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Endologix, Inc. (ELGX)

Q2 2019 Earnings Call

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MANAGEMENT DISCUSSION SECTION

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

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'd 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 involve 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, we encourage you to review the Endologix Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2019 and subsequent reports as filed by the company with the Securities Exchange Commission (sic) [Securities and Exchange Commission] (00:01:22).

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, August 8, 2019. Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances after the date of this call.

With that said, I'd now like to turn the call over to John Onopchenko, Endologix's Chief Executive Officer. Mr. Onopchenko?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon everyone, and welcome to our second quarter conference call.

Today, I'll provide a brief overview of our second 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 second 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 second quarter as our focus on execution continues to drive incrementally positive operational and financial results. Total revenue grew sequentially in the second quarter and we had solid contributions from both Ovation and AFX2 as our team continues to leverage positive outcomes data. Operationally, we had an active quarter that included several developments related to Nellix, Alto and ChEVAS which I will discuss in further detail in a few minutes.

Near term, we continue to execute and work diligently to stabilize then grow sales of Ovation and AFX2. As I have said before, accountability is the center piece of our culture and a key factor in maintaining this level of execution. I am pleased with the strides we have made in the first half of the year. Looking forward, we are positioned well to achieve our 2019 financial targets, and our team remains committed to sustaining this momentum through the back half of the year.

I will now turn to our quarterly highlights. Our total revenue for the second quarter was $36.2 million representing a 19% year-over-year decrease. Our U.S. business realized strong sequential growth in Ovation for the quarter while continuing to stabilize AFX2. We are effectively managing attrition while continue to make meaningful progress on base business case coverage and increasing our presence with high-volume customers.

Our OUS commercial teams delivered a solid first half performance and consistent with the teams in the U.S. continues to leverage our expanding body of clinical evidence to secure cases and gain credibility in the marketplace as we steadily advance into high-volume centers. We continue to make solid operational progress against our goals for operating expense and cash burn and we remain confident that our efforts to strengthen our balance sheet have provided us with additional flexibility as we continue to execute against our long-term strategy.

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, AFX2 and Ovation. First, turning to EVAS2 IDE, we are now entering the last phase of Nellix EVAS2 U.S. trial and have 32 sites able to enroll patients with another three sites in the final steps of activation. Enrollment for the trial currently sits at roughly 70%, and we expect to see enrollment increase over the next few months as we approach the maximum number of participating sites. Our cadence of enrollment has steadily increased since the trial commenced and this pattern gives us confidence that we will complete enrollment of this trial by the end of the year.

Additionally during the quarter, we announced the reinstatement of our Nellix CE Mark in Europe. This reinstatement was granted following our submission to our EU notified body of the latest evidence demonstrating positive outcomes achieved by the Nellix system when appropriately used within the anatomical indications for use. Concordant with our announcements in January of this year, the Nellix system will be made available for use outside of the U.S. at approved centers in a post-market clinical investigational setting.

Within the U.S., the Nellix system remains an investigation device as part of the EVAS2 study. We are pleased with the reinstatement and we remain confident that when used within the indications for use, EVAS will prove to be a transformational therapy that can more effectively treat patients with abdominal aortic aneurysms. That said, we do not expect the reinstatement of the CE Mark to have a meaningful impact on revenues in 2019.

Turning now to Alto. We are in the process of submitting our written responses to what we believe are the remaining open questions from the FDA in regard to our approval submission. I would like to stress that this is a normal step in the approval process as the FDA analyzes all of the available data. Our ongoing conversations with the agency have been constructive and collaborative and we remain confident in our ability to address the FDA's recent deficiency questions and that Alto will receive FDA approval. However, we will experience a short delay in approval timing relative to our prior expectations as we submit our responses to these questions. We now expect Alto approval in the U.S. in early 2020. Additionally, we are still on track to receive Alto approval in Europe before the end of the year.

