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Endologix, Inc. (ELGX)

Q1 2019 Earnings Call

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MANAGEMENT DISCUSSION SECTION

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

As a reminder, this 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 the call.

Before we begin, I would like to caution listeners that comments made by the management during this conference call will include forward-looking statements within the meaning of federal securities laws. These forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the company's actual results, performance, and 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 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 2, 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 first quarter conference call. Today, I'll provide a brief overview of our first quarter 2019 results, discuss our top priorities for the remainder of 2019, and provide an update on our product portfolio. I'll then turn the call over to our Chief Financial Officer, Vaseem Mahboob who will review our first 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'm pleased with our solid performance in the first quarter as we continued to achieve results consistent with the goals that we first outlined nearly a year ago. Our culture has embraced the power of accountable performance across each function and in every geography. In addition to our solid financial performance during the quarter, we recently strengthened our balance sheet by raising $52 million in cash, refinanced the majority of our 2020 convertible debt and renegotiated our financial covenants with Deerfield Capital. We believe these actions have granted us the necessary cash and balance sheet flexibility to build sustainable long-term success.

With increasing frequency there is growing evidence that conventional EVAR is consistently falling short of eliminating device related re-intervention and aneurysm related mortality. EVAR has met the challenge of enabling more patients to survive an initial aneurysm repair, but the long-term outcomes that patients are facing which are directly related to the devices that they have been implanted with, remains very challenging.

However, the outcomes-based evidence supporting the use of Endologix products, as well as our commitment to expanding and strengthening that evidence is bringing the market toward us in a meaningful way. The first group of medical professionals to respond to our use of evidence as our basis for competing is from the highest volume most data-driven customer segment. This group simply wants better solutions and is prepared to upgrade from the status quo in order to improve quality of life for their patients.

Our team remains committed to maintaining our high level of execution, building off of our solid first quarter results, and continuing to drive operational and financial improvements throughout the year.

I will now turn to our quarterly highlights. Our total revenue for the first quarter was $35.6 million, which was in line with our pre-announcement and represents a 15.8% year-over-year decrease. Our U.S. business continues to stabilize, as we see attrition risk being effectively mitigated. We had no regrettable losses within the U.S. aortic account management team and continue to monitor this key driver of sales performance closely.

We continue to make meaningful progress on increasing our presence with high volume customers. Overall, our commercial team is hitting stride at all regions. EU, capital and U.S. are all performing well after the consistent adoption of our go-to-market thrust, which is leading with evidence.

As I mentioned earlier, we also delivered on one of our key objectives for the year by raising $52 million in cash and refinancing the vast majority of our 2020 convertible debt, addressing a major balance sheet overhang for our equityholders. I am very proud of our team and very thankful to our partners who worked tirelessly to get this deal done. I firmly believe that our investors will begin to see the rewards of strengthening clinical evidence, improved execution and a healthier balance sheet going forward.

Now I'd like to give you an update on our current product portfolio including the AFX2, Ovation and our U.S. EVAS2 IDE trial. Regulatory approval for Alto in both U.S. and Europe remains on track and we continue to

anticipate the introduction of this exciting product in the back half of 2019. As we have said before, we expect sales of Ovation iX to improve over the course of the year as we continue to receive very positive customer feedback, manage the FSN's impact constructively and continue to build and share the strong clinical evidence represented by the ENCORE registry.

With regard to clinical evidence, there were two key podium presentations at the recent Charing Cross Symposium in the late-breaking trial section. Professor Verhagen shared the latest findings from the ENCORE registry that investigated the clinical performance of patients treated with the largest size of the Ovation platform in comparison to smaller sizes. The registry data report that the largest size of Ovation endograft did not experience more late failures in comparison to the smaller sizes in contrast to traditional EVAR. This implies a different mechanism of action to the usual self-expanding stents when protecting the proximal neck from a loss of proximal seal and again suggests that the Ovation platform may be expected to provide excellent durability which would solve a clear unmet need within EVAR.

Dr. Schermerhorn presented new data illustrating a significant reduction in all-cause mortality after a patient is treated with EVAS as compared to a patient treated with EVAR. These new data were concordant with the VQI analysis that was presented at Charing Cross last year and we regard these findings of having the utmost importance for the evolution of EVAS as a therapy we continue to drive evidence-based improved outcomes for AAA patients.

