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Endologix, Inc. (ELGX)

Q1 2020 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix First Quarter 2020 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 call 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 site approximately one hour after the end of today's call.

Before we begin, I'd like to caution listeners that comments made by 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 the impact of COVID-19 pandemic on the company's operations, 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, 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 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and subsequent reports as filed by the company with 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, May 11, 2020. Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances after the date of this call.

In addition, today's discussion will include references to adjusted EBITDA which is 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 like to turn things over to Mr. John Onopchenko, Endologix Chief Executive Officer. Please go ahead, sir.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon everyone, and welcome to our first quarter conference call. Thank you all for joining us today and I hope you and your families are in good health. Not surprisingly, the ongoing COVID-19 pandemic and resulting economic destruction has had a material impact on Endologix. I'd like to take a moment and thank each and every one of our employees here at Endologix and our partners for the determination and flexibility they have shown over the course of the past two months.

Several of us are at different locations for today's call, so please bear with the logistical challenge that may accompany this change from prior earnings calls.

On today's call, I'll provide an update on the impact of COVID-19 on our results and product portfolio before detailing our response to this unprecedented crisis. I will then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our first quarter results, cost actions, and liquidity profile in more detail. After that, we will 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. Our latest business update, January and February saw a continuation of the operational momentum we had developed through 2019. Sales of AFX2 and Ovation were trending in line with our guidance early in the quarter before being significantly impacted by a decline in procedure volumes in the second half of March due to the broad deferral of the elective procedures in the United States, Europe and [indiscernible] (04:05) necessitated by the COVID-19 pandemic.

AAA procedures toe the line between elective and non-elective with larger diameter aneurysms and symptomatic patients receiving treatment for national guidelines and representing approximately 20% of cases that would be treated under normal circumstances. We took recommendations from the Royal College of Surgeons in the UK suggests that patients with AAA may consider deferral treatment for up to three months, plus will eventually require treatment. For this reason, I am confident that the bulk of the decline we have experienced in procedure volumes is driven by deferrals and not cancellations, and that many of these procedures will take place once hospitals begin to reopen for non-COVID-related treatment.

These unprecedented times has necessitated unprecedented action. The safety of our employees and customers is and always has been our top priority at Endologix. In response to this crisis, we have taken actions to create the safest possible working environment while also ensuring that there is an adequate supply of our products available to treat patients in need. We have continued to manufacture product at our production facilities in both Irvine and Santa Rosa under the exemption of the critical service in the state of California, while a lot of essential employees have been working from home since the issuance of the shelter-in-place orders.

With very few exceptions, only employees who produce our distributed product have entered our facilities. We have separated workstations in accordance with social distancing recommendations and improved our cleanliness practices including [ph] materially (06:08) disinfecting all surfaces within the facility. We now have

registered nurses stationed at both of our facilities that are responsible for screening each employee prior entrance while restricting entry and exits at each facility to facilitate optimal screening.

From a supply standpoint early on in the pandemic, we increased product availability in the field by shifting inventory to forward stocking locations from our warehouse in order to have it closer to our customers in case logistical or transportation difficulties arose. We have also taken a number of cost actions to manage operating expenses and liquidity, which Vaseem will review shortly. We continue to make progress against our operational and clinical goals, but these mitigation and cost actions combined with the ongoing uncertainty around procedure [ph] bargains (07:07) may result in changes to our anticipated timelines over the coming quarters. The timeline that Vaseem and I will discuss today are based on the facts as they currently stand, which as we all have seen are subject to change quickly and unpredictably.

Turning now to quarterly highlights including the status and timelines related to EVAS2, ChEVAS, Alto and Ovation iX. Total revenues for the first quarter was $28.5 million compared to $35.6 million for the same period in 2019 and was meaningfully impacted by COVID-19 in the latter half of the quarter. We were extremely pleased to announce this afternoon that we completed enrollment in our EVAS2 IDE or Nellix 3.5 on March 4, 2020.

In response to the COVID-19 and the related enrollment delays seen across multiple clinical trials, we submitted an IDE supplement to the FDA with a revised statistical analysis plan which aligned with the recently published FDA guidance document [ph] comes (08:26) up with clinical trials of medical products during COVID-19 pandemic.

Our submission proposed a minimum sample size of 95 patients with no alteration to define endpoints. The power of the two-year effectiveness endpoint has been reduced from 93.8% to 87.4%, but the power of the study where May endpoint remains – the power of the safety endpoint remains 99.9%. The power of both endpoints remains well above the 80% typically seen in this therapeutic area. We are now working on the PMA submission which we plan to submit shortly after the first 95 patients in the trial reach one year of follow-up currently anticipated in March 2021.

