Corrected Transcript

25-Feb-2019

Endologix, Inc. (ELGX)

Q4 2018 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Fourth Quarter and Fiscal Year 2018 Earnings Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions]

As a reminder, this conference is being recorded. This conference call is also being broadcast live over the Internet at the Investors section of the company's website at www.endologix.com, and a 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 management during this conference call will include forward-looking statements within the meaning of federal security 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 March 13, 2018 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 accurately -that is accurate only as of the date of the live broadcast, February 25, 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 would now like to turn the call over to Mr. John Onopchenko, Endologix's Chief Executive Officer. Thank you. You may proceed.

John Onopchenko

Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator, and good afternoon, everyone, and welcome to our fourth quarter conference call. Today, I'll provide a brief overview of our fourth quarter and full-year 2018 results, discuss our top priorities for 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 fourth 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 a supplemental slide deck on our Investor Relations website directly below the webcast link.

Onto the business update. I am pleased with our solid performance in the fourth quarter and second half of 2018, as we achieved the annual targets set at our Investors' Meeting in October, driven by a team that is dedicated to a culture of accountability. While there's still plenty of ground to cover, the team's execution against the strategic plan that we laid out on our second-quarter call and then again at our Investors' Meeting, fosters confidence that we are trending in the right direction as we enter 2019.

Our team is committed to maintaining our executional focus and to driving operational and financial improvement throughout the year.

I will now turn to our quarterly highlights. Total revenue for the fourth quarter was $34.7 million, which was in line with our pre-announcement, representing a 21.2% year-over-year decrease. Our U.S. business outperformed in the quarter, driven by a lower-than-anticipated attrition and effective implementation of the Ovation Field Safety Notice to improve patient outcomes while our OUS business performed in line with expectations. Attrition remains a critical focus; nonetheless, we are shifting from a defensive position to an offensive position and have instituted a consistent application of performance management that now has us back to managing out under performance.

Revenue for the full year was $156.5 million, slightly better than the $155.8 million that we pre-announced in January, but representing a 13.6% decline compared to 2017. Despite this decline, we continue to see encouraging signs of improvement, consistent with our plan for the back-half of the year. Our second-half performance provided a solid foundation from which to grow and I am confident that we can build on this performance and continue to improve in 2019.

It was another productive quarter for our commercial team. In the U.S., the implementation of our territory-specific sales force plan is now in place. We now have a clear understanding of the volume, share and pricing by customer, enabling us to effectively target sales growth in specific higher-volume centers, while maintaining our base business in 2019 and beyond. Specifically, each of our aortic account managers averages roughly nine growth target accounts. Each growth target account averages over four traditional EVAR procedures per month, compared to our base accounts which averaged just over one procedure per month. Sales calls and targeted growth accounts have grown to nearly 40% of total calls, ending the year.

I'm pleased to announce that in early January, we also welcomed a new member to our executive team, Chief Commercial Officer, John D. Zehren, who has a strong track record implementing world-class commercial processes and driving consistent, impressive results. We look forward to John's complementary leadership and expertise, as we continue to stabilize and then improve sales of AFX2 and grow Ovation in 2019. We believe that this improved execution will continue through 2019 and beyond.

And now, I'd like to walk you through our five key objectives for this year. First, we're going to enhance the balance sheet and the overhang it is creating for our equity holders. Vaseem will provide you with more details on this shortly. Second, we will meet our top-line commitments beginning with the U.S. and Japan, our two largest homogeneous markets. We are moving more purposefully into higher volume centers, challenging incumbencies with the need to improve EVAR outcomes, and engaging centers and advancing existing and new clinical studies that will increasingly create positive momentum globally.

Third, we believe that we will secure clearance in both the U.S. and EU for Alto with a highly-targeted introduction focused on establishing large customers one at a time, without diversifying too broadly or too quickly. We anticipate launching Alto in both the U.S. and Europe in the second half of 2019, and are convinced that the long-term outcomes using our unique patient-specific sealing capability offers meaningful and durable advantages over traditional EVAR. We have plans to prove these claims in a direct comparative study using the methodology of a randomized controlled trial.