With regard to Nellix enrollment in our U.S. EVAS2 IDE trial is progressing nicely. Momentum is building and we remain on track to complete enrollment in the third quarter of 2019. Additionally, we are continuing to discuss with our Notified Body in Europe, GMED, the best way of introducing Nellix back into clinical practice in the EU. Discussions are ongoing and we plan to confine the therapy to patients who meet the anatomical indications for use under a clinical trial protocol as well as compassionate use. I'd like to reiterate that we see no discernible impact from the CE Mark suspension on our U.S.-based Nellix trial.

To provide an update on ChEVAS, we continue to have constructive conversations with the FDA regarding the study design and testing plan for our ChEVAS IDE and have resolved most of the issues with this complex trial. We continue to anticipate approval toward the middle of the year and initial enrollment to follow shortly thereafter.

As I mentioned earlier, AFX2 continues to stabilize as we advance customer acceptance of the comparative strength found in the LEOPARD study. As we continue to lead through evidence, it is important to recognize that AFX2 is the only endograft in the history of EVAR that has been benchmarked against contemporary comparators in a randomized clinical trial. The level one clinical evidence from the LEOPARD trial continues to show that AFX2 has a freedom from aneurysm related complications that is similar to competitive endografts and trends toward better performance in some outcomes such as graft occlusion.

While we recognize that there is significant work ahead, I am very pleased with the financial and operational performance delivered during the quarter. We have made several key strides toward driving sustainable performance and renewing our credibility, as we continue to deliver against both near and longer term targets.

Our mission is to treat more patients suffering from this life threatening highly heterogeneous disease and have each of our patients realize a superior outcome that's maintained for the rest of their lives. We want to achieve this level of outcome performance with unmatched consistency. Our aim is to elevate EVAR and realize the vision EVAR pioneers described over 25 years ago.

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

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon, everyone. Our total revenue for the first quarter of 2019 decreased 15.8% year-over-year to $35.6 million, compared to $42.3 million in the first quarter of 2018. U.S. revenue decreased 22.4% to $22.8 million in the first quarter of 2019, compared to $29.4 million a year ago. The expected decline was driven by the impact of the previously communicated commercial restructuring.

These results reflect solid execution in the field as well as our ability to manage both the impact of the field safety notices and the sales attrition due to the restructuring. And as John mentioned, we did not have any regrettable losses in the U.S. aortic account management team and are now pivoting to performance management recognizing the ongoing commercial risks.

First quarter OUS revenue of $12.8 million remained nearly flat on a reported basis compared to our first quarter of 2018. On a constant currency basis, our first quarter 2019 OUS revenue increased 2.7% year-over-year, driven by solid performances in our capital markets, primarily the strength in Japan.

On a product line basis, we saw global sequential growth in both AFX and Ovation system sales which is encouraging, as we think about our stated goals of driving sequential sales growth in 2019.

First quarter gross profit was $23.2 million, representing a 65.2% gross margin compared to 67% in the prior year period. The decline versus prior year is driven primarily by unfavorable geography mix, driven by sales decrease in the U.S. We are also seeing the impact of lower overhead absorption as we continue to lower our inventory to manage our cash. We have been actively managing our variable costs and direct labor spend to mitigate this reduction in volume and we'll continue to monitor for the remainder of the year.

Total operating expenses excluding restructuring for the quarter were $34.8 million compared to $41.2 million a year ago, which is a 15.5% reduction year-over-year. This is the result of our purposeful cost management and our restructuring efforts last year.

Our successful cost reductions this quarter follow a similar performance in the back half of 2018. This gives us confidence that we can achieve our previously communicated 2019 OpEx guidance and reduce our overall cash consumption.

Looking more closely at our first quarter operating expenses, marketing and sales expenses were down 22.7%; research and development expenses decreased by 12.9% year-over-year and general and administrative spend decreased 9.2%. Our clinical and regulatory expenses increased 6% year-over-year, reflecting continued investments in building clinical evidence in support of our anticipated new product introductions.

Net loss for the first quarter of 2019 was $22 million or $2.12 per share, compared to a net loss of $19.8 million or $2.36 per share a year ago. Adjusted net loss totaled $11.7 million compared to an adjusted net loss of $12.9 million for the first quarter of 2018.