Turning to Alto. On March 16, we were excited to announce that we had received FDA approval on the basis of a panel track PMA supplement that included beta from the ELEVATE trial. Alto approval is a critical milestone for Endologix as we seek to introduce a portfolio of devices designed to address the current unmet needs of EVAR. Ultimately, differentiated EVAR device that offers significant design features that we believe will enhance ease of use, improve acute outcomes, and preserve the long-term durability associated with patient-specific anatomically adaptive sealing. We believe Alto's ultra-low profile and its 7-millimeter aortic neck length indication gives it the broadest applicability of any endograft in the US.

As a condition of approval for Alto, Endologix has committed to perform in two post market clinical follow-up studies. Once the protocol receives FDA approval, the first 100 commercial Alto implants will be included in a sizing study to describe aortic measurements and device sizing assessed on diagnostic CT scans by both the implanting positions and Endologix imaging services.

The second post market study will be designed to address device performance in the real world. We have designed a global prospective randomized trial to compare the performance of Alto to contemporary comparator endografts. The aim will be to prove superiority of the Alto platform across multiple parameters of performance, including an assessment of the aortic neck dilatation alongside traditional clinical endpoints.

In the EU, we are working to finalize the last set of test results and confirmation of the final IFU with NSAI, our notified body. Based upon what we know today, we are expecting final CE Mark approval for Alto by the end of June, although as I stated earlier, our timelines are subject to change as the environment remains fluid. We are also completing final production readiness for Alto across our supply chain ensuring that our component suppliers and those who produced certain [ph] some of (12:10) assemblies achieve on target performance.

In line with our previous comments regarding US introduction of Alto, our first phase will convert existing Ovation iX customers to Alto by effectively trading sties on the differences in advantages of Alto. We are targeting 40 high and mid-volume Ovation iX sites [ph] where used (12:36) proficiency in our 100-patient sizing study can be executed appropriately.

Given the current situation, our Alto training program has been designed to be delivered remotely using virtual classrooms and virtual reality simulation. By Q4, we would train and introduce Alto through remaining Ovation iX accounts and further develop site specific strategies to grow Alto's relative competitive position compared with Ovation iX base line.

Turning now to Ovation iX. In Q3 of 2019, we issued a field safety notice regarding polymer leaks with the Ovation iX platform. Since that notice, we have continued our investigation and have recently defined the root cause for the majority of polymer leaks, which is a material weakness adjacent to the polymer fill channel which maybe compromised during pressurization with liquid polymer. This investigation has been time consuming and technically complex due to the infrequency of the complication, and with regard the completion of this analysis as a significant achievement. The manufacturing and device design changes required to rectify the material weakness had been delineated and have already been incorporated on the Alto platform.

As a result, we believe that Alto will immediately decrease polymer leak rates compared to Ovation iX. It is our intention to transition customers to Alto in geographies where Alto is approved. Given our determination of root cause, we held a medical advisory board whose members suggested that a further safety update was warranted on the Ovation iX platform. This recommendation was made as the current polymeric leak rate, incidence of clinical harms and defined root cause is relevant for physicians when considering treatment options and that reaffirmation of treatment recommendation for polymer leaks into a responsible action.

We have been working collaboratively with our regulatory partners on the content and the implications of the update to the 2018 Field Safety Notification, which was issued globally last week. The update contains information on the reduction in clinical harms associated with polymer leaks since the 2018 notice. We remain confident of the risk benefit profile of the Ovation iX platform based on [indiscernible] (15:33), a real-world vascular registry, and our internal analysis of complaints.

We continue to work through the site activation process for ChEVAS in the expectation that clinical research will become increasingly viable as the year progresses. We have identified our first 15 sites for the ChEVAS IDE and expect two to three sites to be ready to enroll patients around the midpoint of the year. We anticipate starting enrollment in the second half of the year as recovery from the COVID-19 pandemic allow us. ChEVAS remains a priority for our clinical teams due to the considerable unmet need for patients with complex AAA in the US alongside developing aneurysm sealing as a paradigm altering therapy in the treatment of patients with AAA.

Lastly, we've recently also announced key additions to the Endologix team. On March 12, we announced Jane Kiernan's appointment to serve on the Endologix board. We are thrilled to add an executive of Jane's caliber to our board; I am confident that Jane's extensive industry experience both operationally and financially will be a key asset as we continue to pursue our long-term growth strategy.