I am pleased to announce that as you hopefully saw in our press release this afternoon, we have received IDE approval from the FDA to begin a new pivotal study to evaluate the use of ChEVAS in the treatment of AAA in complex anatomies. This study will recruit 120 patients with complex AAA in up to 50 centers both in the U.S. and internationally and we plan to begin enrollment in early 2020. We are genuinely excited to commence this study as we believe ChEVAS is truly innovative product that will bring more effective treatment to a large segment of the AAA market where only 34% of patients treated received endovascular therapy through limited and highly heterogeneous treatment approaches.

Next, I'd like to discuss the distribution agreement with Boston Scientific that we announced in conjunction with earnings earlier this afternoon. We recently signed an agreement naming Boston Scientific, the exclusive distributor of Endologix products in China beginning with AFX2, but eventually including all of the products in our EVAR and EVAS portfolio. China represents a roughly 200 millionend-user market opportunity for EVAR and EVAS and we are excited to partner with Boston Scientific, a company with extensive experience of introducing products for the treatment of vascular disease into this large and strategically important market.

Our teams will work closely together in order to establish a strong EVAR and EVAS brand identity in China leveraging Boston's scale, established distribution network in the region and proven track record of success in the vascular space. We also view this as a validation of our technology and our ability to draw the market to us by way of our focus on outcomes data. We are currently working through the regulatory process in China and we will continue to update you on our progress in this exciting venture as we move forward.

Complexity in our business is a function of both products and markets and sometimes we need to make decisions that simplify the business in order to position us better for the long term. An example of a market-based choice we recently made is exiting South Korea where likelihood of profitability was low and primarily driven by reimbursement. Over the past 12 months, we have shown that we are taking a disciplined and strategic approach to our portfolio and to the geographic areas that we serve in order to improve execution and profitability.

Lastly, turning to AFX2 and Ovation iX. As I mentioned earlier, AFX2 continues to stabilize as our team utilizes a growing body of clinical evidence to drive sales with our customers. We remain confident that this clinical evidence will continue to prove that AFX2 produces equivalent overall outcomes when directly compared to other EVAR devices, while combining ease-of-use and anatomically-adaptive attributes that customers have valued for many years. We see an ongoing trend that support AFX2 stability in the back half of 2019, at which point, we can turn our focus to growth across the portfolio.

We continue to expect sales of Ovation iX to improve over the course of the year as we receive very positive customer feedback and continue to build on the case for change based upon 16 peer-reviewed publications, 12 in the last two years that showed large proximal aortic neck diameter is associated with adverse outcomes and that include data from Medtronic's ENGAGE and Gore's GREAT Registry.

ENCORE evidence shows that our largest aortic body versus four smaller-sized aortic bodies have equivalent performance against four key EVAR outcomes: freedom from device-related reinvention, freedom from rupture, freedom from AAA-related mortality and freedom from all-cause mortality. While our execution in the first half of the year was solid, we recognized that there is still significant work to be done in order to return to sustainable long-term growth. We made several key strides in this regard during the quarter and we remain focused on reinforcing a culture of accountability in order to drive continued on time, on budget execution and rebuilding credibility with customers and shareholders.

In the back half of the year, we remain and maintain our focus on executive while continuing to generate data that support the superior outcomes of our next-generation EVAR and EVAS products. We are well-positioned to achieve our targets for 2019 and we further our mission to transform aortic care by providing differentiated products that enables 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 second 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 second quarter of 2019 decreased 19% year-over-year to $36.2 million compared to $44.7 million in the second quarter of 2018. U.S. revenue decreased 19.9% to $24 million in the second quarter of 2019 compared to $30 million a year ago. As we noted last quarter, the expected decline was driven by the impact of previous commercial restructuring.

And as John mentioned, we are effectively managing attrition while continuing to make meaningful progress on our base business case coverage, leveraging our technical data and increasing our presence with high-volume customers. Second quarter international revenue was $12.2 million, declined 17.1% compared to revenue of $14.8 million in the second quarter of 2018. This is largely driven by a smaller OUS footprint as a result of the exiting smaller and less profitable markets last year as part of the reset.