Adjusted EBITDA totaled a loss of $7.6 million for the first quarter of 2019, compared to adjusted EBITDA loss of $7.8 million for the first quarter of 2018.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were $10.9 million as of March 31, 2018 compared to $24.7 million as of December 31, 2018. Our cash burn for the quarter was approximately $13.8 million, driven by largely our 2018 bonus payout combined with some timing shift in our U.S. collections. We realize that this level of cash burn is higher than the $10 million to $12 million which we were expecting and a big portion of our $20 million target for the full year.

However, the $20 million annual cash burn target is predicated on an approximately $30 million of total cash burn for the total year 2019, offset by $10 million of working capital improvements. The working capital improvements will be driven by our conscious efforts to drive down inventory and improve our DSOs. We do expect to see some benefits of those working capital improvements in the second quarter, but we anticipate that the vast majority of that benefit won't be reflected in our financials until the second half of this year. We remain confident in our ability to achieve our previously discussed full year cash burn target of approximately $20 million and expect to reduce our cash consumption in the fourth quarter to less than $5 million.

As John mentioned earlier, we also addressed significant balance sheet and operational overhangs during the quarter by raising $52 million of gross proceeds in an equity raise, refinancing the majority of our 2020 convertible debt and renegotiating the terms of our financial covenants with Deerfield. Specifically, our largest 2020 convert holders agreed to exchange approximately $73 million of the 3.25% 2020 convertible notes for approximately $67 million with the new 5% convertible senior notes due 2024.

Additionally, we amended our agreement with Deerfield to lower the 2019 trailing 12 month net revenue covenant from $130 million to $119 million. We also lowered the 2020 to 2023 trailing 12 month revenue covenant to $129 million, down from the prior covenant of $140 million. However, these covenant changes do not have an impact on our revenue guidance of at least $140 million for the year. These adjustments improve our overall capital structure, allowing us the balance sheet stability and flexibility to focus on growth and execution moving forward.

Additionally, making our financial covenants less restrictive should provide investors with increased confidence as we continue to improve our operating structure and focus on generating durable revenue growth.

Turning to guidance, we are reiterating our previously provided guidance. In 2019, we expect revenues of at least $140 million, while operating expenses are anticipated to be in the range of $130 million to $140 million. For the second quarter of 2019, we expect revenues of approximately $36 million.

Overall, our first quarter performance represents a solid start to the year and 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 plan.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. We will now begin the question-and-answer session. [Operator Instructions] Our first question comes from Mathew Blackman with Stifel. Please go ahead.

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

Q

Good afternoon, everyone. I got a couple of questions, maybe to start. John, on the fourth quarter call you commented that you were able to move from defense to offense. I was hoping you could provide a little bit more detail on what that means practically speaking for reps specifically, what are they able to do now that they couldn't do before?

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

A

Matt, thanks for the question. It's less about what they were not able to do before, it really reflects the position that we are now taking, which is we needed to retain our reps, getting through the transition period of obviously the restructuring and the impact of the field safety notices. And then in that process, we built a competitive, tiered incentive plan for the commercial group and we were setting expectations around our culture of accountability of making and meeting commitments.

And so the shift is really toward purposeful performance management of how each of our representatives and specifically a verdict account managers and clinical specialists are performing against their stated objectives and in the case of a verdict account managers, the clear assignment of moving upmarket with their growth targets. So it's moving from, in essence, retaining folks during a turbulent time or a more turbulent time to now expecting high levels of performance as we're executing against our strategic plan.

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

Q

Okay. That makes a lot of sense. Just a couple of follow-up questions on the pipeline starting with Alto and the second half 2019 launch. You've talked about it being a "controlled launch", just curious how you define the controlled launch? Is it fair to characterize that you'd start with the highest current volume ovation accounts?

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

A

Well, two things there, Matt. First, we want to take existing high volume ovation accounts and establish proficiency, given the changes between iX and Alto. In addition, we certainly want to target new growth accounts where, again, job one is establishing proficiency. We want to take our time with that because, first and foremost, that initial use experience is critical in overcoming a significant amount of counter-detailing headwind that is ever present. And with that positive initial use experience introduces the propensity of continuing to adopt at ever increasing rates or ever increasing penetration within any given account. So nothing but a very purposeful and thoughtful introduction to the product. The ambition is not to see how many accounts we can open. The ambition is to ensure that when an account is targeted and opened, we're penetrating those accounts before moving to the next.