On April 14, Tim A. Benner was appointed the company's Chief Commercial Officer. Tim brings to Endologix over a decade of experience in the medical device industry. Most recently, he served as General Manager and Division Vice President of the US region for Abbott's Structural Heart business with responsibility for sales, marketing, and the P&L across the MitraClip, Amplatzer, Surgical Valves, and TAVR franchises. Prior to that he spent nine years in Edwards Lifesciences and was a member of the senior leadership team. We're excited to have Tim on board and his broad commercial and strategic experience will be invaluable in taking our commercial team to the next level as we launch Alto and build out the Nellix platform.

In line with the broader medical device industry, the first quarter of 2020 was challenging. While we are continuing to see many of the same headwinds here in the second quarter, we are seeing signs of improvement in procedure volumes, which Vaseem will touch on in more detail. Despite limited visibility, we will continue to vet our assumptions and scenario plan in order to manage through these challenges and come out the other side of this pandemic.

And now, I'd like to turn the call over to Vaseem to discuss the first quarter of 2020 financial results as well as our cost and liquidity actions in response to COVID-19. Vaseem?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon everyone. Our total revenue for the first quarter of 2020 was $28.5 million compared to $35.6 million in the first quarter of 2019. As John mentioned in his prepared remarks, sales of AFX and Ovation were trending in line with our guidance for January and February before being impacted in March by the global shutdowns and the before look elective procedures related to the COVID-19 pandemic. US revenue for the quarter was $18.6 million compared to $22.8 million a year ago. International revenue was $9.9 million compared to $12.8 million for the first quarter of 2019. On a product line basis, global sales of both AFX and Ovation were impacted by the slowdown related to COVID-19.

First quarter gross profit was $15.1 million, representing a 53.1% gross margin compared to 65.2% in the prior year period. While some of this gross margin decline can be attributed to lower volume associated with the COVID-19 crisis, 700 basis points of the decline is related to an inventory reserve for AFX2 product that is expected to expire before usage in the first half of the year. This is driven by the lower case volumes expected due to the COVID-19 impact in the first half of the year. Excluding the impact of these one-time items, gross margin operationally would have been higher than reported. Total operating expenses for the quarter were $31.3 million compared to $35.2 million in the previous year's quarter.

In the past, we have discussed our plans to implement further cost control measures in 2020 to improve the overall operational profile of our business. In response to the abrupt onset of COVID-19, we have accelerated the implementation of these actions already scheduled for 2020 in addition to some temporary cost control measures.

Our key focus to improve liquidity has been supporting the manufacturing ramp up of Alto and all compliance-related programs. We do expect these cost management actions to impact deliverables and commitments we have made and as visibility until revenue improves, we will communicate those changes.

Net loss for the first quarter of 2020 was $18.1 million or $0.90 per share compared to a net loss of $22 million or $2.12 per share a year ago. Again, these results were primarily impacted by the slowdown of revenue related to the COVID-19 shutdowns in March. Adjusted net loss for the quarter totaled $16.2 million compared to an

adjusted net loss of $11.7 million for the first quarter of 2019. Adjusted EBITDA totaled a loss of $13.2 million for the first quarter of 2020 compared to an adjusted EBITDA loss of roughly $7.6 million for the first quarter of 2019.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were $42.2 million as of March 31, 2020, compared to $42.8 million as of December 31, 2019. The March 31, 2020 balance included $10.5 million outstanding under the company's revolving credit facility with certain affiliates of the Deerfield Management Company.

Our operating cash burn for the quarter was approximately $9.3 million. We continue to closely monitor and manage our cash burn and have taken the necessary steps that focus our cash expenses only on the most critical activities. As announced in the Form 8-K filed today, we received $9.8 million from the Small Business Administration as part of the CARES Act under the Payroll (sic) [Paycheck] (22:34) Protection Plan, also called PPP.

Turning now to guidance. On April 6, we withdrew our guidance due to the uncertainty surrounding the magnitude and duration of the impacts from the COVID-19 pandemic. Our visibility into the magnitude of these impacts remains limited, and therefore we will not be issuing guidance at this time. Since we are not providing guidance, I want to offer some additional color on our performance through the month of April in order to give you a better idea as to what we are seeing in the business.

Since the beginning of March, we saw six weeks of continuous declines in our case creation numbers. Our April US average daily sales was down 58% versus April last year and approximately 52% lower than February before the pandemic. The good news is that we saw an inflection in the mid-April and have now seen three weeks of sequential improvements although still well below where we were prior to the impacts of the pandemic.