On a constant currency basis, our second quarter 2019 international revenue decreased 14.8% year-over-year. On a product line basis, we saw global sequential growth in Ovation system sales, which is encouraging as we work towards our stated goal of driving sequential sales growth in 2019. Sales of AFX were down single digit sequentially but we continue to see tangible evidence of stability.

Second quarter gross profit was $23 million, representing a 63.4% gross margin compared to 66.2% 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 to – continue our efforts to drive better turns and working capital improvements.

Total operating expenses for the quarter were $32.9 million compared to $45.1 million a year ago, which is a 27.2% reduction year-over-year. Our improved expense management continues to drive operating costs lower

which gives us confidence that we can achieve our previously communicated 2019 OpEx guidance and reduce our overall cash consumption.

Looking more closely at the second quarter operating expenses on a year-over-year basis, marketing and sales expenses were down 24.6%, research and development expenses decreased by 30.2%, general and administrative spend decreased 36.3% and our clinical and regulatory expenses remained roughly flat as we continue to make investments in our pipeline and work to bring new products to market.

Net loss for the second quarter of 2019 was $27.1 million or $1.62 (sic) [$1.50] (00:17:01) per share compared to a net loss of $23.9 million or $2.83 per share a year ago. The net loss for the second quarter of 2019 includes $11.8 million loss on debt extinguishment related to the debt restructuring we announced on April 1, 2019. This is a noncash charge that reflects the change in valuation of the amended debt facility with Deerfield, partially offset by a gain on the debt of extinguishment related to the exchange of a large majority of the 3.25% convertible senior notes originally due in 2020.

Adjusted net loss totaled $6.6 million compared to an adjusted net loss of $15.6 million for the second quarter of 2018. Adjusted EBITDA totaled a loss of $5.6 million for the second quarter of 2019, compared to an adjusted EBITDA loss of $9.3 million with a second quarter of 2018.

Moving to the balance sheet. Our total cash, cash equivalents and restricted cash were $52.1 million as of June 30, 2019, compared to $24.7 million as of December 31, 2018. Our operating cash burn for the quarter was approximately $6.8 million which represents a nearly 50% improvement compared to our operating cash burn in the first quarter as we benefit from the impact with the seasonality of our spend as well as from our conscious efforts to improve our DSOs as a result of better collections.

With year-to-date operating cash burn of roughly $20 million, we remain on track to achieve our full year cash burn target. As we have discussed previously, our $20 million annual operating cash burn target is predicated on a $30 million operating cash burn offset by $10 million of working capital improvements. We anticipate that our cash burn to improve in the second half of 2019 and we remain on track to reduce our cash consumption in the fourth quarter to less than $5 million as previously communicated.

As we had previously discussed, we want to give you an update on our debt to equity conversions 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 of our 2024 convert holders and $25 million with Deerfield was subject to a mandatory conversion to our common stock. These mandatory conversions happen when certain conditions are met. We are happy to report that we converted approximately $3.3 million of our debt in the second quarter that resulted in us issuing approximately 500,000 additional shares. These new share issuances are included in the 17.4 million shares outstanding at the end of the second quarter.

As of July 1, 2019, an aggregate of approximately $42 million of the original $50 million are remained subject to these mandatory conversion features.

Our overall debt is down approximately $8 million in the second quarter. We will continue to provide you updates every quarter if and as these conversions happen.

Now, turning to guidance. We are reiterating 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 range of $130 million to

$140 million. For the third quarter of 2019, we expect revenue between $35 million and $37 million. This reflects the seasonality of the third quarter, but our goal remains to drive sequential growth in the third quarter.

Overall, our second quarter performance down the P&L provides a great base for the rest of 2019. We are pleased with our performance in the quarter and remain committed to executing on our strategic priorities that we laid out at the Investor Day in October last year, especially our culture transformation, focus on accountability and the high say/do ratio.