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

Q

Okay. And then one last question. It's a little bit further out obviously, but just curious thinking about that the next-gen Nellix, what can you tell us about, at least conceptually about the new design, obviously hoping to address the migration issue. But should we think about that product as potentially serving similar or maybe even broader IFU than current EVAR devices. Just give us a flavor of sort of what the concept is and what you're trying to accomplish with that device?

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

A

Sure. First, it's a critical understanding of the failure modes that it led to obviously us requiring a subsequent confirmatory trial of EVAS2 under a narrowed field of use. I think the most important criteria entering the design of the product is really a clear separation of fixation from sealing, from sac management. Before, and with Nellix, often times physicians found themselves needing to trade-off between those three requirements in order to complete a case. Instead with next-gen EVAS, we want to make sure that each of those important steps in a procedure are fulfilled to the highest quality possible. And so there isn't any trading off or a competition for an offset of one to the betterment of another. That's probably the biggest takeaway I'd like you and others to keep in mind as we advance the development of next-gen EVAS.

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

Q

All right. I appreciate it. I'll get back in the queue. Thanks again.

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

A

Thank you.

Operator: The next question comes from Matt O'Brien with Piper Jaffray. Please go ahead.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Thanks, John and Vaseem. This is Kevin Farshchi on for Matt today. Congrats on the continued momentum. I think my main question is on the outlook. Now that we're kind of in the middle of the year, the attrition seems very low and stable. You have financial flexibility. It seems like we got a little bit of color on the Alto launch. I just wanted to see if you could remind folks how much of that [ph] flour baked (25:10) in the Alto launch. You're going to go and do ahead of $140 million if you take the quarter and assume zero sequential growth, which I'm assuming will not happen. So, how do you think about how much the launch could contribute for the year and then just have one follow-up?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So Kevin, listen, thanks for the question. The way we're thinking about it is, as we have said that it launches in the second half of the year, so whether it launches in Q3 or Q4. But as John mentioned here, we don't expect a huge meaningful uptake for Alto here in the year. We'll probably make sure that we introduce it the right way, drive the right efficiency and eventually the right adoption. And as you think about what we had said at the beginning of the year, the $140 million base was kind of predicated on the fact that we manage some of the risks

that we had identified at the Investor Day, and then at JPMorgan. What we are really thinking about here is, how do we kind of accelerate the adoption of our new strategy which is to kind of [ph] march up market (26:20) into some of the high volume centers. And if we can drive the right amounts of productivity and right amounts of penetration, that helps us get above the $140 million.

So, again, I think we have done a great job managing the risks here in the first quarter and also in the second half of last year after the restructuring. And as an example, attrition which we feel really confident about and I talked about as being more a performance management approach now versus a risk management approach, we'll continue to look at the second quarter, and that experience in the second quarter will give us a lot of comfort about what the second half looks like. So I'm really optimistic about where we're going. But at this point, I'd say that the $140 million above or $140 million plus is the right way to think about the business, and we'll continue to monitor the risks ahead of us.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Okay. That makes a ton of sense. I just wanted to ask a higher level market question, kind of, how you're seeing the traditional EVAR in the U.S., now that you're more data-driven, you're more focused on some of these higher volume centers? And you mentioned earlier in the call how long-term outcomes kind of remain subpar and you're seeing that this is device specific. So really the question is, how much room is there to go on the utilization front from what you're seeing in some of these growth accounts? And then, what do you think needs to happen in terms of your commercial or clinical education efforts to convince some of these growth accounts that, hey, we can really show you some of these longer term outcomes and it's going to matter and you're going to be able to further penetrate within traditional EVAR. Just wanted to get a little pulse on what you've seen thus far in your learnings? Thanks so much.

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

A

Sure. Matt (sic) [Kevin] (28:12), it's John Onopchenko. I think, if you allow me, I'd like to share two separate customer experiences recently both of which I've had the privilege of being involved with and both of them involve leading academic medical centers and each resulted from the efforts that we started last year in segmenting and targeting in order to really distill down for each aortic account managers this year's plan of five growth targets.

