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Endologix, Inc. (ELGX)

Q3 2017 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Greetings and welcome to the Endologix Third 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 Investor 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 federal 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 a subsequent report 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, November 7, 2017. Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances at the date of this call.

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

Mr. McDermott?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Thank you, Operator. And good afternoon, everyone, and thank you for joining us for Endologix's third quarter 2017 earnings call.

This afternoon, I'll provide a brief overview of our third quarter results and key business updates. I'll then turn the call over to our Chief Financial Officer, Vaseem Mahboob, who will review our third quarter financial results and our revised 2017 financial guidance. After that, I'll review our top priorities for the company through the end of 2018, and then we'll open up the call for questions.

Before I begin, I want to say that we continue to keep in our thoughts and prayers our employees in Santa Rosa and all of those affected in the region, whose lives have been adversely impacted by the recent fires. We've been maintaining regular communications with the affected employees and are committed to providing them and their families whatever support we can during this difficult time. We are very grateful that our Santa Rosa facility, where we manufacture and develop our Ovation product line, is safe and secure. We resumed shipment from Santa Rosa on October 10, and manufacturing resumed shortly thereafter.

As an administrative note, we have posted our slide deck in the Investor Relations section of our website and would point out that we made the following changes. On slide 14, which is the new product pipeline slide, we moved anticipated Nellix ChEVAS approval in Europe from the second half of this year to 2021.

I mentioned that this was a possibility during our last quarterly call, and I'll provide more details on that decision in a few minutes. We also updated slide 15 to reflect the shift in the anticipated ChEVAS timing. And on slide 16, we have updated our financial guidance.

So starting with our commercial results, global revenue in the third quarter totaled $46 million, which was in line with expectations, despite the disruption from Hurricanes Harvey and Irma. In the U.S., third quarter revenue was $30.9 million, down 15% compared to the third quarter of 2016. This decrease was attributed to slower than anticipated sales of AFX2. While the AFX recapture has been less than expected, we are encouraged by the continued adoption of Ovation, which we expect to be our primary growth product through 2018.

With regard to our U.S. sales force, the team has been stable during the third quarter, and we expect to finish the year at roughly 110 reps and clinical specialists, which we believe gives us good customer coverage over the next couple of years.

Outside the U.S., our third quarter revenue was $15.1 million, a decrease of 4.5% from the third quarter of 2016. Both AFX and Ovation posted year-over-year growth, which was offset by a decline in Nellix due to the continued transition to the narrowed IFU.

Looking forward, we expect some continued impact from the transition to the refined Nellix IFU, as well as from increasingly difficult regulatory and reimbursement challenges in our international markets.

Now I'd like to give you an update on our clinical and new product development programs.

At the end of September we received CE Mark approval for our Nellix EndoVascular Aneurysm Sealing System with the refined IFU. Following that, in October we received IDE approval from the FDA to start a confirmatory clinical study. The confirmatory study is called EVAS2, and will evaluate the safety and effectiveness of the Gen2

Nellix EndoVascular Aneurysm Sealing System with the refined IFU. The study is approved to enroll up to 90 patients with one-year follow-up data required for the pre-market approval application.

We're excited to commence this confirmatory study and look forward to collaborating with the investigators to achieve our goal of enrolling the first patient by the end of this calendar year. Based on the anticipated enrollment timeline, one-year follow-up period and regulatory review process, we continue to estimate PMA approval by the end of 2020.

Turning now to ChEVAS. In September, the clinical data from the ASCEND study was published in the Journal of Endovascular Therapy, reflecting very good clinical outcomes in the treatment of complex aortic aneurysms with ChEVAS. We hope this data will be sufficient to obtain the CE Mark. However, given the approval delays that medtech companies are experiencing from the adoption of the new medical device regulations in Europe, we think it's prudent to move our estimated CE Mark approval date back to match the anticipated timing of FDA approval in 2021.

