sequentially once again with physicians seeing the benefits of this data and the product as reported in the LEOPARD study. For 2019, our global AFX business generated revenues of $93.3 million, Ovation revenues were $48.8 million and Nellix revenues totaled $1.2 million. As mentioned before, we did not see US sequential growth from Ovation in the fourth quarter as our sales team spent a significant amount of time defending AFX2 in the US at the expense of Ovation sales. Our Ovation System sales in the second half of 2019 were up high-single-digits versus the second half of 2018 and sequentially higher in each of the first three quarters of 2019.

Fourth quarter gross profit was $21.8 million, representing a 61.1% gross margin compared to 32.8% in the prior-year period. As a reminder, gross margin in the fourth quarter of 2018 was negatively impacted by approximately $8.7 million of inventory reserves related to the voluntary Nellix recall. Excluding the impact of the recall, gross margin during the fourth quarter of 2018 was 58.7% (sic) [57.8%] (00:14:37). Gross profit for the year was $91.1 million, representing a 63.5% gross margin compared to 58.7% in 2018. Excluding the impact of the recall, gross margin during the full year of 2018 was 64.3%.

We had another strong quarter of continued cost controls. Total operating expenses for the quarter were $31.7 million compared to $35.1 million a year ago, which is a 9.6% reduction year-over-year. Looking more closely at the fourth quarter operating expenses on a year-over-year basis, marketing and sales expenses were down 6.2%, research and development expenses increased 7.6%, G&A spend decreased 7.6%, and our clinical and regulatory expenses decreased 11.1%.

I'm pleased to say that our operating expenses for the year were $133.6 million, towards the lower end of our previously communicated OpEx guidance range of $130 million to $140 million, which is a testament to our improved expense management. We will build on this momentum by continuing to reduce operating expenses in 2020 as we drive towards our goal of cash flow breakeven in 2021. Looking more closely at the 2019 operating expenses as compared to 2018, marketing and sales expenses were down nearly 16%, research and development expenses decreased 13%, G&A decreased 17.2%, while our clinical and regulatory expenses increased 1.3%.

Net loss for the fourth quarter of 2019 was $7.8 million, or $0.40 per share, compared to a net loss of $25.9 million, or $2.65 per share, a year ago. This net loss reflects the structural changes we have made since the

August 2018 reset and the strategy that we laid out at the Investor Day in October of 2018. For the year, net loss totaled $64.8 million, or $3.84 per share, compared to $79.7 million, or $9.07 per share, in 2018.

Adjusted net loss for the quarter totaled $8.1 million compared to an adjusted net loss of $21.3 million for the fourth quarter of 2018. Adjusted EBITDA loss totaled a loss of $5.2 million for the fourth quarter of 2019 compared to adjusted EBITDA loss of roughly $17 million for the fourth quarter of 2018. For the year, adjusted net loss totaled $36.9 million compared to an adjusted net loss of $62.7 million in 2018. Adjusted EBITDA in – totaled a loss of $23.9 million compared to adjusted EBITDA loss of $43.4 million in 2018.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were $42.8 million as of December 31, 2019, compared to $24.7 million as of December 31, 2018, and $47.8 million as of September 30, 2019. The availability on our revolver with Deerfield as of December was approximately $18 million providing us with approximately $60 million of available liquidity. Our operating cash burn for the quarter was approximately $5 million, bringing our year-to-date operating cash burn to roughly $29.6 million, within our previously communicated range of $30 million in total cash burn. As we had discussed previously, we had anticipated $10 million of working capital improvements in 2019, however, these improvements did not being to accrue until we received the [ph] AFX during (00:18:17) the three-year shelf life expansion in October 2019. We expect our inventories to remain at current levels as we ramp our production for the pending Alto launch.

Regarding our balance sheet and debt overhang, we have been in active negotiations with our senior lender and certain other stakeholders to restructure our debt in a manner that would address the near-term balance sheet overhang and also provide a pathway to significant deleveraging of the company's debt. We hope to be able to announce the consummation of this transaction in the very near future.

Turning now to guidance, in 2020, we expect revenue of at least $145 million while operating expenses are anticipated to be approximately $130 million. Additionally, as you can see on slide 17 of the investor presentation, we're also providing quarterly revenue guidance for 2020. For the first quarter of 2020, we expect revenue of at least $30 million. When looking at the negative year-over-year growth for the first quarter of 2020, recall that our results in the first quarter of 2019 included revenue from South Korea and a one-time inventory adjustment order from our distributor in Japan.