We are also seeing a heterogeneity in case creation based on the extent of COVID-19 impact geographically. We attribute some of the improvements to certain hospital systems starting to treat patients beyond the prescribed emergent and symptomatic screening. As a result of COVID-19 related decline in our revenues and limited ability to accurately predict our recovery, revenue recovery over the next several quarters, our auditors have raised a [ph] growing concern doubt (24:04) related to our ability to satisfy our financial obligations for the next 12 months. We are taking actions to preserve liquidity so that we can continue to serve our customers without disruption.

Additionally, as a result of the impacts from COVID-19, we think it's highly unlikely we will achieve the conditions precedent in the required timeframe that were established as part of the February 2020 debt restructuring. We are actively engaged in discussions with our lenders to ensure we remain adequately funded through this period of temporary uncertainty so that we can continue to deliver the most innovative products for the treatment of AAA.

Lastly, I want to provide some color on the delayed filing of our Form 10-Q. We are working closely with our auditor to finalize the memo related to the complex debt restructuring transaction that occurred in February 2020. Most of the remaining work is related to documentation surrounding the debt transaction. And we do not expect any financial impact on our results posted in today's press release and the Form 8-K. We expect to have the Form 10-Q on file no later than the week of May 25.

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

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Vaseem. Once again, I would like to sincerely thank our entire team here at Endologix for all their hard work and ongoing commitment during this unprecedented crisis. This level of resiliency is what will allow the company to emerge from this crisis in a position strength as we continue our mission to transform aortic care for life.

Again, given the logistical challenges of being apart from one another, please allow me to direct the questions we'll receive from each of you today to members of my team who would best address each.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] We'll hear first today from Mathew Blackman with Stifel.

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

Q

Good afternoon, everyone. Thanks for taking the questions. To start, I wanted to flesh out a little bit how we should be thinking about 2Q. Appreciate the commentary on March and what you're seeing in April. But sort of on the most basic level, if I heard you correctly, really should start about thinking about the base being down 50% to 60% in March and that's sort of the starting point, and then we can obviously figure out what we think that sort of coverage trajectory is with what you're mentioning obviously some improvement in April. Is that the right way to – is the right starting point to think about how Q2 will shape up?

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

A

Vaseem?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. Hey, Mat. I think as I mentioned on in my remarks here, we did see some improvement in April. But again I qualified it with the fact that it's in its way below where we want to be, and we are way below where we were expecting to be before the pandemic. But we do see April, to your point, of being the 50% to 60% range decline and then start to see some sequential improvement in May, and then try – depending on how the hospitals have [ph] them start to do (27:32) some of the procedure volumes and things like that and how they prioritized EVAR and their OR capacity continue to see some sequential improvement in June. So that's at least a very imperfect way to kind of give you a sense on what we are hearing. And as John mentioned, all of this is subject to change, and we're all continuing to [indiscernible] (27:54) results. So, 50% to 60% reduction in April, sequential improvement in May, and then obviously better numbers in June.

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

Q

Okay. I appreciate that. [indiscernible] (28:05) sort of a list of a couple of other quick questions, John, you can direct them. Just observationally, if you just look at sort of the US and OUS growth performance or decline in the quarter, they're both fairly similar down 20%. So, again, as we think about sort of the recovery trajectory, is there

anything about US versus the OUS business sort of make one more likely to accelerate or re-accelerate faster? Any thoughts on how to think about sort of the geographic recovery from a US-OUS standpoint?

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

A

Mat, I'll take that, and then maybe have Vaseem fill in. I think it's important to recognize that the return to kind of pre-pandemic procedure volume we believe will be affected by five factors.

First is ultimately relaxing the size and severity on the [ph] debility (29:02) criteria for scheduling for AAA. Two is our ability to support cases without PPP or other site-specific restrictions like the testing of our reps. So far, we've been able to support our teams thus far. Third is the availability of the OR given the bolus of backlog in elective cases, and then again I believe we'll see a significant amount of heterogeneity. Fourth is I think a consistent high level of patient confidence in returning to a hospital to receive the necessary care. This has been a daunting observation with many healthcare providers and institutions. And then, the fifth relatedly is that ultimately the relaxation in the shelter-in-place is lifted thereby allowing family members to support patients into and out of their hospital stay. I don't believe there's been a significant difference in the effect of the pandemic regionally, but I'll let Vaseem highlight further if warranted.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. And I think on the numbers basis, Mat, what I'd say is you're right, I think Europe and US were kind of tracking in a similar fashion vis-à-vis some of the negative month-over-month or year-over-year declines. But I think when you look at the OUS market, I still think that some of the indirect markets are going to be under a lot of stress for the remainder of the year. I think the distributors are seeing their credit lines frozen. Liquidity is a massive challenge in Latin America, and they're very reluctant to take product. And second, the ability to pay is going to be impacted as well. So, I think outside of the impact of just the pandemic on procedure volumes I think there will be some more financial distress in some of the non-European, non-US markets, and that's a source of concern.