With that said, we have had encouraging discussions with our notified body and will work diligently to try and achieve the CE Mark approval before 2021, if possible.

Regarding our new Alto device, during the quarter, we continued enrollment in our ELEVATE IDE study, which is a 75-patient trial with six-month follow-up. We expect to complete enrollment in the first quarter of 2018, setting us up for potential FDA and European CE Mark approval in early 2019. Feedback from investigators involved in the ELEVATE trial has been very positive and we expect Alto to treat a broad range of patients and become an important future growth driver for the company.

Moving now to our thoracic program. During the third quarter, we signed a joint research and development agreement, as well as an exclusive distribution agreement with Japan Lifeline for the development and distribution of thoracic endovascular stent grafts. JLL is our exclusive distributor in Japan and has done an outstanding job supporting physicians in capturing market share with our AFX device. We are currently working with JLL on a full market release of our AFX2 device in Japan after receiving approval earlier this year.

One final update, I'd like to welcome John Onopchenko as our new Chief Operating Officer. John is responsible for managing our manufacturing, supply chain, and quality organizations. He brings to Endologix almost 30 years of executive leadership experience in medical devices and will strengthen our operations, quality, and global product availability.

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 third quarter of 2017 was $46 million, an 11.8% decrease from $52.1 million in the third quarter of 2016.

U.S. revenue decreased 15% to $30.9 million, compared to $36.3 million a year ago, while the U.S. Ovation business grew north of 30%, it was not enough to offset the decline in our AFX2 business, which was impacted by slower than expected sales recapture. The recent hurricanes also had an unfavorable impact on our U.S. revenue

of roughly $750,000 to $1 million and had the most significant impact in the Florida region, where we saw case volumes dropped significantly from the week prior to the hurricane. We also saw an impact in our Houston region, but that was less meaningful.

International revenue decreased 4.5% to $15.1 million on a reported basis. Our European markets were down year-over-year as growth in Ovation and the rebound in AFX2 were not enough to offset a significant decline in Nellix sales as a result of the narrowed IFU. On a constant currency basis, the third quarter 2017 International revenue decreased 6.9%.

Our third quarter gross margin declined 7.6 points to 63.3% compared to 70.9% in the third quarter of 2016. On an operational basis, our year-over-year margins declined by 10.3 points, driven by a combination of less favorable geographic mix, higher costs related to the AFX2 sampling methodology and the phase-out of AFX1, somewhat offset by better absorption as we continue to strengthen supply and service levels for AFX2.

We are actively looking into projects to improve the yields on AFX2; and as stated on prior calls, we expect to be subject to our current sampling methodology through the end of 2018. Looking forward, we remain on track to deliver full-year gross margins of 64%, unchanged from our prior guidance.

During the quarter, we continued to manage our costs, while driving additional synergies across our portfolio. As a result of our total operating expenses decreased substantially to $38.5 million in the third quarter of 2017 compared to $48.2 million in the third quarter of 2016.

Excluding restructuring and merger-related costs, operating expenses in the third quarter of 2017 were $9.4 million lower than the prior year period, representing a decline of 19.6%, which was driven by effective cost controls and synergy projects across the organization. We expect that these cost savings will be able to largely offset the cash impact of the reduced Q4 outlook.

Looking more closely at our operating expenses, marketing and sales expenses were down 17.2%. General and administrative expenses decreased 14.2%. Research and development expenses decreased 35.9%, and clinical and regulatory expenses decreased 14.6% year-over-year. While these are substantial reductions, we believe we have the right capital allocation approach and we are making the right investments in the key priorities for the future of the business.

Our net loss for the third quarter of 2017 was $14.3 million or $0.17 per share, compared to a net loss of $15.2 million or $0.18 per share a year ago. Adjusted net loss totaled $9.3 million, compared to an adjusted net loss of $9.1 million for the third quarter of 2016. We reported a negative adjusted EBITDA of $4.3 million for the third quarter of 2017, compared to a negative adjusted EBITDA of $3.8 million for the third quarter of 2016. Excluding the impact of lower gross margins, our adjusted EBITDA loss would be less than $2 million.