Additionally, we expect sales from Brazil in the first quarter of 2020 to be down significantly year-over-year due to the unavailability of AFX1 and Ovation Prime as a result of our pending regulatory approvals. We made a deliberate choice [indiscernible] (00:19:46) both AFX1 and Ovation Prime in order to simplify our supply chain footprint and improve our cash performance. We expect to receive approval for AFX2 in Brazil in April, which will allow us to make up for the Q1 AFX revenue loss in the second, third and fourth quarters of 2020. However, we expect the Ovation Prime headwind to persist until we receive Alto approval. Both of these headwinds are already factored into our guidance for the full year.

The key takeaway for investors is that the negative year-over-year growth is primarily due to the [indiscernible] (00:20:19) headwinds in Japan and Brazil. We have also experienced some softness in the US business due to competitive counter detailing as a result of the recent stock price decline which we believe is largely attributed to the near-term balance sheet overhang. At the end, we believe we can address this overhang in the very near future. We anticipate delivering mid-single-digit year-over-year revenue growth in the second and third quarters and accelerating year-over-year revenue growth to the high-single-digit range in the fourth quarter on the heels of an Alto launch.

Between Brazil, Japan and Europe, we expect the second quarter sales pick up in the range of $4 million to $5 million, and coupled with the pending Alto launch in the US and the seasonality of our business, we have good line of sight to the mid-single-digit growth guidance for the second quarter and beyond. Overall, our fourth quarter and full year 2019 performance positions us well as we head into 2020. We're pleased with this performance and we remain committed to execution in order to deliver value to our customers, our patients and our shareholders.

And now, let me turn the call back to John. John?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Vaseem. This marks the sixth consecutive quarter since our 2018 reset in which we delivered on our commitments for revenue, operating expenses, reducing operating cash burn through both expense reduction and working capital improvements. We're encouraged by sequential growth in our AFX2 System sales during the fourth quarter as our ability to secure existing and new customers continues to improve with promising early results. We will continue this aggressive but disciplined approach in 2020 across our product portfolio, including the upcoming Alto release. Looking ahead, we plan to present our ELEVATE clinical trial data at the SCVS in March of 2020. Finally, we continue to make progress on Alto, EVAS2, and ChEVAS in pursuit of realizing our mission of transforming aortic care for live.

I wanted to take the last few moments of the call to reiterate what we presented at JPMorgan last month and to place our current product portfolio and clinical evidence strategy in a contemporary perspective. Traditional EVAR using self-expanding oversized stents with proximal fixation has been adopted as the primary treatment for patients with abdominal aortic aneurysms due to the excellent short-term outcomes which mitigate the perioperative morbidity and mortality seen with open surgical repair. However, these early advantages are eventually offset by the lack of long-term durability, that is manifest by a high rate of both reintervention and aneurysm rupture.

The challenges of traditional EVAR are illustrated by a recent report authored by [ph] Columbo (00:23:30) which was partially funded by the FDA and published in the Annals of Surgery. This study reported on 12,911 patients undergoing EVAR between 2003 and 2015. Nearly 95% of the patients received an endograft from Cook, Gore or Medtronic. The mid- and long-term outcomes of traditional EVAR were poor, with one-third of the patients requiring reintervention at 10 years. Most concerning was the fact that at least 5% of the patients rupture their aneurysm at 10 years and that reintervention was associated with a 20-fold increase in the incidence of aneurysm rupture.

As Dr. Conte from UCSF stated in the commentary, "It would not be a stretch to say 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." In light of these findings, it is imperative that we strive to develop a therapeutic modality that achieves excellent acute outcomes, but addresses long-term durability. We resolutely believe that our product portfolio addresses these challenges. Our anatomically fixed endograft AFX2 has been rigorously tested in the only randomized trial of contemporary endografts and our LEOPARD data reports some significant performance advantages.

The Ovation iX and Alto platforms use a differentiated mechanism of achieving seal in the proximal aortic neck without the use of oversized self-expanding stents, and we believe that this differentiation will be manifest in a lack of aortic neck dilation and subsequent improved durability when compared to traditional endografts. We plan to test this hypothesis in a randomized controlled clinical trial and believe that physicians will be compelled to using therapy that addresses the failings of traditional EVAR. Over the longer-term, our view is that EVAS will be

a paradigm altering therapy that will revolutionize aneurysm sac repair through eradication of aneurysm sac flow and a modification of the biological response to EVAR that offers the promise of an all-cause mortality benefit.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] We'll take our first question from Robbie Marcus with JPMorgan. Please go ahead.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Hi. This is Allen on for Robbie. Congratulations on the great quarter.

