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Endologix, Inc. (ELGX)

Q2 2017 Earnings Call

CORPORATE PARTICIPANTS

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OTHER PARTICIPANTS

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Ravi Misra
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Cecilia Furlong
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Denis Kelleher
Analyst, Oppenheimer & Co., Inc. (Broker)

MANAGEMENT DISCUSSION SECTION

Operator: Greetings, and welcome to the Endologix Second Quarter 2017 Earnings Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference call is being recorded. This conference call is also being broadcast live over the internet at the Investors section of the company's website at www.endologix.com and 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 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, I encourage you to review the Endologix Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2017, 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 on its live broadcast, August 2, 2017. 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 McDermott, Endologix' Chief Executive Officer. Mr. McDermott?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

Thank you, operator. Good afternoon, everyone and thank you for joining us for Endologix' second quarter 2017 earnings call. This afternoon, I'll provide a brief overview of our second quarter results and key business updates. I'll then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our second quarter financial results and our revised 2017 financial guidance. Then we'll open up the call to your questions.

As an administrative note, we have posted our slide deck on our Investor Relations website and would point out that the only changes in the deck are small updates to the Safe Harbor statements and slide 16, where we have provided our updated financial guidance.

Starting with revenue, our global revenue in the second quarter was $48.6 million which represented a decrease of 4.7% versus the comparable quarter a year ago. Double-digit sales growth from Ovation was more than offset by a decline in sales of our AFX products due to lower than expected customer recapture in the U.S. and sales force attrition. We also experienced lower worldwide Nellix sales due to the narrowed IFU although still in line with our expectations.

Our U.S. revenues in the second quarter were $31.9 million, down 12.1% compared to the second quarter of 2016. This decrease is the result of slower than anticipated sales recapture with AFX2 and the impact of sales force attrition. Following the postponement of the Nellix approval, we decided to gradually reduce the size of our U.S. sales team through attrition down to roughly 110 reps and clinical specialists. This will still give us excellent customer coverage and is the right size for our business over the next couple of years. Despite the fewer reps we have seen continued strong adoption of Ovation which posted another quarter of double-digit sales growth.

In line with our prior expectations, during the second quarter, we resolved the AFX2 production issues and built up sufficient inventory levels. We still expect sequential quarterly growth in the U.S. but not at the levels previously anticipated due to the lower sales recapture of AFX2. We have several sales and marketing initiatives planned in the second half of 2017 to build momentum and set us up for growth in 2018.

Outside the U.S. our second quarter revenue was $16.7 million, an increase of 13.3% from the second quarter 2016. Both the AFX and Ovation product lines posted strong double-digit year-over-year growth which was partially offset by a decline in Nellix sales reflecting the narrowed IFU. On a constant currency basis, our second quarter international revenues increased 14.8% year-over-year.

Now I'd like to give you an update on our clinical and new product development programs. Regarding Nellix, as you may recall based upon our meeting with the FDA in May we have decided to seek U.S. approval of the Nellix EVAS system by conducting a confirmatory clinical study with the previously updated IFU and the Gen2 device which is currently sold in Europe and other international markets.

We are prepared to file the Nellix IDE submission in July as planned, however, the FDA recently informed us that due to resource constraints at the agency, it would prefer that we file a pre-submission to give them more time to review the new study design. As a result, this will push back the IDE submission and anticipated approval to the October-November timeframe. We still hope to begin patient enrollment by the end of this year, but depending upon FDA review times and IRB approvals, it could move into early 2018.

As evidenced by the update provided by Dr. Jeffrey Carpenter on the two-year clinical data from our Nellix IDE trial at the Society of Vascular Surgery Meeting, our previously updated Nellix IFU provide excellent patient outcomes. We will collaborate with FDA to continue moving forward to bring this groundbreaking product to patients to the U.S. as soon as possible.

Turning to Nellix ChEVAS, we are planning to submit our design dossier to the notified body during the third quarter of this year and remain optimistic that we could potentially have CE Mark for Nellix ChEVAS by the end of 2017. That being said, the European regulatory agencies have been getting more conservative in their adoption of the new medical device regulations and requesting data more aligned with the FDA requirements. If that happens, it could push the ChEVAS CE Mark approval to 2021, matching the anticipated timing for FDA approval. This is our most cautious potential scenario, but we believe it's worth bringing to your attention given the uncertainties in the European regulatory environment.