And so the first example is an experience with a physician at an academic medical center in the Western U.S. In addition, the same physician performs cases at a nearby VA Hospital. Now, this physician had used Ovation previously only twice over the course of 2017 and 2018 and his reasons for not using it more frequently were that there were limited data available and he believed that to be a technically challenging product to deploy. And frankly he chose as those initial cases really a challenging reversed tapered neck presentation and late last year, we initiated multiple conversations with this physician of explaining the why behind the design of Ovation paired with now the evidence in the form of five-year ENCORE data. And I got to tell you these initial conversations had intrigued the physician enough, had committed a day to come to our Santa Rosa facility in late January, meet with myself and the local team that accompany them. He gained a better understanding of the evidence and he also saw the manufacturing process where Ovation is created first hand.

And I got to tell you, I've now witnessed this several times. When physicians see how the device is created, it is quite a remarkable experience. Additionally while we were in Santa Rosa, he completed a successful simulated Ovation device deployment which is a huge step in uncovering why he initially believed it was technically challenging. And so, you think about it, the value of being able to spend time purposefully describing the why behind each of the steps in the process of deploying the endograft and the thinking behind each of these steps, it

demystifies and greatly reduces kind of the initial reaction that our competitors feel about being a technically challenging procedure.

So the knowing why when you spend the time in the simulated deployments greatly impacts how the device is perceived. The visit also allowed him to better identify appropriate Ovation patient selection. And then with this knowledge that he gained literally over the course of just a few months, he incorporated Ovation into his practice and I'm pleased to say he's completed five Ovation cases in the last 60 days. And then when asked why he had begun to integrate Ovation in his practice, and by the way, he is also now an active EVAS2 site. He cited a few reasons. First, he was able to treat more patients on IFU, thanks to the low profile and trackability of the device. Second, he now has a better understanding behind the science of sealing. He says that, "it just made logical sense." We believe that it's currently the only device that does not cause aortic neck dilatation based on the five year data and the subsequent rates for re-intervention type 1 and no neck expansion.

And third, he told us that he truly appreciates why we're the only company that is actively trying to improve the technology in the infrarenal EVAR category. As an academic in – in academic medical center obviously teaching and evaluating and investigating is central to the mission, we're the only company that's doing the kind of market research and indication expansion. And so it was a great fit. So in this case data education including simulated deployments and a positive early use experience, encouraged this physician to expand the use of Ovation fairly quickly and the benefits were obvious to him.

I'd also share a kind of a second experience. Again, this one includes both AFX2 as well as Ovation. I recently connected with a physician from a large Northeast teaching institution. He had been an active user of AFX2 through every generation of products since 2005. And he traditionally used AFX to really treat niche anatomies that he deemed uniquely suited for our unibody design, but then over time began to use a product less and less and then actually used it in zero procedures in 2018.

And our team keeping track of this late last year and into 2019, the team began to be more persistent in leading with evidence and had a really a two-pronged approach. First, the use of ENCORE and Ovation in hospital neck anatomy and then AFX2 in LEOPARD for those traditional niche anatomies that now were no longer being adopted. And then based on this approach as well as the data demonstrated in LEOPARD, and by the way, it's a study that he participated in, this physician once again began utilizing AFX2 in the same patient anatomies that were previously known to benefit from our design. He participated in LEOPARD and he believed that the data supported the continued use of the graft.

And with respect to Ovation, the team increased this physicians interest by showing him the long-term data that demonstrates the durability of seal and as a leading key thought leader at this institution, he has seen many failures of [ph] EVAR (34:50), particularly in hospital neck anatomies and he did expressed that despite 20 years of EVAR he still sees kind of a learning curve and how to improve the long term durability as an opportunity, particularly since patients are living longer. So he believes the durability of seal in the lack of aortic neck dilatation demonstrated an ENCORE, shows real promise for polymer based technology. But in fairness, he also believes more study is required, which is again directly in lockstep with how we see moving forward with customers just like him.

So, again, the evidence that supports the increased use of our product in traditional and challenging anatomies with our evidence-driven approach is taking hold. We believe that we're on the right path. Both of these physicians want to provide their patients with the best possible outcome. Next step in EVAR performance is moving them toward adopting our products both traditional as well as polymer based with increased frequency. So, again,

there's clearly more work to do Matt (sic) [Kevin] (36:00), but we do have no doubt that we are on the right path and the data is backing this up.

Kevin M. Farshchi
Analyst, Piper Jaffray & Co.