Fourth, we are aiming to complete enrollment of EVAS2 by the end of Q3 and have secured agreement from the FDA to enlist additional sites to help us achieve this objective. Fifth, we plan to initiate enrollment in our ChEVAS IDE this year. We have had a productive dialogue with the FDA over trial design and plan to submit our IDE imminently. We are starting site selection now for the global ChEVAS study and anticipate approval of the trial design in the first half of the year. We have reprioritized several critical projects and now anticipate that next-gen EVAS first-in-human will occur in 2020, which is a slight delay from our previous guidance of late 2019.

As we complete these objectives, we firmly believe that our investors will begin to see the rewards of improved execution and a stronger balance sheet.

Now, I'd like to give you an update on our current products, including Ovation in Japan and the recent withdrawal of Nellix CE Mark in Europe. Last week, we received regulatory approval for the use of Ovation Prime in Japan. As is typical in the Japanese market, we expect that re-imbursement will trail this approval by roughly six months and expect that to occur in the second half of this year. I'll note that this is a market where physicians are not well-versed in the use of polymers, so it will be a very tightly controlled release, as clinicians build proficiency in the use of Ovation.

With regard to Nellix, as we recently disclosed on January 22, we received an update from our Notified Body, GMED, that our CE Mark for the Nellix system had been suspended. This news followed a voluntary recall and field safety notification issued by Endologix on January 4, 2019, and is not a response to any new information beyond this Field Safety Notice. I'd like to reiterate that the voluntary recall will have no material impact on the company's overall revenue in Europe. Additionally, I want to stress that this will have minimal impact on our U.S.-based Nellix trials. Clinicians will continue to treat patients under investigational umbrellas, including the EVAS2 IDE, which we expect to complete enrolment in the third quarter of this year.

As I've said in the past, we believe strongly that Ovation, Alto, Nellix, ChEVAS and our next-generation EVAS platform are the future of endovascular aortic repair. Traditional EVAR has reached the limits of its potential and our portfolio offers the only set of differentiated solutions that address the unmet needs that are persistent over 30 years of EVAR.

Interestingly, at a recent Critical Issues America Meeting, the first two sessions of the meeting were dedicated to the unmet needs of EVAR with regard to the durability issues now being identified with grafts based on self-expanding stents and active fixation. In particular, the difficulty of treating patients with wide aortic necks was outlined as we plan to release favorable data from our ENCORE study pertaining to this indication at the forthcoming Charing Cross Meeting.

While we recognize there is significant work ahead, I am pleased that the company delivered against its targets in the fourth quarter and met the full-year targets we set during our Investor Day. Furthermore, we continue to carefully manage our financial covenants.

And now I'd like to turn the call over to Vaseem to discuss the fourth 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.

The total revenue for the fourth quarter of 2018 decreased 21.2% year-over-year to $34.7 million, compared to $44 million in the fourth quarter of 2017. Revenue for the full year was $156.5 million, a 13.6% decrease from $181.2 million a year ago. U.S. revenue decreased 18.6% to $24 million in the fourth quarter of 2018, compared to $29.5 million a year ago. The decline was driven by the impact of previously communicated field safety notices and the result of commercial restructuring. These results reflect solid execution in the field, as well as our ability to both manage the impact of the field safety notices and also sales attrition due to the restructuring. We did see sequential Ovation system sales growth in the fourth quarter, which gives us confidence that Ovation will return us back to growth in the second half of 2019.

For the full year, U.S. revenue was $109.1 million, an 11.5% decrease from $123.2 in 2017, driven primarily by the impact of our declining AFX business, the strategic reset, and our field safety notices for both the AFX and Ovation platforms.