Moving on to the balance sheet. Our total cash, cash equivalents, restricted cash and marketable securities were $77 million as of September 30, 2017, compared to $49.1 million as of December 31, 2016.

As a reminder, during the second quarter, we entered into an agreement for $170 million in funding, through $120 million six-year secured term loan and a $50 million three-year secured asset-based revolving line of credit. As of September 30, 2017, we had $15.4 million drawn on the Deerfield revolver that we plan to use for our general operating purposes.

The cash balance includes $18.3 million of outstanding 2018 notes. Our cash burn for the quarter was approximately $8.7 million.

Now turning to guidance. As a result of the ongoing AFX2 sales recapture headwinds in the U.S. market and the impacts of hurricanes, we are reducing our previously issued revenue guidance. We now anticipate 2017 revenue in the range of $181 million to $184 million compared to the previous range of $185 million to $190 million, representing a reported decrease of 5% to 6% compared to 2016.

That being said, we now expect full-year operating expenses of approximately $165 million to $170 million compared to our prior guidance of approximately $170 million. As I mentioned earlier, this reduction largely offsets the impact of the lower top-line expectations in the fourth quarter. Our cost actions this year and this new guidance range on OpEx helped improve our liquidity profile, as we head into 2018, despite the ongoing challenges in our international markets, to which John alluded earlier. As a result for full year 2017, we now anticipate 2017 GAAP loss per share in the range of $0.91 to $0.93 compared to our prior guidance of GAAP lost per share in the range of $0.91 to $0.95.

With that, I'll hand the call back to John. John?

John D. McDermott

Chief Executive Officer & Director, Endologix, Inc.

Thanks, Vaseem.

As I mentioned in my introductory remarks, I'd now like to review our top priorities between now and the end of 2018. We believe the achievement of these priorities will strengthen the business and increase shareholder value. First is to continue stabilizing the AFX2 business, while we keep driving growth with Ovation. We expect to have at least two new clinical data presentations on Ovation in 2018, and we'll keep driving adoption of this novel technology.

Second is to enroll the EVAS2 confirmatory clinical study with the next-gen Nellix device and also start enrolling patients in the ChEVAS study in 2018. Combined, these two indications for Nellix represent a $1.2 billion market opportunity and a significant growth driver for Endologix in the future.

And lastly, in 2018, we're planning to finish enrollment in the ELEVATE IDE clinical study and complete our regulatory submissions for U.S. and European approval of the Alto device. We expect to receive approval in 2019 and view Alto as a great workhorse device that will be able to treat a broad range of patients.

As we execute on these priorities, we expect to deliver significant value to our customers and shareholders, while providing patients with the best possible devices for the treatment of their abdominal aortic aneurysms.

With that, we'll now open the call up for questions. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you. Ladies and gentlemen, we will now be conducting a question-and-answer session. [Operator Instructions] Our first question comes from the line of Glenn Novarro with RBC Capital Markets. Please proceed with your question.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Hey. Good afternoon, guys. Thanks for taking the questions. My first question is just broadly speaking, I am surprised and I think others, even you guys are surprised AFX2 has not ramped faster. Has anything changed in terms of the competitive landscape that's made this more challenging to ramp? In other words, I haven't seen anything, but have the competitors put out some differentiated product? So maybe, just talk about the competitive landscape and whether or not that's impacting the AFX at all.

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

A

Yeah, Glenn, I wouldn't attribute any new product introductions to the slower than expected rebound with AFX2. Medtronic recently got approval for a broader indication with their Aptus screw device, but that really is a broader indication, and I would not attribute that to the issue.