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

A

Hey, Allen.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

I just wanted to ask about kind of the second quarter, going from declining quarter in first quarter to growing mid-single-digits. Obviously, you do have a bit of dynamics laying on the first quarter there with comps and Brazil. But I guess, it sounds like you mentioned Ovation Alto really potentially being a driver of second quarter strength. How should we think about the launch? Should – is it like kind of gradual limited launch still really the way to think about it with a bigger benefit, I think, you mentioned in the fourth quarter, is that the right way to think about it?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yes. Allen, so there's two parts to the pick up from the $30 million guidance for the first quarter to the mid-single-digit number for the second quarter. So, what we mentioned here is that the pick up just from Europe, Brazil and Japan, the non-Alto pick up is about $4 million to $5 million is where we would like to be on a normalized basis, that's the true kind of run rate of the business. And then on top of that, we would expect to see some acceleration on the heels of Alto on two dynamics, one is just the use of Ovation and Ovation iX and then some purposeful pickup in sales and not a huge number to kind of get back to north of that mid-single-digit 5% growth number for the second quarter.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Got it. And then, a final question kind of on really balancing profitability and sales. So, you're approaching the Alto launch, which I think we can all agree is going to be a very exciting one for you and you also – it looks like you're on track in Nellix into the pipeline for, say, like a 2021, 2022 PMA approval. But at the same time, you're also really looking to cut down on spend where you'll hit the 2021 spending target. So, I guess like how should we think about your priorities, if the Alto opportunity, if the Nellix opportunity really do prove to be major ones for you, would we think of you maybe prioritizing a little bit of spend, say, on your sales team to really accelerate those launches and maybe push our profitability or is 2021 like a hard target?

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

Well, I mean, I think no different from where we left you guys at the Investor Day on October 2018 in terms of the priorities. So, we have prioritized a world-class Alto launch here in 2020, and as you saw, the actuals for the [indiscernible] (00:29:27) towards the bottom half of the guidance of $130 million to $140 million and remember, Allen, we have said this many times in the past that that one-time restructuring that we did was not to restructure to take cost out of the business, it was to rightsize the business to kind of ahead of the capacity that we saw within, for example, our sales organization in the US and outside of the US. In the countries that we executed, we've left some revenue on the table, but on the cash basis we came out on top.

So, as we think about the new number for operating expenses for 2020, the $130 million number represents a very similar capital allocation process where we will continue to invest in the clinical evidence generation, we'll continue to invest in the PMA and where we're taking cost out is in G&A, in some of the more discretionary items, and at the same time, being mindful that we have a compliant quality management system that we don't risk any compliance and controllership infrastructure of the company that we have worked so hard to continue to invest and over the time that we were taking cost out. So, this is very deliberate, very purposeful cost management approach and not one that was just predicated on taking cost for cost out sake.

Operator: We'll take our next question from Richard Newitter with SVB Leerink. Please go ahead.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Hi, guys. It's Jaime on for Rich. Thanks for taking my questions.

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

Hey, Jaime.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

I guess first one being just kind of on the guidance. You're guiding to the $130 million in operating expenses. Could you give us a sense of how we should be thinking about the gross margin cadence as we move through the year?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yeah. I think very similar to as we have done in years past, we haven't formally given our guidance, but we expect the business in 2020 to be in that low-60% range. So, I will say, in the 60% to 62% range for the year, but again, it's predicated on volumes, it's predicated on the ramp up of Alto, and how we launch it and where we launch it. So, again, we haven't formally given guidance, but I would keep you in the 60% to 62% range and that will [indiscernible] (00:31:54) where we ended the year.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Got it. Okay. And then just two product related questions. So, I appreciate kind of some of the commentary around the 1Q impacts and headwinds from the OUS business on some of the products. But looking specifically

at the AFX business in the US, given that you kind of rebounded into the positive territory in the fourth quarter, just curious on how you guys are thinking about the cadence of growth for the US business specifically over the 2020 time period.