Q

Thank you so much. Extremely helpful.

Operator: The next question comes from Richard Newitter with SVB Leerink. Please go ahead.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Hi. This is Jaime on for Rich. I have two questions, so quickly just to start off. On gross margin, it came in a little bit better than expected. So I was just curious if you could provide any additional color on how we should be thinking about that cadence for the remainder of the year.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So, Jaime, let me take a crack at that. So as I mentioned in my prepared remarks, the margins came in nicely higher than where we were at the end of fourth quarter obviously with the big Nellix recall and the inventory write-off we took at that time. The year-over-year reduction was really driven by the geography mix, primarily shrinking of our U.S. business which is down 22% but it was offset by some favorability in our mix in Japan. But really the year-over-year change that is driven here is also a significant part of our conscious effort to drive down inventories, manage our absorption quite frankly, and we have done a pretty good job with addressing the head count both in Irvine and in Santa Rosa on the direct side. But as volumes have come down, we saw the pressure on the year-over-year basis.

But on a go forward basis, listen, I don't think it's going to be a higher uptick versus where we are. To the contrary, I think we'll probably continue to see some pressure in our margins as we head into the second half of the year because we are making trade-offs. And as I mentioned on the cash management piece, taken inventories and our working capital improvements to contribute $10 million to our cash burn reduction, we'll see continued pressure on gross margin. So again, it came in slightly better than expected. But I expect these to taper off towards the 60% range for the year.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Great. That's helpful. Thank you. And then just another quick question strategically. I saw on your catalyst slide that you guys have, under product approvals, initiate Ovation in Japan. So, I was just wondering if you guys could provide a little bit more color on your strategy and efforts that you're doing there? What we can expect from timelines and potentially how much growth opportunity does this present for you guys in that market? Thank you.

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

A

Hi, Jaime, it's John Onopchenko. Thanks for the question. Some context obviously, Japan and JLL represents a significant growth driver for us. We've reached mid-teens share in Japan with a single product, AFX2. That very same product obviously is – we're in the midst of re-establishing its presence with the customers in the U.S., EU and Latin America.

And as a reminder, customers of Japan never experienced AFX Strata. So with Ovation Prime, we're excited about approval of this category of defining leading technology-based platform and as well as the evidence that supports its durable and consistent performance. But we also have a responsibility to make sure that its use is really safeguarded by establishing a tightly controlled limited release. Again, building proficiency because it will be their first use of polymer enabled EVAR and so that also includes a respect for the unique failure modes of that device. So again, the approach initially is to build proficiency slowly with few customers that we can then penetrate before we expand.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Okay. But just a follow-up on that, so is that an approval that you already have in hand and you're just getting ready to roll it out or you're still waiting on the approval?

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

A

Well, to be even more specific, while we have approval for the commercialization of the device, we've probably got another five-and-a-half months before customers will receive reimbursement for the product, which then further informs why it is such a controlled release initially.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Got it. Thanks.

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

A

Yeah.

Operator: The next question comes from Joanne Wuensch with BMO Capital Markets.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yeah. Hi. This is Matt Henriksson in for Joanne.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hey, Matt.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Just following up on the international markets, you highlighted Japan as a positive driver. How did the rest of Europe perform during the quarter, especially those that kind of have remained as your legacy countries?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, Matt, obviously we messaged at the Investor Day on some of the changes that we have made on our global footprint, right. We've narrowed the number of countries not only in Europe but also OUS, in our capital markets. So the headline, listen, the capital markets or the OUS markets performed as expected and maybe even slightly better than expected, but are down significantly primarily because of the restructuring that we did not only on the number of countries but also as we have messaged in the past, we took our commercial head count in Europe down 40% when we did the restructuring last year. So where we were expecting slightly better than expected, but again aligned with the plan that we have that was tied to the guidance of at least $140 million.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Understood. And then following up with Ovation Alto, kind of a two part question. First, is there any update that we should expect between now and the kind of announcement that you received approval? And then also kind of with the controlled launch, how many procedures does it take for a surgeon to be kind of, okay, I'm comfortable with Ovation Alto and then you guys can go and start training those next physician or the next hospital?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hey Matt, it's Matt Thompson. Hi. So in terms of what you should expect nothing really until we announce approval. In terms of controlled launch, that is a question that obviously depends on the physicians experience to start with, how familiar they are with the Ovation technology, their infrastructure in the hospital and everything else. So there is no simple answer to what's a learning curve, because it's very heterogeneous across the surgical fraternity. In terms of generalized ability, however, Ovation is slightly different to EVAR grafts that are based on self-expanding modalities. So we would like to see most people get through five cases before we move away from pre-approval of cases and from careful supervision.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

That's very helpful. Thank you very much.