Fourth quarter international revenue decreased 26.3% on a reported basis to $10.7 million, compared to $14.5 million a year ago. On a constant currency basis, our fourth quarter 2018 international revenue decreased 25.1% year-over-year, driven by our previously communicated exits from various markets, primarily in Europe. The impact of these exits was as expected at approximately $4 million in the second half of 2018.

Fiscal year 2018 international revenue decreased 18.2% on a reported basis to $47.4 million, compared to $57.9 million in 2017, driven mainly by our exit from smaller and less profitable markets. The total impact on sales due to these changes was approximately $6 million to $7 million, including our exit from France in 2018. We will continue to assess the profitability of our OUS business as we look to lower our cash consumption and strive for better visibility and durable growth.

We continue to make progress in Japan and our partner, JLL, is driving AFX sales growth in that market, bolstered by the launch of AFX2 in 2018. As we did on our fourth quarter call last year, we will provide global revenue for our three product lines. For 2018, our AFX – global AFX business generated revenues of $96 million, our Ovation reported revenues of $54.8 million, and revenues from Nellix totaled $5.7 million for the year.

Fourth quarter gross profit was $11.4 million, representing a 32.8% gross margin. However, this number was negatively impacted by approximately $9 million of inventory reserves related to the voluntary recall of Nellix systems. Excluding this impact, gross margin for the quarter was 57.8% compared with 71.3% in the prior-year period. Gross profit for the full year was $91.9 million, which includes the impact from the Nellix reserve discussed above. Excluding this impact, gross margin for the year came in at 64.3%, compared to 67% in the previous year.

As part of our ongoing cash management efforts, we reduced our inventory by approximately $7 million excluding the impact of the Nellix recall.

Total operating expenses for the quarter were $35.1 million, compared to $40.3 million a year ago, as the result of our purposeful cost management efforts and successful restructuring. We continue to reduce our operating expenses as outlined in our strategic plan communicated to you at our October investor meeting. The cost performance that we reported in the third quarter and now again in the fourth quarter gives us confidence that we can hit our previously communicated 2019 OpEx guidance and reduce our cash consumption.

Looking more closely at the fourth quarter operating expenses, marketing and sales expenses were down 20%. Our research and development expenses decreased by 10.4% year-over-year. General and administrative spend decreased 14.1%. Our clinical and regulatory expenses increased 5.6% year-over-year, reflecting continued investments in building clinical evidence in support of our anticipated new product introductions.

For fiscal year 2018, our operating expenses totaled $160.1 million, compared to $163.1 million in the previous year, again aligning with the target laid out at our Investor Meeting in October. These numbers included $5.1 million of one-time items and our restructuring charges. Excluding these charges, our operating expenses came in just below $155 million.

Net loss for the fourth quarter of 2018 was $26 million or $0.26 per share, compared to a net loss of $14.5 million or $0.17 per share a year ago. Adjusted net loss totaled $21.3 million, compared to an adjusted net loss of $7 million for the fourth quarter of 2017. Adjusted EBITDA totaled a loss of $17 million for the fourth quarter of 2018, compared to adjusted EBITDA loss of $2.7 million for the fourth quarter of 2017.

The fourth quarter net loss includes a favorable $3.8 million impact as the result of the mark to market impact of our derivative liability and the $2.8 million favorable impact of fair value related to our Nellix contingent consideration, driven by a lower stock price at the end of 2018. For the year ended December 31, 2018, we reported a net loss of $79.7 million or $0.91 per share, compared to a net loss of $66.4 million or $0.80 per share for the year ended December 31, 2017.

Adjusted net loss totaled $62.7 million, compared to an adjusted net loss of $39.5 million a year ago. We reported a negative adjusted EBITDA of $43.4 million for the year ended December 31, 2018, compared to a negative adjusted EBITDA of $19.2 million for the year ended December 31, 2017. The total year net loss includes a favorable $12.1 million impact as a result of the mark to market impact of our derivative liability and a $7.1 million favorable impact of fair value related to our Nellix contingent consideration driven by the stock price at the end of 2018.