So I don't think it's – that they have been active at competitive counter detailing. So there's been quite a bit of that, but it's not really related to a new product introduction. I would say that we just haven't seen the rebound in the second half that we expected. That said, the sales have remained flat. Most of our long-term customers are okay, but we just haven't been able to recapture some of the smaller accounts and the less frequent users like we expected to.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay. And then just for my follow-up, you said that the overall guidance we're taking down because of AFX and for hurricanes, and by our math it looks like we have to lower guidance for the fourth quarter at lease our modeling by $4 million to $5 million. So is the hurricane impact $1 million for the fourth quarter and the remainder AFX, or are you anticipating more of a hurricane impact in the fourth quarter? Thanks.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. So, Glenn, let me take that. So the total change in guidance from where we were in the past is about $4 million to $6 million. So we are revising guidance from $185 million on the low end to $181 million, and then $184 million on the high end from $190 million. So it's $4 million to $6 million change on that guidance.

The hurricane impact at best is about $1 million of that and then the rest of it which is about $3 million to $4 million of the impact of this lower AFX, and then there is some softness on our timing in our OUS markets. Those are the three big drivers. So to answer your question, hurricane is a small piece of it. It's mostly AFX recapture driven.

Glenn John Novarro
Analyst, RBC Capital Markets LLC

Q

Okay, great. Thanks for taking the questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah. Thanks, Glenn.

Operator: Our next question comes from the line of Joanne Wuensch from BMO Capital Markets. Please proceed with your question.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yeah. Hi. This is Matt Henriksson in for Joanne. Thanks for taking my call.

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

A

Hey, Matt.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

My first question is with regards to the ChEVAS delay. You mentioned at the very end with your top priorities as the ChEVAS study in 2018. Is that different from earlier conversations where you mentioned that data from the IDE for EVAS2 could be used for that ChEVAS study?

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

A

No. Let me just clarify to make sure you understand. What we mentioned in the prepared remarks was that the ASCEND clinical study data that was published in September, and that it's our intent to use that data for CE Mark approval. So while we still – we've had encouraging conversations with our notified body and we're still hopeful for an approval prior to 2021, we feel that in light of the delay being experienced by most of the medical device companies, it's prudent to shift that back and align it with the U.S. approval. We will still endeavor to try to get that accomplished sooner, but we think 2021 is more prudent. That is separate from what I mentioned at the end, which is the IDE clinical study for ChEVAS, which we expect to start enrolling patients in the middle of 2018, go through the enrollment process, the follow-up process and a targeted approval of around 2021.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. And so if there was an approval before the 2021 date, it would be most likely from the ASCEND data. Is that correct?

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

A

Yes, in Europe. That's what we're working towards here. But we just, again, feel like with the more difficult regulatory environment outside the U.S., it's safer to match it with the U.S. timing and then we'll work hard to try to get it done sooner.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. And then just as a follow-up in the international market, I have heard the commentary that the Nellix offsets the year-over-year gains in Ovation and AFX, but could you provide a little more color, especially because last quarter kind of a similar commentary, but it was – the final results were up in the mid-teens versus down low-single digits. So is there any additional color for the difference between second quarter and third quarter cadence?

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

A

Well, the transition to the new IFU for Nellix has been a gradual process. So we sent out a notice at the end of last year, but only recently received formal CE approval for the new IFU. So it has been what I would characterize as a gradual process. We think Nellix will be soft until we announce some new clinical data, which is planned for the second quarter of 2018. And then we'd expect another boost from the EVAS2 confirmatory clinical study results, but the big growth for Nellix will come when we expand the indication to ChEVAS, which together with the infrarenal indication represents an opportunity of over $1 billion.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. Thank you very much.

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

A

Sure.

Operator: Our next question comes from the line of Michael Weinstein from JPMorgan. Please proceed with your question.

Q

Hey, this is [ph] Andrew (24:12) in for Mike. Thanks for taking the question.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Hey, Andrew.

Q

Hey.

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

A

Hey, Andrew.