Operator: [Operator Instructions] The next question comes from Robbie Marcus with JPMorgan. Please go ahead.

Q

Hi. This is actually [ph] Alan (43:53) on for Robbie. Thanks for giving the question.

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

A

Hey, [ph] Alan (43:55).

Q

I guess just for, kind of looking at your full year guidance, I think now that we have first quarter out of the way, we have your second quarter guidance on hand. It looks like your third quarter and fourth quarter you really are

pointing towards a return to, kind of, like the kind of like low to mid single-digit growth, which if you look at the traditional EVAR market, you are just right around there. So I guess the question I have is, once we get past that, go into 2020, you get Alto out albeit in limited launch, maybe start capturing some of that faster growth in complex AAA. And you obviously have AFX2 also stabilized. Where do you think like we should be thinking about growth for say 2020 and beyond? Or do you think the kind of like mid to high single-digit range is correct, kind of, starting point for those years or why or why not?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, [ph] Alan (44:48), thanks for the question. Listen, I think we've had three really solid quarters where we have outperformed consensus and our own guidance and are really proud of that. I think we have managed the headwinds vis-à-vis the FSNs, the attrition risk that we were seeing, but at the same time, listen, there's a lot to go from where we are today even at that $36 million 2Q guide to returning back to growth in the second half. And I think that's predicated on some serious execution especially driving Ovation sequentially and then stabilizing AFX in the U.S.

So, I would love to sit here and give you a number for 2020 and say that here is what we think is going to happen in 2020. But honestly, I think it's too early to kind of comment about 2020. We're still focused on stabilizing the business executing on what we have committed for the year. And while the early read is very good and we're very confident, I think it's too early to throw [indiscernible] (45:55). So I just defer that for now and I think at the end of the second quarter when we come back to you guys, I think we'll have at least two quarters and a few days of experience, I think we are in a better position to give you a good answer on your question. I think it's a great question. I just don't have the answer at this point.

Q

Got it. And then I guess kind of touching on a question that was actually asked before and kind of like – maybe like little bit on the competitive front, right. Obviously not kind of – it's pretty well known that your competitors are definitely not innovating as much as you guys are even though the complex AAA market is pretty underpenetrated and definitely lacking in innovation. So I guess, is there anything that you think competitors are doing on that side maybe even early clinical trials, early testing? And if not, why don't you think that these competitors are really maybe kind of missing out on this opportunity? Thank you very much.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Hey, [ph] Alan (46:50), it's Matt Thompson again. I just wanted to maybe highlight one of the evidence pieces John referred to that was presented at the Charing Cross Symposium. So there's a lot of attention being given at the moment and particularly by our competitors to treating patients who have a wide aortic neck. So, there have been probably somewhere in the order of 15 to 20 publications in the last 12 months to 18 months showing that with traditional self-expanding endografts. If you look at the outcome of patients who've received the biggest size of those endografts and compare them to patients with smaller sizes, the patients with the wide aortic necks are doing very much worse in terms of degeneration of the proximal neck type 1 endoleaks migration.

And you'll be aware of how competitors have different solutions for those whether that's the use of staples in the neck or whether it's the use of complex fenestrated grafts. I think what our presentation at Charing Cross showed is that there is no such differential performance with Ovation and if you use polymer sealing, you can actually, in fact, simplify the procedure and use that infrarenal graft rather than reverting to a more costly, a more complex

and a much more difficult procedure that our competitors are posing as a solution for those patients. So I think that's a good example of how innovation in this field can actually simplify the solutions posed to patients and therefore gives them better outcomes.

Operator: This concludes the question-and-answer session. I would like to turn the conference back over to Mr. Onopchenko for any closing remarks.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you very much, operator. And thank you all for joining our Q1 2019 call. We look forward to catching up with you next quarter. Thank you.

Operator: This concludes today's conference call. You may disconnect your lines. Thank you for participating and have a pleasant day.