Moving to the balance sheet, our total cash, cash equivalents and restricted cash were $24.7 million as of December 31, 2018, compared to $42.4 million as of September 30, 2018. As of December 31, 2018, we have no amount outstanding on the Deerfield Revolver and as of September 30, 2018, we had $10 million outstanding on the Deerfield Revolver.

Our cash burn for the quarter was approximately $7.7 million. As expected, we experienced a slightly higher burn rate in the fourth quarter due to the semi-annual interest payment on our convertible debt and an extra payroll cycle. Putting this altogether, our operating expense and cash burn in the fourth quarter are both within the target ranges that we provided during our Investor Meeting in October. As messaged at that Investor Meeting and reinforced at JPMorgan Conference, we continue to look at the options available to us to strengthen our balance sheet and liquidity position. [ph] As per (00:20:12) these efforts, we are aggressively looking to address our 2020 maturities in the first half of 2019.

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 dollars. For the first quarter of 2019, we expect revenue of approximately $35 million. While we still have a month to go between now and the first-quarter close, we see continued improvements in our underlying business.

Overall, we are pleased with our financial performance in the fourth quarter and believe that we are trending in the right direction in continuing to execute against our strategic plan. We remain focused on improving the company's operational profile and on remaining an innovative force in the treatment of AAA.

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

QUESTION AND ANSWER SECTION

Operator: At this time, we will be conducting a question and answer session. [Operator Instructions] Our first question comes from the line of Matt O'Brien with Piper Jaffray. Please proceed with your question.

Q

Hi, guys. This is [ph] Kevin (00:21:51) on for Matt today. Thank you so much for the question. I think the number one thing that I heard from the call that was interesting to me was that Ovation was up sequentially, which seems like a great near-term trend. What do you think was the primary driver for that outperformance? I know you mentioned less attrition than expected, but anything at the product or center level that you think about for that outperformance?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah, so Kevin, let me take a crack at it and John can add. As we messaged at JPMorgan, when we looked at the performance for Q4, you know, attrition – we did a great job in managing the attrition, and John can give you more color on that, but more importantly, the impact of the field safety notices that we announced in August, we saw that the impact on AFX was expected – as expected, so it continued to decline, and then on the Ovation side, we saw good rebound if you will.

And as we have mentioned, we think that the impact of the FSNs overall is a transitory phase in the business and it was really good to see Ovation recover rather quickly and it actually aligns well for 2019 because as we have said, we expect AFX to stabilize in the second half of the year, and then Ovation to sequentially to continue to grow from Q1 into Q4 and return us back to growth in the second half of the year.

So, John, I don't know if you want to comment on the attrition.

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

A

Well, with respect to attrition, as we've been messaging, carefully monitoring attrition, we now have the benefit of putting our territory-specific sales force plan into place in addition to the tiered performance and retention plan, and all told, that has been very favorably received. That tiered plan has really done three things: first, it's created excitement around our focus on the move upmarket by frankly disproportionately incentivizing sales in high-volume accounts. The second thing that it's done is it's created a desire by reps to achieve the next comp level in the upcoming year. And then finally, as intended, it's created a retention tool for top talent where we've not had that in the past.

So, while it remains an issue that is front and center, we were pleased as to the progress that we're making getting through it.

Q

Thanks so much. Those are very helpful comments. I mean, you mentioned that you're now on the offensive with regards to the sales force. You have a new product coming on in the back-half of 2019. I guess number one, where is the sales force add and are you are you going to be making any add to support that product growth, or do you know – do you have exactly who you need and can you break down, when you return to growth in 2019, how much of that is stabilizing AFX in the U.S. versus launching Alto and growing Ovation?