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

Q

Okay. Got it. That makes sense. [ph] And I can (31:15) speak two last points, and these are probably for you, John, so I don't think you have to pass them off.

Well, you sort of – you brought it up sort of the fight for cath lab time after some of these restrictions are lifted and resources are reallocated, if can you just remind us of the relative profitability of a AAA service line for a hospital versus other endovascular procedures? My recollection is that it's up there pretty high on some of the profitability side for hospital [ph] scheme (31:42), just help us with that.

And then [ph] might as well (31:44) for the last one in there, so as we think about coming out of this, do we have to be concerned about, say, price overall? I think the concern would be you compete against some much larger competitors with much broader portfolios, the question about their ability to bundle and what impact they may have on you in sort of a normal environment has always been out there. I just wonder if we should be even more sensitive now [ph] with all the issues (32:13), obviously, with hospital profitability and such that there could be bigger risk to pricing as we move forward in AAA broadly?

Thanks, guys. Appreciate it.

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

Sure, Mat. Let me start off and certainly defer to others. First, we don't see a significant threat to pricing at this point there, but again it is a pandemic and all resulting competitive actions have yet to be – make their appearance. But by and large, we don't see pricing to be a significant threat in the market, actions by the competitive markets at large had been relatively price buoyant through the last several years. Bundling is certainly a consideration, but I don't believe the underpinnings of why procedure volumes have declined would be favorably affected by an increased level of bundling. I think really it's a capacity constraint at the institution level.

AAA is a marginally profitable procedure by and large, and I believe that it is a disease state obviously that is not – is insensitive to the pandemic relative to its progression, meaning AAAs do not start to diminish in their growth rate as a result of obviously a pandemic, that continue to – these AAA patients continue to experience an increase in their diameter – size of aneurysm. And as a result, it will ultimately reach thresholds that can no longer be deferred, and therefore the delay is ultimately a transient condition and one that's not sustainable in the long run.

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

Right. That's all I had. Thank you.

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

Thank you, Mat.

Operator: We'll hear next from Marie Thibault with BTIG.

Marie Thibault
Analyst, BTIG LLC
Q

Hi. Thank you for taking the questions, and I'm glad you guys are doing well. One quick question on some of the cash containment measures you're making, perhaps this question is for Vaseem. I know in the past you had guided to about $130 million in operating expense for the year. Looks like you track well below that run rate for Q1, would we be wrong to assume that you've come in, if all goes as planned, well below that $130 million or is it too soon to say?

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

Vaseem.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Marie, thank you for the question, and glad you guys are doing well too.

So, listen, I think there is – as you saw, I didn't kind of break down the numbers for you guys. But yes, our operating expenses, we control the spend pretty hard here. And as much as we could, in the month of March, R&D was down 26%, [ph] clinical (35:27) regulatory was down 16%, sales and marketing was down 14%, G&A was up 7%, but really when you exclude the cost of the financing it was down 15%. So, we'll continue to watch it.

And as John and I mentioned in our prepared remarks, so these are unprecedented times, we hope that we can start to invest some money back into the business, into the Alto launch, into the manufacturing of ramp of Alto and making sure that we don't move any foundational work on the shelf. So – but it all depends on how the top line is going to do, and that continues to be a very big challenge vis-à-vis visibility.

So, I think we'll continue to manage expenses and cash as we have done in the years prior, and I hope [ph] probably (36:15) we have enough credibility on that. But the reality will be to see what the top line does, and that's going to drive our decisions around liquidity and cash. But till then, we are all bottoms up not spending too much on anything at this point.

Marie Thibault
Analyst, BTIG LLC
Q

Okay. That's great to hear. You mentioned Ovation also, I know you're about to enter Phase 1 of that launch. Can you tell us a little bit more about exact timing of that? Is that happening this quarter? Is it happening later this summer? And I'd be curious to hear a little bit about the stickiness of Endologix brands throughout this pandemic with some of the high volume centers given that was part of the strategy for growth going forward.