Q

Hey. I wanted to start with AFX2 if I could. So, we've seen – so AFX2 in Europe sounds like it did pretty well considering. So if I look at the recovery in AFX2 in Europe versus what's happening in the U.S., are there any specific reasons as to why we might be seeing recovery in Europe versus maybe not in the U.S.? Is that more of a perception issue by the physician base, or how should we be thinking about that?

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

A

Yeah. Europe didn't take as much of a hit with AFX as we did in the U.S. So, it's a much smaller mix of the total business. So, AFX still the majority product in the U.S. where that wasn't necessarily the case. It was an important product in Europe, but we in orders of magnitude just didn't suffer the same kind of an impact.

Q

Got it. And then in terms of the guidance, so I think guidance is – for the fourth quarter is down 8% to 1% or down 1%. And I guess my question is, when we look towards 2018 and I know you're not giving guidance, but should we expect the business to grow in 2018, or how are you all thinking about that, Vaseem?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, obviously, we're not talking about 2018. And as I've said in the past, [ph] Andrew (25:44), there's still a lot of learning as we are – as is kind of evidenced on the call here. It's been a tough road so far to kind of get clarity on this whole AFX recapture rebound. And I still think that we got to give this quarter the time and give us the read to see where we can end up. But as John pointed out, that AFX2 business is stable, okay. It stabilized for the last three quarters now at a certain dollar amount at a certain caseload. And we expect that we'll take some time to grow out of but at least that that part is working.

Now, what we do expect is Ovation to kind of take the front seat and be the growth driver for 2018. But in terms of the comments for 2018 on whether we'll grow or not, I would just point that question right now to our guidance, when we give out the guidance in February, but we just think that there's a lot of learning here left in Q4.

Q

Got it. And if I may just one last question on Nellix. I mean, we're – John, were you surprised by Nellix performance in Europe this quarter, and what should we expect moving forward?

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

A

Well, we had originally thought that the transition to the new IFU would be a little bit quicker, and it's just kind of been a slow, steady evolution with different physicians adopting the new IFU at different paces. So I guess in light

of the fact that we didn't get the formal CE approval for the new IFU until September, maybe it's not entirely surprising, but I think it's just going to be a little soft until we're able to introduce some new clinical data, which again we'll have in the second quarter and then additional new data from the confirmatory study. So I think to really get Nellix growing again after everybody has fully transitioned to the new IFU will be driven by some new data, and then ultimately ChEVAS will be, obviously, a big impact, but that's how I see it [ph] playing out (27:57).

Q

Right. Got it. Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks, [ph] Andrew (28:01).

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

Jaime L. Morgan
Analyst, Leerink Partners LLC

Q

Hi, John and Vaseem. This is Jaime Morgan on for Rich Newitter. So I guess I'll start with a question on the guidance that you guys gave. So looking at the 4Q guide, does that assume any further acceleration of Ovation in the U.S. and in Europe? And then talking to the OUS softness that you guys have highlighted, when you parse out the moving parts within the guidance reduction, is this mostly or all attributed to Nellix?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, sure, let me take it and thank you for the question here. I think the revision in the guidance of $44 million to $47 million, let me kind of walk you through the assumptions for that. So that is assuming a U.S. number, which is in the range of $31 million to $33 million. And on the low end at $31 million, the assumption really is that it's flat AFX2 to the year-to-date volume, so that base business that I've been talking about that we stay there and we don't increase from there. And then Ovation also continues at that run rate, and if you realize on my commentary, I actually referred to the Ovation growth in the U.S. north of 30%. So we feel that that's what it takes to stay at the $31 million, but towards that $33 million, there's a lot of work that John talked about on the Confidence campaign, and if we can really bend the curve or slightly improve that average daily sales number, as a result of that I think that should kind of take us towards the $33 million.

And then the rest of it is also driven on [indiscernible] (29:46) and some of the initiatives there because it's really focused on Ovation, so that acceleration towards the $33 million bottom line we are saying is going to come from our ability to move Ovation faster than we have seen in the first three quarters of the year.