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

A

Very similar to – when I answered Allen's question, the Investor Day presentation [indiscernible] (00:32:38) we expect the US AFX business to stabilize at the level that you're seeing here in the fourth quarter and then Ovation to pick up. And as we've said on the prepared remarks, we did see softness in the Ovation number in the fourth quarter and [indiscernible] (00:32:56) because we were so busy defending the AFX business, which actually resulted in some higher AFX volumes. So, it gives us not only confidence in the AFX business, but also the fact that as we go back to selling Ovation and also getting ready for the launch of Alto in the US, we would expect to see sequential improvements in our Alto business. So, a flattened US AFX business is stable and growing Ovation business through the year is how we continue to build the business and build the 2020 like we did in the second half of last year.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Great. Thanks for taking my questions.

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

A

Thank you.

Operator: We'll take our next question from Mathew Blackman with Stifel.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Good afternoon, everyone. Thanks for the question. Maybe just for Vaseem, your comments about a potential – I think I heard you right, a potential near-term resolution on the balance sheet were encouraging. So, I guess the question is, is your hope that all the major [indiscernible] (00:33:59) major balance sheet headwinds would be resolved near-term? And I guess, the follow-on to that is, the best of your ability to answer this, conceptually is there a way to do all this while minimizing dilution?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, Matt, I'm just going to go back to the comment I made, we continue to look at opportunities, we've been working really hard looking at the near-term challenges and also the long-term challenges. Definitely, the near-term challenges we can work through and while the key stakeholders have to come together to solve some of those challenges, we feel very confident we can do that. But at the same time, some of the longer term challenges, we are looking at various options to address those and we'll give you more color on that as we get ready to announce that transaction. So, I'll just leave it at that.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. Fair enough. Maybe second to John. I guess you did mention it briefly in your comments, but I'm curious to sort of hear how you think you're tracking against the – I'll call it, the high-volume center initiative that you laid out at the Analyst Day about a year-and-a-half ago. Are you tracking on plan there? Is it moving faster or slower, just give us a sense as we wrap 2019, how that initiative is playing out?

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

A

Yeah. Back in October of 2018 at the Investor Event, I set expectations in concert with a crawl, walk, run approach as we moved up market. So, in 2019, Matt, we were successful and we define success in getting at least three cases in a trailing six-month period in 30 targeted accounts. And in those 30 targeted accounts, we generated 205 cases and roughly $3.8 million in revenue. Now, 12 of those 30 target accounts were in that top-two high-volume center segments that I defined back in October of 2018 so-called innovation and performance, and 18 new accounts were in the third and fourth high-volume tiers. Those high-volume segments represented 91 new cases or roughly 44% of that new case volume. And so, we are diligently making progress, this is on the back of expanding support of evidence in LEOPARD and expanding support of evidence in ENCORE.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

All right. I appreciate the details there and I don't want to leave Dr. Thompson out [indiscernible] (00:36:47) could you just remind us of the ChEVAS, the study protocol, the number of patients, follow-up duration, et cetera, are there any other endpoints that are worth calling out? I'm sure you'll be tracking all-cause mortality, things like that, aneurysm-related mortality. But is there anything that you can provide us on the study protocol?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Sure, Matt. Actually, I can kind of point you now to ClinicalTrials.gov, so the abbreviated ChEVAS protocol is actually posted now as we get ready to start enrollment. That's kind of a requirement as we go through site activation. The [indiscernible] (00:37:24) 120 patients and the primary endpoints [indiscernible] (00:37:29) the typical short-term ones and then an effectiveness endpoint [indiscernible] (00:37:34) 50 sites, of which 15 can be outside of the US. And in reality, the study endpoints are exactly as you'd see in any of the more complex aortic study, so all-cause mortality, aneurysm-related mortality, [indiscernible] (00:37:54) and then, all the usual sac expansion and endoleaks endpoints that one would usually see.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

And I guess one last follow-up on that. Just conceptually, is there any reason why we shouldn't see – and I'm not going to hold you guys to it, obviously, but [ph] obviously (00:338:13) the mortality thing, the positive mortality thing that you've seen in the EVAS studies is encouraging. Is there anything – any reason why you conceptually wouldn't potentially see that same sort of benefit in the ChEVAS studies?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

No. Matt, I mean I think we're – if we kind of look at it historically, we're really still in the infancy of [ph] KATHERINE (00:38:33) clinical data on EVAS therapy. As John mentioned in the prepared remarks, we continue to see the same signal with regards to all-cause mortality in the EVAS patients and we're probably going to look very, very carefully at EVAR and ChEVAS patients. But no, you're quite right, conceptually we're using the Nellix

platform [indiscernible] (00:38:56) the same pressure. So, we've hypothesized that we'd see the same effects on all-cause mortality.