And with that, I'll turn the call back to John.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Vaseem. This marks the fourth consecutive quarter since our reset one year ago in which we delivered on our commitments for revenue, operating expenses while addressing the near-term balance sheet overhang. We continue to work collaboratively with the FDA as we adjust out to approval to early 2020, and are excited about the approval of the ChEVAS IDE in what will be a landmark study in the category.

We are also excited about our new partnership with Boston Scientific and the valuable work we will be doing together in China. We are pleased with the reinstatement of the CE Mark for Nellix and reaffirming our commitment to EVAS2 where we are entering the last phase of enrollment.

Finally, we believe that AFX2 stability is on track in the second half of this year on the heels of sequential growth in the Ovation platform globally. Our ability to secure new users and high-volume centers is taking hold with promising early results.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. We'll now be conducting a question-and-answer session. [Operator Instructions] One moment, please, while we poll for questions. The first question is from Mathew Blackman with Stifel. Please go ahead, sir.

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

Q

Good afternoon, everyone. If I could start maybe in China, what do you need to do exactly to get regulatory approval? It doesn't seem like with the 2021 timeline for commercialization that there would be a significant trial or a new clinical data requirement, I just wanted to make sure. And John, you gave us the size of the market. Can you just remind us how many players are in the Chinese market? Who's there? Is the market growing? And any color on the economics for the distribution agreement fee and then I've got one quick follow-up.

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

A

Well, Mat, thanks for the question. As you most certainly know, there is the clearance that a company needs to achieve just like with any country or region. But then even after clearance, you need to be able – you need to establish yourself on regional tenders in China. And then finally, after establishing regional tenders, you need to achieve local hospital listings in order to ultimately commercialize the product. That takes time. That's the reason for the timeline that we've cited.

The players in China include obviously the players that are in the U.S. and the rest of world, Medtronic, Gore, Cook. In addition, there is MicroPort which competes in China and there is a number of local national players within China to make it obviously a fairly competitively robust country.

Growth rates are in excess of 8% on a year-to-year basis. It continues to be a very attractive market in terms of the percentage of cases that remain as open procedures versus endovascular procedures. And like the rest of the world, complex is the largest unmet opportunity with virtually less than 30% of those cases now being treated to an endovascular approach.

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

Q

Okay. That was really helpful, John. I appreciate that. And then just shifting to the Alto, how impactful is this the way, not obviously so much on 2019, but as you're likely still going to undertake a controlled launch without or next year, does it dampen it all how you're thinking about the growth outlook for 2020? And I guess, relative to your comment about being able to grow above market in 2020, how should we think about this delay relative to that commentary? And thanks so much.

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

A

No, my pleasure, and thank you for the question again, Mat. So, as I've messaged previously, we are going to introduce Alto in what I would generally describe as a crawl walk run fashion. Job one is to first establish used proficiency beginning with our current Ovation iX customers. Then it's to expand use with existing Ovation iX customers that are using Ovation iX infrequently and then ultimately, it's to expand use in high-volume centers

that gives you a sense of kind of the purposeful and stepwise progression through the introduction. This delay does not represent material financial impact to Endologix in either 2019 or in the way we are considering in terms of assumptions for 2020.

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

Q

All right. Thank you, guys.

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

A

Thanks, Mat.