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

Yeah, Marie, it's John. You could look for us introducing Alto in that Phase 1 period by mid-year. As I mentioned in my prepared remarks, we have a sizing study to complete. In addition, the second clinical elements of our post market work will be the randomized controlled trial which the FDA will have visibility into. And then from there, it's obviously getting Ovation iX customers converted to Alto first with higher to mid-volume centers, and then eventually going in to the fourth quarter continue that to lower volume Ovation iX customers, and then really spending a considerable amount of time in developing what maybe modest to low volume Ovation iX use integrator Alto use competitively on route to obviously establishing broadened use proficiency and then ultimately identifying the sites that would help us do the randomized controlled trial, which is part of the upmarket strategy that we've described previously.

We believe the compelling reasons that support Alto's introduction, the design differences that we believe will translate into outcome differences, and that is the work that we want to engage high volume academic medical centers in helping us conduct.

Marie Thibault
Analyst, BTIG LLC
Q

Make sense. Last question from me on the EVAS2 trial now that it's completed enrollment, should we still look for a first peek at the data on some of those patients that [indiscernible] (38:56) this year whether it's virtual or in some other format or is that being superseded kind of by the one-year follow-up that you'll show in March?

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

Matt, are you going to take that?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Sure. Thanks, John. Hi, Marie. So, yes is the simple answer to your question. We still plan on trying to show the EVAS2 data that will be a substantial proportion of those 95 patients at one year. At least, we'll be [indiscernible] (39:24) one-year follow-up [indiscernible] (39:26) in March 2021.

Our focus now really in the trial is to ensuring that we get the best follow-up that we can with those patients given the challenging circumstances we find ourselves into clinical trials. But yes, we do plan to give visibility to the results in those end of this year.

Operator: Anything further, Marie?

Marie Thibault
Analyst, BTIG LLC

Q

[ph] No, that's it (40:02). Thank you.

Operator: [Operator Instructions] We'll hear next from JPMorgan's Robbie Marcus.

Allen Gong
Analyst, JPMorgan Securities LLC

Q

Hi, guys. This is actually Allen on for Robbie. I just had one quick question on kind of your OUS performance this quarter. I remember heading out of the last quarter that there were some puts and takes to your OUS business, you had kind of the one-time benefit from stocking in the prior year, you also had some headwind from Brazil because you pulled – I believe you pulled Ovation there, if I'm not incorrect, ahead of the Ovation, Alto approval in 2Q. So, I guess given how the quarter really did come in better than expected, and optically, it looks like actually kind of a thin line with the US business with respect to COVID, what really went better than expected there?

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

A

Vaseem?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So, listen, I think, as I mentioned, Allen, I don't think in the first quarter there were things kind of better than expected. We were tracking through the guidance that we have put out there. And if you remember, you're right to point out Brazil, one of the big walk from – walk items from Q1 to Q2 to go back to growth was the fact that we actually had no product to ship for Latin America. We made a decision last year to not restart the length of Ovation Prime which is what we were selling in Brazil, and we did not have regulatory approval obviously for Alto or Ovation iX. And then we also did not have regulatory approval for AFX2 because Brazil was the last market that was still continuing to take AFX1. So, again – so those were the walk items, if you will, to take us from the Q4 number down to the guidance of $30 million.

But in terms of kind of the puts and takes just still in the US business, I think it was tracking as expected for January and February and then obviously we hit the pandemic in the last three weeks of March. But just to give you guys an update on that, we still haven't received the AFX2 approval for Brazil, and that's going to be a continued headwind for the remainder of the year. And at this point, based on input from the regulatory bodies in Brazil and some of the challenges with COVID-19 there, we expect now AFX2 to ship sometime in the fourth

quarter after the regulatory approval. So that's really in a nutshell on what will happen in the US and kind of the impact on Brazil because of the AFX2 regulatory issues.

Operator: Anything further Mr. Marcus (sic) [Gong] (43:03)?

Allen Gong

Analyst, JPMorgan Securities LLC

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No, that'll be all. Thank you.

Operator: Thank you. At this time, I'd like to turn things back to Mr. Onopchenko for any closing remarks.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and again thank you everyone for joining us today. I hope, again, you and your families remain safe and in good health, and we look forward to updating you on our progress in the next quarterly earnings call. Thank you.

Operator: Again, that will conclude today's conference. Thank you all for joining us.