Turing to Alto, during the quarter we continued enrollment with our ELEVATE IDE study which is a 75-patient trial designed to demonstrate the efficacy of the Ovation Alto system. We expect to complete enrollment in the first quarter of 2018, pending a potential FDA and European CE Mark approval in early 2019. Feedback from investigators in the ELEVATE trial has been very positive and we look forward to introducing Alto and expanding the endovascular market for patients with abdominal aortic aneurysms.

At the SVS in June, we announced 30-day results from the LUCY study. The data showed that at least 28% more women became eligible for minimally invasive endovascular aneurysm repair when using the Ovation's abdominal stent graft system. The Ovation system is better suited to the female anatomy than traditional EVAR devices and demonstrated lower mortality and complications when compared to previous EVAR studies. Our LUCY study is the first to specifically evaluate EVAR outcomes in women who represent 20% of the market and a big growth opportunity for Endologix.

Lastly, I'd like to update you on a pending change to the executive team. Today we filed an 8-K announcing the retirement of Bob Mitchell, the company's President. Bob has been our President since the acquisition of Nellix in 2010 and has been responsible for all our global commercial operations, including sales, marketing and compliance. He has decided to retire from Endologix at the end of 2017. Bob has made many significant contributions to the company and has represented us extremely well with thought leading physicians around the world. We look forward to continuing to work with Bob to the end of this year and wish him well in his retirement.

To enable me to focus more on the commercial side of the business, we plan to hire a Chief Operating Officer who will be responsible for overseeing manufacturing, quality and supply chain. We believe this change will enable us to further strengthen the product and operations side of our business while enabling me to spend more time driving growth with our global sales and marketing leaders.

With that, I'll now turn the call over to Vaseem to review the company's financial results and guidance in more detail. Vaseem?

Vaseem Mahboob

Chief Financial Officer, Endologix, Inc.

Thank you, John, and good afternoon, everyone. As John mentioned earlier, our total revenue for the second quarter 2017 was $48.6 million, a 4.7% decrease from $51 million in the second quarter of 2016. U.S. revenue decreased 12.1% to $31.9 million compared to $36.3 million a year ago. While we saw continued strong adoption of Ovation, AFX sales were down significantly due to the sales recapture headwinds and the impact of attrition that John just mentioned.

International revenue was up 13.3% to $16.7 million on a reported basis, with strong performances from Asia Pacific and Latin America. Our European markets were down year-over-year as the robust sales growth in the Ovation and AFX businesses was offset by a significant decline in Nellix sales as a result of the narrowed IFU. On a constant currency basis, second quarter 2017 international revenue increased 14.8%.

Our second quarter gross margin expanded 860 basis points to 66.4% compared to 57.8% in the second quarter of 2016. Adjusting the second quarter 2016 gross margin to 66.9% to account for the $4.6 million purchase price inventory step-up, our margins actually declined 50 basis points year-over-year. This was primarily driven by geographic mix, coupled with some impacts of the AFX2 testing plant that we put in place earlier this year. We are tracking as expected on our assumptions as it relates to our AFX2 testing and sampling methodology.

Looking forward, we are on track to deliver full year gross margins of 64% as indicated on our earnings call last year. During the quarter we remain focused on managing our cost and continuing to drive synergies across our product lines. As a result, our total operating expenses decreased substantially to $40.1 million in the second quarter of 2017 compared to $52.7 million in the second quarter of 2016. Second quarter 2016 operating expenses included $1.9 million of expenses related to the TriVascular merger.

Excluding these items, operating expenses in the second quarter of 2017 were $10.7 million lower than in the prior year period, representing a decline of 20.9%, which was driven primarily by the synergy work last year and the cost controls put in place during the first half of this year.

Looking more closely at our operating expenses, marketing and sales expenses were down 17.5%, G&A expenses decreased 22.6%, research and development expenses decreased 25.7% and clinical and regulatory expenses decreased 31.9% year-over-year. As mentioned, these savings are the result of synergy benefit, as well as more focused capital allocation, as we concentrate our investments in what we believe are the key priorities for the future of the business.

Our net loss for the second quarter of 2017 was $16.3 million or $0.20 per share compared to a net loss of $66.8 million or $0.81 per share a year ago. Adjusted net loss totaled $8 million compared to an adjusted net loss of $16.7 million for the second quarter of 2016. We reported a negative adjusted EBITDA of $2.3 million for the second quarter of 2017 compared to a negative adjusted EBITDA of $10.4 million for the second quarter of 2016. This $2.3 million adjusted EBITDA loss is the smallest in the last ten quarters, highlighting the synergy efforts and the progress the business has made towards our profitability goals.