Operator: The next question is from Richard Newitter, SVB Leerink.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Hi. This is Jaime on for Rich. A quick question to start, you guys are kind of citing the – that you're still effectively managing the attrition. I was just curious, did that impact the AFX sales in the quarter because it seems like you guys are saying that it took a step down this quarter, but you're still expecting to stabilize in the back half. So, could you just share a little bit about what happened in the quarter? Do you still consider the sales force there stabilized? And how should we think about that trending between 3Q and 4Q?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Jaime, let me take a crack at it, and John can kind of follow up. So, I think from an attrition perspective, I think we've done a great job managing it all through the year, especially post the reset. In my comments when I talked about AFX that it was a steady decline. It was actually a decline that was better than expected on AFX, especially here in the U.S. So, again, if you remember what we had talked about that what we effectively want to do is stabilize AFX in the U.S. and the definition of that stability is that we would expect to see revenues from Q2 equal Q3 and Q4 as a sign of stability and on the heels of that stability we would have sequential growth on Ovation that would lead us to growth in the second half of the year. So, really we are on track to do that.

The AFX performance was better than expected here in the second quarter, and in the third quarter and in the fourth quarter on the heels of that flattening of the AFX business, as I mentioned, Ovation continues to drive sequential growth and we had double-digit sequential growth with Ovation. So, listen, I think the product lines are doing as expected here and we continue to march that path towards growth in the second half of the year.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Okay. And then just one follow-up. On gross margins, it came in better than we were modeling and I think the [ph] Street (00:29:01) as well. So, just curious how we should think about that trending over the back half of the year? I think previous commentary was saying that it should step down for the remainder of the year. So, just trying to get a sense of if the sequential step down between the first quarter and second quarter is the fair way to think about in the back half of the year as well? Thanks.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Absolutely. So, I think as we have messaged in the past and exactly the same pattern as last year, it's kind of the way our business has been kind of operating, especially with some volumes that we have seen in the declines. So, really, the 63.4% gross margin was down 2.7% versus last year and was down 1.8% versus the first quarter. And really, the delta there between the expected performance and the actuals has been some of our manufacturing variances, and the fact that we continue to manage our costs better through the supply chain. So what we would expect to see is this – these revenues to kind of continue to – sorry, the gross margins to stabilize in the third quarter, and then have a big decline in the fourth quarter, essentially when we turn our inventory and the variances actually have flown through the P&L. So again, we are not changing the previously messaged gross margin and the 60% range for the total year.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. You're welcome.

Operator: The next question is from Joanne Wuensch, BMO Capital Markets. Please go ahead, ma'am.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yes. Hi. This is Matt Henriksson in for Joanne. Congrats on the nice quarter. Just diving a little deeper into the international results, I heard the commentary about how the markets that you exited over the past 12 months was a contributing factor. But when you look at the first quarter results in international, they were kind of flat. And so, I'm kind of trying to figure out what made the first quarter results better than the second quarter results there. You mentioned the exiting of the South Korea market, did that have an impact? And how was the momentum in Japan so far?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure, Matt. Again, as we had mentioned, that 12.8% number that we posted in OUS in the first quarter, we had said it was going to be the peak of the number and we would continue to see declines in that business. The second quarter number is 12.2%, which was down 18%, it's purely the seasonality of our strength – of our revenue and also some timing of our distributor orders in the second quarter of last year. So, we expect that number to kind of, again, stabilize and kind of add that $12 million to $13 million number for the remainder of the year. And again, we should expect to see some better comps on the heels of the restructuring and some of the exits that we did in the second half of last year.

So, like I said, I expect to see some positive [indiscernible] (00:31:56) in the international business year-over-year, but at the same time on a dollar basis, I don't think you see any acceleration beyond the numbers that we've been at the second half – in the first half.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. And then just anything on South Korea exit, how that's going to potentially impact the second half?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So, really, no change, no impact on our guidance. I think as John said, we continue to look at us – our business on a portfolio basis and we're being opportunistic. And as you hear the news about China, we're opportunistic to get into the second largest market outside of the U.S. But at the same time, in the less profitable markets, we are continuing to monitor these markets for durability of the growth and the profitability of these businesses, and Korea was a great example of where the business case did not make any sense in light of the lack of reimbursement in that market and we decided to pull out and restructure that business in the first quarter and the second.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. And then just my follow-up question, you are in the 12 months now of restructuring, what have you viewpoints been of the market? Have you still seen kind of that mid-single-digit growth in traditional AAA with high-single-digit growth in the complex cases? And then, how has the competitive landscape changed during those 12 months? Thanks very much.