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

A

I'm going to answer the last part of the question first. It's a combination of both, which we expect to see in the second half. In this move upmarket, we are targeting the top 600 high-volume centers. We think we've got the team in place to execute this, even in light of Alto's introduction. As I've mentioned previously, the fourth quarter of 2018 and going into 2019, the capacity that allows our reps to spend more time upmarket with more – with a greater number of sales calls is that we've also enhanced the productivity profile of our clinical specialists who are now increasingly covering base business accounts.

We clearly do not want to lose any base business accounts. That's a shared responsibility primarily that of the clinical specialist, secondly with the aortic account manager, and then the move upmarket, clearly primarily the remit of our aortic account managers.

Q

Great. Thank you so much and congratulations.

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

A

Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, [ph] Kevin (00:26:30).

Operator: Our next question comes from the line of Richard Newitter with Leerink. Please do with your question.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Hi, this is Jamie on for Rich. Thanks for taking my questions. I guess you guys had mentioned that you're looking to refinance these 2020 converts in the first half of 2019. I was just looking to see if you could share any additional color on really what you're evaluating from an avenue perspective on how you're going to refinance these.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah, so, Jamie, that's – thank you for the question. We continue to monitor the financial covenants, as John mentioned, and we'll take the necessary steps to work with our creditors including [ph] their field (00:27:11) to improve our balance sheet by potentially looking at how to reduce leverage, enhancing our liquidity and then extending the 2020 maturities.

You know, we have engaged a banker and those discussions are progressing and we plan to address those as soon as practical. And as you can appreciate, these negotiations are complex, but we're very hopeful and we're working really hard to address the balance sheet overhang.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Okay. Great. Thank you. And then I guess just a quick follow-up; on your guidance, so $140 million floor reiterated, and I appreciate that you guys shared some incremental color on the actual revenue amount for – by business for the full year of 2018, could you give us a sense, you know, directionally, how we should be thinking about full-year growth rates for those respective products, given that you've mentioned some of the dynamics around returning to growth in the second half of the year for both AFX innovation platforms?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. So, listen, nothing has changed as I mentioned in my remarks from where we left off in the Investor Day, and Jamie if you remember, we put out a chart on global revenue dynamics and also on the U.S. revenue dynamics, and essentially what we said was what we expect for 2019 is sequential growth on Ovation from Q1, Q2, Q3, Q4, and we expect the USA FX business to stabilize here in the second half of the year. And we walked you through the details on why we believed it would stabilize in the second half based on the implantation rates and 3D incidents with the historical [indiscernible] (00:28:59).

So we still are kind of holding to exactly the same trajectory here, and we feel that Q4 was a real shot in the arm from that perspective because as [ph] Kevin (00:29:09) asked the question earlier, we did sequential growth on Ovation come relatively a quarter sooner. So we're very confident that going into 2019, the return to growth is going to happen in the second half of the year on the heels of that flattening of the – or a stabilizing of the AFX business. And then top of that, Ovation starting to grow sequentially in Q1, Q2, Q3, Q4. So, really, no change from Investor Day, and we feel really optimistic about that direction.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC

Q

Okay, great. And then I know it's global, but could you give us a sense at all around the potential geographic split between the businesses from a modeling standpoint or are you not willing to provide that color?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Yeah, and we decided to do that last year to help you guys kind of get your models right, and we'll continue to work with you on that, so at this point, we're just sticking to the global numbers for the three product wins.

Jaime Lynn Morgan
Analyst, SVB Leerink LLC
Q

Okay, great. Thanks for taking my questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

No problem. Thanks, Jamie.

Operator: Our next question comes from line of Chris Cooley with Stephens. Please proceed with your question.

Chris Cooley
Analyst, Stephens, Inc.
Q

Good afternoon, John and Vaseem, and congrats on wrapping up an impressive conclusion to the year. Just two from me.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Thanks Chris.