Moving to the balance sheet, our total cash, cash equivalents, restricted cash and marketable securities were $94.5 million as of June 30, 2017, compared to $49.1 million at December 31, 2016. As a reminder, during the second quarter, the company entered into an agreement for $170 million in funding through a $120 million six-year secured term loan and a $50 million three-year secured asset-based revolving line of credit. Subsequently, on June 23, 2017, the company drew $25 million under the aforementioned revolver that we plan to use for G&A purposes. The cash balance does include $18.3 million of outstanding 2018 notes.

Now turning to guidance, as a result of the lower than expected AFX sales recapture in the U.S. market and our decision to optimize our U.S. sales footprint, in light of the Nellix delays, we are reducing our previously issued revenue guidance. We now anticipate 2017 revenue to be in the range of $185 million to $190 million compared to the prior guidance range of $193 million to $200 million. This represents a reported decrease of 2% to 4% compared to 2016.

As a result, for the full year of 2017, we now anticipate a GAAP loss per share of $0.91 to $0.95 compared to our prior guidance of a GAAP loss per share of $0.83 to $0.86. This revised guidance also reflects increased interest expense related to the $120 million term loan and $25 million draw under the company's revolver. Additionally, we now expect full year operating expenses of approximately $170 million which is at the bottom end of our prior guidance range of $170 million to $175 million.

When accounting for the AFX sales recapture headwinds I mentioned earlier, we expect revenues for the second half of 2017 in the range of $94 million to $99 million. We expect Q3 revenues to be in the range of $46 million to $48 million. This third quarter range reflects the seasonality of our business and a sequential increase in our U.S. business amid an improving AFX2 recapture rate. Based on our experience in the first half of the fiscal year and the sales and marketing initiatives already underway, we are confident that we can rebuild the customer demand in the second half of this year after which we expect the business to stabilize. The impact of this will be felt primarily in the U.S. market where we had already transitioned to AFX2 early last year.

And now, I would like to turn the call back to the operator for Q&A. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Our first question is coming from the line of Mathew Blackman with Stifel. Please proceed with your question.

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

Q

Good afternoon John, Vaseem.

[indiscernible] (16:16)

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

Q

Can you hear me okay?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, we can hear you.

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

Q

Okay, so a couple of questions. Just struggling a little bit with the 2Q beat and then your full year guidance coming down and maybe it's just semantics, but should we think about the bulk of this downward guidance revision as a function of the sales rep attrition versus the lower recapture of AFX? And I'm only saying that because we really didn't see that much of an impact relative to your guidance here in the second quarter. I'm just curious what the biggest contributor is to this guidance revision downward?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, Matt, the attrition represents about 50% of the second half impact and the slower AFX2 recapture is the other 50%. But with the U.S. team at around 110 we think we've got good customer coverage and growth potential in each territory. For the AFX2 recapture, we've got several sales and marketing programs planned in the second half and also we have more good clinical data come in with Ovation. So we expect to start building

momentum. The problem is that just our run rates over the past couple of months have been less than forecasted. So we felt it was prudent to adjust the second half guide.

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

Q

Okay, understood. And I think you've sort of touched on it, but maybe going into a little bit more detail, when do we reach solid footing again in the U.S. business and should we be thinking any differently today about the long term growth outlook for the U.S. business? I know in the past you said you're confident you can still grow in excess of the underlying market, but any change of the way we should be thinking about the growth trajectory?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

No, not at all. We remain very bullish on the overall outlook. If you just look back at the past year, we've struggled with several issues, the Nellix indication change, followed then by the activities related to AFX. And we've been frankly just dealing with issues and playing defense. We've got those things fixed. Nellix is on solid ground. The new IFU works great. We've already seen the clinical data from that. AFX2 clinical results are outstanding and we've now put behind [ph] these (18:29) manufacturing issues. So we're finally now kind of transitioning from defense back to offense and we feel good about the second half and certainly 2018 and 2019 thereafter, but we are still just kind of working at it [ph] as a whole (18:42).

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

Q

Okay, understood.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And Matt, just to add to that, listen, I think the new number for the U.S. footprint, it's a conscious choice that we have made that while we had the attrition to right size the business because, if you remember, after the merger with TriVascular we had positioned 125 number as the right number we needed for kind of the U.S. capacity ahead of the Nellix launch. And as this opportunity presented, I think we decided to make a [ph] trail up (19:08) on our expenses, take the operating expenses guide down and then make sure that we right size the business ahead of kind of the new capacity that's needed. So we feel that going into 2018, this will actually give us the flexibility that we needed with having the right capacity in the U.S. and having the right cost structure.