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

A

The market growth rates are in line with what you've just recited, Matt. Not a significant change there. Competitively, we continue to see Gore advance its competitive position globally at the expense of Medtronic as well as Cook. There are clearly signs that as we approach more high-volume customers that long-term outcomes in EVAR continue to surface as an important conversation and our focus on making an impact, a positive impact on those long-term outcomes are resonating well with those customers. And so, again, I think we are making our advance with our differentiated products on the back of evidence and that evidence we believe is what's going to make [ph] them (00:34:26) a meaningful difference in, not only the uptake of our products, but ultimately the long-term outcomes that they would favorably represent.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay.

Operator: The next question is from Robbie Marcus, JPMorgan. Please go ahead. Mr. Marcus, your line is open.

Q

Hi. Sorry. Can you hear me? This is...

Operator: We can hear you now, yes.

Q

... [indiscernible] (00:35:06)

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

A

Hey, [ph] Alan (00:35:07). Yes.

Q

Sorry about that. I just had a quick question on China. I get why you guys are going out with AFX, but given the kind of strong uptake that you've been seeing with Ovation, I guess I just wanted like dig a little bit into your rationale behind maybe going with AFX over Ovation as you [indiscernible] (00:35:27) the [indiscernible] (00:35:27) market. And given that you are going with AFX, how quickly do you guys think you can get Ovation also out in that market?

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

A

We've been working on AFX2 in China for a bit of time. We think it's an important product to enter the market with. As we've cited globally, it is a product that has been cited by our customers as very easy to use and adopt. We think that's important in establishing our initial footprint. And then, on the heels of that, we certainly want to prepare for submissions in our subsequent product portfolio. But again, it's a stepwise entry beginning with AFX2.

Q

Got it. And then, I know China probably is not the only geography that you guys are looking to enter. Is this kind of distribution agreements, something that we should expect to see more of? Or is China just – it's pretty well-known that China has a fairly difficult kind of environment for getting approvals and really succeeding commercially. So, is this a China-specific strategy or is this something that we could see in other or U.S. markets as well? Thanks for the time.

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

A

My pleasure, and thank you for the question, [ph] Alan (00:36:52). So, markets the size of Japan, markets the size of China, it is – it became clear to us that in order to affect our presence, we really had to do it with a sizable partner so that the complement of our differentiated portfolio could be met with a significant footprint presence and immediate credibility, which in Japan is represented by JLL today, our most commercially productive partner, a terrific partner to work with, and now featuring Boston Scientific in China.

There's one thing to enter the market. It's quite another to, in essence, have reach in that market that is going to be meaningful and not take a long period of time the way you would otherwise think of local, regional distributors in typically smaller markets. So, it was very purposeful that we needed to have a partner who could effectively compete against the likes of Gore, Cook, Medtronic and MicroPort and others in order for us, obviously, to realize the benefits of that large market.

In terms of other markets that we would consider, it's again part of our ongoing portfolio conversation, be it products or markets, nothing more to report on our thinking beyond how valuable it is to enter with scale.

Operator: [Operator Instructions] We have a question from Matt O'Brien, Piper Jaffray. Please go ahead, sir.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Hey. Thanks, guys. This is Kevin Farshchi on for Matt O'Brien. My first question is – I mean looking at the results you mentioned that in the – throughout the year, very impressive as you've increased sequentially for the last four quarters and in addition to the outlook for Q3. So, just wanted to tease out some of the factors here as we're in the middle of the year. So, one, can you share the growth rate on Ovation in the quarter? I know you mentioned AFX was down single digits. And curious within that platform, did you see some more engagement post Charing Cross and ENCORE? And then secondly, in addition to that last attrition, are you seeing rep productivity improving? Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So, Kevin, listen. First of all, we haven't given out product line details or the actual growth rates kind of midyear. We do that as a matter of process at the end of the year so that you guys can get your models right. But like I said, we did have a low-single-digit decline in the U.S. on AFX, which was I think really better than expected.