Chris Cooley
Analyst, Stephens, Inc.
Q

First, just in the past there was always [ph] a little bit (00:30:28) question about potential for disruption [indiscernible] (00:30:31) commercial team in the States and obviously the commercial infrastructure outside of the U.S. as you went from 23 down to 10 markets. But when I look at your results to the back half of the year from a sales perspective, very impressive there, is it safe to say at this point that you feel like that risk has been mitigated and we're now basically on the field with the team that will play, and this is kind of a good baseline to think about when we think about the sales and marketing team going forward? And I've just got one quick follow-up.

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

It's John. Thanks for the question. It's a tough one to answer precisely, but my sense is that the risk of attrition subsides with each passing month, partly because momentum is building around our cultural transformation and that is in step with our improved performance.

Our investment in customer data, which enables better account targeting, our new tiered compensation model, we've also added a new key account manager role, we've refreshed Out Of The Money options with contemporarily priced or RSUs, we're heading into our national sales meeting with updated evidence and related training into how to most effectively position and present our clinical data, momentum is building with EVAS2, making real progress in securing ChEVAS study approval; all of that is just moving us in the right direction. And I will tell you that we have a gritty, experienced, commercial team that have never stopped believing in our products. And since our reset, we're re-establishing that same belief they have in Endologix as a whole.

Chris Cooley
Analyst, Stephens, Inc.

Q

Thanks so much. That's pretty helpful. And then just lastly – just maybe to push a little bit, Vaseem, on the cash burn, really impressive there at $7.7 million in the quarter, even with the incremental expenses there in the period. Have you further bent the cost curve if we kind of think about your prior verbiage there, or do we still need to think about that as essentially kind of a $20 million burn that you're targeting for this year because of additional expenses when we think about like the launch in the back half for the year and other items that – from a commercial type operation? Thanks so much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. No, Chris, listen, we have bent the cost curve and we did that on the heels of the restructuring in Q3, and now you can see the full quarter impact of that in Q4. And that's what gives us some pretty good confidence here that we can hit the OpEx guidance of $130 million to $140 million in 2019.

So, the second part of the question, listen, the total year burn, we're still forecasting to be in the $29 million range, but at the same time, it's tied to various assumptions, Chris, as you can appreciate. But going in, we feel really confident it'll be front-end loaded because as you know, we have a heavy cash burn in Q1 with the payment of our bonuses for the year. And then, as we kind of get into the second half of the year, we tend to collect cash off of a pretty big quarter in the second quarter. So there's a seasonality to our cash burn where it's front-end loaded, but we do expect to exit 2019 in Q4 with a cash burn of less than $5 million.

Chris Cooley
Analyst, Stephens, Inc.

Q

Got it. Thanks so very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, Chris.

Operator: [Operator Instructions] Our next question comes from the line of Mathew Blackman with Stifel. Please proceed with your questions.

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

Q

Good afternoon, everyone. Maybe this first question is for either John or Vaseem. Just reflecting on the revenue outperformance in 4Q, and I know you called out less intense headwinds from the FSN, I was hoping you could frame the better 4Q results relative to the new targeted high-volume account strategy. Any way you could characterize whether you're beginning to see inroads in these higher-volume centers or any signs of early momentum? And then I've got a couple of follow-ups.

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

A

Thanks, Mat. This is John. Two things to think about; again, the return to growth, that road begins with AFX2's stability, so let me address that first. We've been invited back to cases where customers had previously discontinued the use of AFX2 over Type III endoleaks, and upon being invited back, they specifically [ph] compended (00:35:27) that having data from our LEOPARD RCT, gives them the confidence that we've addressed the issues.

Additionally, we've received feedback that the procedural safety and device performance demonstrated in LEOPARD matches what they've seen in their own practice with AFX2. So, that's obviously, a very reinforcing realization. That, in combination with renewed confidence and positive prior experiences, that's starting to allow us to win back a number of customers and it's opened the door with the others.