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

Q

Got it. Makes sense. I'm going to sneak in one last one, let's assume that the European ChEVAS label is pushed out to 2021, can Nellix grow in the interim with the existing label?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

I think it's going to be a little flat in the second half, but I do think that, that business will stabilize and we'll start to see that grow. It's not going to grow significantly, Matt, but I do think we'll start to see some more growth as people come back and start to see more and more good results. I was just at a meeting yesterday where we are reviewing all of the latest Gen2 results with the new IFU and they're really outstanding. So I think we'll start to build it back, but I want to have reasonable expectations about that level of growth.

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

Q

Okay. Thanks so much, guys.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Thanks, Matt.

Operator: Thank you. The next question is coming from the line of Ravi Misra with Leerink Partners. Please proceed with your question.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Hi. Good evening, John and Vaseem. Thank you for taking the questions.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Hey, Ravi.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Are you able to hear me okay?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, we can hear you.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Thanks. So I just wanted to follow up a little bit on the commentary around 2018 kind of you anticipated growth but at a little bit lower level than you're setting up for growth entering 2018. Is the way to think about it maybe kind of you're looking at the – obviously the U.S. business is going to continue to decline by the end of the year, but if we don't get kind of – let's just say your business stabilizes which I take to mean kind of flat growth in 2018, can you still drive growth in 2018 through OUS sales, or are you going to need the U.S. business to rebound?

And then secondly, I was hoping you could provide a little bit more detail around the pre-submission comments you made around the FDA, the follow-up study and help us think about that a little bit? Thank you.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Sure, Ravi. I think U.S. will grow next year. It is too early to get into the details of what that level of growth will be, but certainly if for no other reason just lower base in 2017. So I do expect growth from the U.S. next year. Keep in mind Ovation is growing double digits while we firm up AFX which I completely expect to do in the later half of this year. We can even see growth in AFX year-over-year, but certainly Ovation is growing very nicely.

So I think we'll see growth not just in the U.S. but in the international markets as well next year. And then as we give our guidance we'll provide more a fine tuning on what that number looks like. As it relates to the pre-submission, I was in the May meeting with the FDA and they were encouraging us to submit the IDE which we had planned to do in July.

In early July, they asked us to instead submit a pre-sub which is really just an overview that gives them more time to review and provide feedback. We've done that already. And so we're in that process. It just moves the process back a little bit and they asked us to do that for their benefit there. So they were a bit resource constrained and couldn't provide a confident 30-day turnaround to an IDE submission and said that to keep the process going, they prefer a pre-sub. So we gave them that, we're in that process now.

And we still expect to submit the IDE and get approval this year. It's just going to get tighter on when we get the first patient enrolled. But we're doing everything we can internally to expedite that and accommodate the FDA's apparent, hopefully, short term bottleneck.

Ravi Misra
Analyst, Leerink Partners LLC

Q

Great. Thanks a lot, guys.

Operator: Thank you. The next question is coming from the line of Joanne Wuensch with BMO Capital Markets. Please proceed with your question.

Q

Hi this is actually [ph] Matt Hendrickson (23:44) in for Joanne. Just following up on Ravi's question on the pre-submission in the IDE, does that change anything though with the final timeline, is it still expected to be a 2020 FDA approval and launch?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

That's correct, yes. No, it does not change our estimated approval of 2020.

Q

Okay. And then just as a follow-up, talking about the U.S., you're talking about the sales force attrition. How do we know that, that has stopped and has there been any change in how you guys have set up your compensation structure to make sure that those 110 sales reps stay on board?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

Yes, so, just to be clear the 110 is the combination of reps and clinical specialists. Think of that as our total field team, does not include our regional managers and other sales leadership. That's kind of our on-the-ground folks that are interacting with customers on a day-to-day basis and supporting cases. As Vaseem pointed out, we had some turnover a little bit in Q1 and then a little more in Q2 and as we got the news about Nellix we decided not to back fill some of those territories.

We ran our analytics and felt that 110 was a good number to support the business moving forward. So, as it relates to addressing more turnover prospectively, we have provided our team with some income stability measures as we kind of work through this challenging times. The comp plan that's in place rewards very well for growth. We've got a great new product pipeline and an extremely solid team.