Mathew Justin Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. Thank you so much guys. Have a good evening.

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

A

Thank you, Matt.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Thank you, Matt.

Operator: We'll take our next question from Chris Cooley with Stephens.

Chris Cooley
Analyst, Stephens, Inc.

Q

Good evening and thanks for taking the questions. Maybe just with a quick housekeeping one for me [indiscernible] (00:39:22) and then maybe a bigger picture on Alto. So, just as we kind of level set expectations to start the year, cumulatively when we think about South Korea, the inventory step up in Japan and Brazil's decline, are we right to think about that as maybe reducing growth on an annual basis in the 3% to 4% range or $5 million to $6 million on a dollar basis? Just want to try and gauge the magnitude of the impact of that in the first quarter of 2020 here before we start to build the ramp throughout the rest of the year.

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

A

No. That's a great question. Chris, I think we historically have not provided kind of a cadence during the year – during this time around, right. We gave you the first quarter number, but we also wanted to give you Q2, Q3 and Q4 one were to expect. And as I mentioned on the prepared remarks, the goal from this at least $30 million number here in the first quarter to a mid-single-digit number for the second quarter, as I mentioned previously, just the pickup of $4 million to $5 million [indiscernible] (00:40:28) this is mostly distributor business which is under contract and has minimum [ph] strive to it, (00:40:32) that pickup alone is around $4 million to $5 million. So, that takes us to that number, and from there on, we got some growth in the US, because [indiscernible] (00:40:41) better than a lot of people that – the second quarter historically has been our largest quarter in the US business. So, there's a seasonal pickup.

If I were to go back and look at history, we've picked up anywhere from 5% to 8% from Q1 to Q2 in the US business alone [indiscernible] (00:41:01) sequentially. So, again, we still expect to be at least $145 million number, but then when you parse the detail on the $145 million and you look at the consensus for 2020, that number – US number is unchanged, where I got to point you, when you look at the OUS number, we're changing that number or dropping that number from $50 million down to $44 million. And if you do the walk on a normalized basis, you take out the impact of Japan, you take out the impact of Brazil and you take out the impact of Korea, you're essentially going on a normalized basis from $40.6 million in US to a $44 million OUS business, which organically is growing 8%.

Chris Cooley
Analyst, Stephens, Inc.

Q

Got it.

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

A

So, adjusting for the one-time impact, our US guidance is the same, our OUS number is actually up 8% versus the baseline normalized OUS business.

Chris Cooley
Analyst, Stephens, Inc.

Q

Thank you. That's super helpful. I appreciate that. And then, just as we look about your drivers for this acceleration in growth, obviously, you're assuming that Alto gets an early FDA approval and also approval in the EU. So, kind of along those lines, as we think about the ENCORE registry data, definitely seeing favorable results there in larger diameter aortas versus traditional endografts which haven't fared as well in that anatomy.

Could you just help us think about, one, the percentage of cases that would actually be applicable in terms of that definition and in what percent of those cases are being treated by EVAR right now versus open surgical repair? Just trying to kind of size what the incremental kind of sweet spot would be there for Alto as that starts to ramp. And then as a follow-on to that and I'll get back in queue, do you still plan to do an RCT for Alto at year-end? Then so, could you maybe talk us a little bit about the endpoints or some of the details there as well? Thank you so much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hey, Chris. This is Matt Thompson. I can't give you a breakdown by neck diameters yet, but broadly what we should think about is Alto increasing the flexibility on the label for the anatomic indications for use as the ring gets moved up, that obviously increases the proportion of patients that would be treated on label. And in fact, the sealing ring mechanism is pretty much the same as the [indiscernible] (00:43:34) so from a sort of pathological environment [indiscernible] (00:43:37) point of view one would expect to see exactly the same results with wide neck [indiscernible] (00:43:43).