And then U.S. Ovation was actually up double digits. So, we're really, really happy to see the sequential performance on Ovation to be that double-digit growth rate. So, it continues to take market share, and the underlying business continues to strengthen. And that's also a function of a lot of the work that's happened in the second half of last year with the restructuring and actually all of the retention plans and the actual underlying execution improvements that we made here in the first half of the year.

So, John, I don't know if you want to add to that.

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

A

Yeah. Kevin, I think it's important to perhaps add a little color around the first half. We secured – and as we've been messaging this [ph] march up (00:40:53) market, in the first half, we secured actually 77 new users and we defined a new users as physicians who have either never done a case with us or it's been over a year since they've performed a case. Those 77 new users completed 106 cases with us. And 59 of those came from 44 new users who practice in our upmarket targets of both innovative and performance hospitals. So, again, we've made a purposeful effort, and it's slowly starting to reflect in progress in using not only the differentiation of our product but as importantly or more importantly the value of our ENCORE data in order to appeal to the need of producing more durable long-term EVAR outcomes.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Thank you. Really appreciate the detail. My second question is jumping back to the Ovation, Alto moving that back with the question, do you have any just high level, I know you can't share everything but any high level thoughts just on the visibility you have on when the questions might wrap up, how did you get to early 2020 for that? And then I have one follow-up.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hey, Kevin, It's Matt Thompson. So, I have just to give you some color on the Alto PMA. So, I think everyone knows that, yeah, my review is always a very rigorous and collaborative process with the FDA. And it's really not unusual at all for the FDA to have a number of questions towards the end of the PMA and particularly at the 100-day meeting. So, we have some open items at the moment that we are working through. We're very confident we have good answers for all of our open questions, but we will need to submit those formally to the FDA. And we're hoping that we can get the clock restarted again in Q4 this year.

At the moment, I can't really share any details about the specific nature of those open questions though.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Okay. That's helpful. Thank you. And then, the – I wanted to touch also on the clinical side of EVAS2. You guys moved it back a little bit, and I know it's not by much, but anything to point out there? And then, with that study enrollment done and the reinstatement of CE Mark that you got back in June where you showed the outcomes on protocol were much better, this could be a stretch, but do you think that's going to bode well for enrolling ChEVAS in the U.S. faster than you had expected originally with more awareness of the therapy? Thanks so much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Yeah. So, Kevin, let me give you some color on EVAS2 to start with. So, as John said in the prepared remarks, we are coming really to the final aspects of that trial at the moment. We've now really currently got the most sites open we've ever had in the trial. And then, we expect to see enrollment increase as we kind of get to the finish line there. We're about 70% enrolled in the trial at the moment so we've got a really good line of sight to finishing that.

The CE Mark is, of course, a help, having an independent authority, actually, review the submission we sent them and get confirmation that the results of the platform when used, according to the anatomical indications for use, is encouraging. That certainly has given a little bit of an extra confidence boost to EVAS2 sites in the U.S. who are now able to have very detailed conversations with their patients.

With regard to ChEVAS, it's kind of really too early to say anything there about enrollment rates. We are obviously very pleased that many years of hard work have come to fruition with the approval of the IDE and the pivotal study, we're very excited about entering into the complex space, where as we know, there's relatively few alternatives at the moment to treat these patients on label, and you can expect us to give you some color on ChEVAS and its potential milestones going forward.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Thanks so much.

Operator: There are no further questions at this time. I'd like to turn the call back over to Mr. Onopchenko for closing remarks. Mr. Onopchenko?

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you very much, operator, and thank you all for joining us for the Q2 2019 call. Look forward to updating you with Q3 in the near future. Thank you very much.

Operator: This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a good day.