So I think as we come out of this challenging period, there is a – [ph] the bases are reset (25:37) relatively low. The team is well positioned for growth. So I'm not going say we won't have any turnover. But I think the worst should be behind us given the growth prospects moving forward.

Q

Okay. And then just one final one. For gross margin in the second half of the year, how should we look at that for the third and fourth quarter to get to your full year guidance? Thank you very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. And I think very consistent with what we have said in prior earnings call that we are still holding to that 64% number for the second half of the year. That does include the assumptions that I talked about in my commentary on some of the yields on the AFX2. And that's one area that we got to continue to work on and improve but at this point we are holding on to our gross margin commentary at 64% for the total year.

Q

Okay, great thank you very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks.

Operator: Thank you. [Operator Instructions] Our next question is coming from the line of Jason Mills with Canaccord Genuity. Please proceed with your question.

Cecilia Furlong
Analyst, Canaccord Genuity, Inc.

Q

Hi. This is actually Cecilia Furlong on for Jason. And I was just wondering could you provide just a little more color around enrollment trends you've seen in patient ELEVATE so far, and is it progressing slightly slower than you had anticipated or fairly in line?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

A

No, right now, it's right on track. So it's tracking right where we thought it would be at this point in time. And the physician feedback has been extremely positive. So Alto is doing well and the feedback is positive.

Cecilia Furlong
Analyst, Canaccord Genuity, Inc.

Q

Okay, great. And then just secondly, can you talk a little more about just the early impact you're seeing from recently presented LUCY data, how you've been able to leverage these data to-date, what type of response you're seeing from physicians and just generally the potential opportunity to increase penetration in this target market going forward.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.
A

Yes. The impact from LUCY has been very positive. We have a lot of detailed metrics on our targeting activities there. I can't share all that detail with you for competitive reasons, but I can tell you it's having a positive impact on business and certainly contributing to the double-digit growth we're seeing out of the Ovation platform.

As was discussed in my prepared remarks, and then at the SVS conference, women represent about 20% of the total market. So, this is a huge growth opportunity for Endologix and even more importantly, a terrific treatment option for women. So this will continue to be a major focus for us over the rest of this year, leading up to and including the presentation of the one year data at the SVS meeting likely next year. So, we've got a good at least another solid year worth of growth potential and share capture with the LUCY results.

Cecilia Furlong
Analyst, Canaccord Genuity, Inc.
Q

Okay, great. Thank you for the color.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.
A

Thank you.

Operator: Thank you. Our next question is coming from the line of Steve Lichtman with Oppenheimer. Please proceed with your question.

Denis Kelleher
Analyst, Oppenheimer & Co., Inc. (Broker)
Q

Hi, guys. It's Denis Kelleher in for Steve. Actually just one macro question related to overall market growth. Have you seen any changes there, and also just competitive dynamics, any changes you've seen with them as well?

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.
A

Market growth really hasn't changed much. We're still seeing growth rates in the traditional segments of about 3% globally and on the complex segment around 8%, so blended AAA global market at about 4% in terms of procedures. Pricing has been relatively stable, so not much change there. Competitively, there is nothing really noteworthy either that comes to mind that I would say is of particular interest.

Our challenge is that really just come from the things I mentioned earlier, getting through the Nellix refined IFU which we've done and looks great and now coming out the other end also on the AFX, the AFX2 situation, so we're excited about things moving forward.

Denis Kelleher
Analyst, Oppenheimer & Co., Inc. (Broker)
Q

Great, thanks. Just one follow up for Vaseem. Any chance you could break out what drove the downward revision in the OpEx guide? Thanks very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Sure. And I think a big part of that is kind of recognizing the right size for the U.S. team. So, that's going to provide us some flexibility in the second half of the year from a cost perspective then also just some of the cost controls that I talked about that we have put in place and a better focused capital allocation. This is kind of coming back on the heels of all of the synergy work and all the integration work that we did last year that's translating into substantial savings this year. So it's all controlled and managed and we want to make sure that we still make the key investments in the business that are important for the future.

Operator: Thank you. It appears we have no further questions at this time, so I'd like to pass the floor back over to Mr. McDermott for any additional concluding comments.

John D. McDermott
Chief Executive Officer & Director, Endologix, Inc.

Well, 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: Ladies and gentlemen, this does conclude today's teleconference. Again, we thank you for your participation, and you may disconnect your lines at this time.