And in terms of randomized controlled trial, we're absolutely committed to doing that and we have a timeframe at the end of the year to do that. I can't give you the exact study design yet, because we're still really putting the polish on the final version of that. But we're looking in the region of at least 300 patients in the [indiscernible] (00:44:07) a comparator arm similar to LEOPARD would include other commercially available endografts. And then, in terms of endpoints, I think we should think of that as being in two buckets, one would be the traditional clinical endpoints in terms of endoleaks, freedom from mortality, sac rates, et cetera, and you could expect to see that having an effect when we get on to three years. But also we have a hypothesis on the mechanism of improved potential durability [indiscernible] (00:44:42-00:44:50) and the study did call out adjudicated CT scans to actually try and show the difference between what one might call traditional EVAR and [indiscernible] (00:44:58) mechanism of Alto.

Chris Cooley
Analyst, Stephens, Inc.

Q

Thank you very much.

Operator: [Operator Instructions] We'll take our next question from Chris Pasquale with Guggenheim. Please go ahead.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. John, I wanted to start with your comment about the long-term outcomes of EVAR. That conversation seems to be getting more and more negative as the data matures, and yet in the slide deck, you guys continue to project mid-single-digit market growth going forward. So, first, do you think the market grew in 2019, because based on the two public competitors at least, it seems like it may not have? And then, what gives you confidence that at some point this drumbeat of concerning data won't lead to a bigger retrenchment in EVAR use and a shrinking of that pie?

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

A

Excellent question, Chris. We do believe that the market did grow very modestly in 2019. And we also believe based on not only the literature, but our contact with customers that very slowly, but very surely the recognition of the gaps in long-term durability of the EVAR are being recognized. Certainly, that's been described outside of the US with NICE as well as others. But the practice of healthcare typically is very slow to change. And so, we believe this change will take time. Accelerants to that change are favorable alternatives. We don't believe – we do believe that there may be a modest need to rebalance open surgery with EVAR, just simply due to the volume and percentage of off-label cases and the fact supporting that off-label use of EVAR [indiscernible] (00:47:13) points to the potentially disproportionately poor outcome.

Now, the second driver of change would be, obviously, the improvements to durability that is [indiscernible] (00:47:27) in the vascular approach and that is the reason for our company. We certainly believe that the evidence that is afforded by LEOPARD continues to defend AFX2 as a commercially viable alternative to conventional endografts. ENCORE points to a very compelling difference in treating large aortic neck diameters in the lack of difference in outcomes attributed to the various sizes of Ovation iX. And obviously, the subject of the Alto RCT as Matt described a moment ago is to really then further strengthen the ability to, first, show good and acute outcomes, then expand those acute outcome benefits to mid-term benefits of [indiscernible] (00:48:31) ultimately the endpoint that we're focused on is lowering, at a statistically significant difference, the rate of reintervention. The [ph] Columbo (00:48:46) paper clearly points to reintervention as a significant unmet need and the byproduct of that significant unmet need is this 20-fold increase of the likelihood of rupture based on reintervention. So, our drivers are to maintain an endovascular approach by providing a durability benefit comparatively.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. That's helpful. And then, can you talk about the process of rolling out Alto post-approval, will you be ready to go from a sales force and an inventory perspective on day one? And from a customer perspective, if the site is familiar with the Ovation Prime, how much training is going to be required before they feel comfortable with Alto? Thanks.

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

A

Yeah. It's a good question, Chris. And I've mentioned in prior public sittings that as a company, we have learned our lesson in introducing what would otherwise be the potential of a world-changing therapy and product by taking my our time with Alto, first, focusing on high-volume iX customers, as you suggest, the training of Alto with those customers should be modest, but it will be purposeful. Then, we want to shift our attention to lower-volume iX customers that are in high-volume centers.

We certainly want to, in the early stages of it's in production, establish very positive use experience with that second segment of customers in order to demonstrate our ability to gain share. And then, obviously, moving through the introduction targeting new customers who may have moved to iX and have either found it a bit cumbersome or any other potential reason for its discontinuation and really reintroduced the product, because [indiscernible] (00:51:01) mentioned earlier, both an ease-of-use advantage as well as indication expansion advantage that obviously favorably effects high-volume centers with the potential of capturing at least a small portion of the complex population on label. And we will be prepared in terms of inventory, training, customer and rep readiness.

Operator: At this time, there are no further questions. I would like to turn the conference back to Mr. John Onopchenko for closing remarks. Mr. Onopchenko?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and thank you, everyone, for joining the call. We look forward to updating you on our progress next quarter. Have a great evening.

Operator: Ladies and gentlemen, this concludes today's discussion. We appreciate your participation. You may now disconnect.