The second part of it, with respect to Ovation and moving upmarket, I recently participated in a key account visit with a tertiary care teaching institution who, last year, two physicians, used the Ovation once. Very productive visit, they get to understand not only who we are in our strategy and plans, but take a deeper dive in terms of how we produce the product, how we ensure safety of that product and some of the, frankly, misperceptions that have been created in counter detailing. And in that particular case, I'm pleased to say that in the month of February, we've already done two cases with a total of five cases planned in that one account. Not all of them go this way, but – and as I mentioned previously, and as recently as moments ago, this campaign upmarket is kind of account at a time and brick by brick. But we're making real progress.

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

Q

Thanks for that, John. That's very helpful. And Vaseem, I'm going to pepper you with a few questions. First, the international business, were there any unusual order patterns or is that $10.7 million a good baseline to think about going forward?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

No, I think it's a normalized number. As we had said at the Investor Day, we were expecting to see the disruption as a result of the [ph] exits made (00:37:42) of about $2 million a quarter, so that's [ph] LEONARD (00:37:45) – obviously, it's all distributor numbers, or mostly distributor numbers, so we ended up where we thought we were going to be. So no, it's a normalized number and we don't expect any ordering pattern issues or no stocking orders in Q4.

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

Q

Okay. And then as I think about the 1Q $35 million revenue guidance, does that contemplate as similar to 4Q? I'm going to call it $4 million drag from the FSN, the market exits and the cost-to-serve initiatives?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, it's now – on a normalized basis, we do expect AFX to be kind of still down in Q1 versus Q4 and we do expect to see some rebound in Ovation relative to the Q4 performance in the U.S. Now, the OUS business, we might have some seasonality to our orders between the direct business and the indirect business, but we think that starting in Q1 we should start to see that acceleration sequentially and that's what you guys should hold us accountable for. So, sequential growth in Q1, Q2, Q3, Q4.

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

Q

Okay and then one last one. Can you remind us how much of your OUS business is Japan, if only roughly, or maybe even just how large you think the overall AAA market is in Japan?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, round numbers, the AAA market in Japan is about $130 million to $140 million, and our business in Japan is about a, give or take, 15% market share.

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

Q

Okay. That's all I had. Thank you, guys.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Okay. Thanks Mat.

Operator: Our next question comes from the line of Chris Hartstein with Guggenheim. Please proceed with your question.

Chris Hartstein
Analyst, Guggenheim Securities LLC

Q

Hi. Thanks for taking the question. Can you repeat the product level breakdown you provided earlier? I missed that. I apologize.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Okay. Hang on one second. So the AFX was $96 million, Ovation $54.8 million and then Nellix was $5.7 million.

Chris Hartstein
Analyst, Guggenheim Securities LLC

Q

Thank you. And you mentioned part of the upside in the U.S. business was lower than anticipated attrition; could you give us an update on the number of U.S. sales reps and clinical specialists?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

No change in the number, so it's still at 92; 31 clinical specialists and 61 aortic reps.

Chris Hartstein
Analyst, Guggenheim Securities LLC

Q

Thank you. And then I guess one more, a bigger-picture question, have you been able to balance the sales force reductions, at least relative to where you started at beginning of the year, with your new focus on targeting the higher volumes accounts, given historically, a lot of your core accounts were smaller volume implanters? Thanks.

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

A

Yeah. It began really with an understanding of productivity – where were our folks in the field spending their time, and from that, the realization that in order for us to make the march upmarket, we really needed to create the capacity for our aortic account managers. And that meant, in essence, asking, training and incentivizing our clinical specialists to spend more time solo, covering base business accounts.

And with that, again, these aren't overnight behavioral changes, but certainly through the fourth quarter, the clinical team has stepped up huge, as well as our commercial teams, our sales team, specifically, and that productivity on both fronts, that is improving nicely. 40% of our [ph] calls (00:41:49) exiting the year were at these growth target accounts and again, so little coverage in base business account is already almost tilted beyond half in terms of our clinical specialist covering those cases.

Operator: Ladies and gentlemen, this concludes our question-and-answer session. And I would like to turn the call back over to management for closing remarks.

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

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

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