On the OUS side, the guidance range includes the $13 million to $14 million, so it's not a huge range but it's only on some stocking orders that we were expecting and the size of those orders, so it's not anything major from that standpoint. So that's the range on the $44 million to the $47 million and hopefully that answers the question.

Jaime L. Morgan
Analyst, Leerink Partners LLC

Q

Okay. Yes, that was very helpful. And then just one quick follow-up regarding the LUCY trial with the data that you guys put out in June. How have the adoption rates within your new and existing customer base trended in the quarter following those positive results? Have you seen any pickup there, or kind of same sort of trends that you've seen in the past?

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

A

Yeah. I would say LUCY is contributing to the 30% growth that Vaseem touched on. And one of the things I mentioned is that we do expect more good clinical data on Ovation in 2018. We, in June of this year, introduced the 30-day LUCY data. We'll have the one-year data in June of 2018. So I think that we'll continue to keep the LUCY opportunity alive and well throughout 2018 and certainly into 2019 when we're then launching the Alto device.

Jaime L. Morgan
Analyst, Leerink Partners LLC

Q

Great. Thanks for taking my questions.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thank you.

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

Q

Hey, it's [indiscernible] (31:41) for Jason. [ph] You guys are all right (31:42)?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah.

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

A

Yes.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Thanks.

Q

Hey. Quickly on the CE Mark approval in ChEVAS, other than kind of using the ASCEND data, are there really any other factors that would push CE Mark approval sooner than 2021?

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

A

That's really it. At this point, that seems like a viable path. But again, we just feel like it's prudent to push it back. So, we will be proceeding with our submission using the ASCEND data, and we'll see how that unfolds early next year.

Q

All right. And then – thanks. And then, quickly any commentary around the current cash balance and what you're looking forward to as far as breakeven and maybe so far as to give guidance for gross margins, or how we start to think about 2018 over 2007 (sic) [2017] (32:34) kind of working toward the breakeven? Thank you.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, [indiscernible] (32:40), on the cash, we have $77 million of cash in the bank. We have a good credit liquidity profile. We think we'll probably end the year at about $90 million to $95 million of liquidity, so we're not concerned on the guidance, and where we will be when we do give out the guidance in February, we'll talk about, obviously, it starts with the top line kind of our growth profile at that time, our gross margin guidance and also our OpEx spending levels.

But one point I want to make sure here is that even with a revised outlook on our sales number, which is obviously $4 million to $6 million lower, our EPS guidance is actually narrower, and we have offset that through some spending controls that we put in place. So from Q2 to Q3, there is an improvement in our liquidity profile that hasn't gotten worse, and I've commented on the cash burn is also lower. So, we feel very confident that we are – we have adequate cash and we have adequate liquidity at this point. And then we are not walking away from the second half 2019 cash flow breakeven commentary that we have talked about in the past.

Operator: Our next question comes from the line of Matthew Blackman from Stifel. Please proceed with your question.

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

Q

Good afternoon, everyone. Just a couple of quick ones for me. First, John, what's left to do prior to enrolling the first patient in the EVAS2 study? Is it site activation, IRB approval? Just sort of give us a sense of what's still left to be done there? And then I don't think I've heard you mention and if you did, I apologize, any sort of updated thoughts on timing of the ChEVAS U.S. study. Just remind us of the timing and any updates there in terms of filing for IDE approval, all that kind of stuff. Thanks.

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

A

Sure. So, for the EVAS2 study, we are actively involved in the IRB approvals and the contracting process with the sites. The sites have been selected and we are moving through that as quickly as we can and still expect to be able to enroll our first patient by the end of this year, so that is progressing on schedule.

As far as the ChEVAS study is concerned, we're working with the FDA, met with them fairly recently. And similarly to what we did with the IDE confirmatory trial, we're working through a pre-submission process, where we're

exchanging information back and forth to try to get it in good shape before we file the formal IDE. They requested that for the IDE, that worked well. They requested it again for ChEVAS, which is fine, since it was so effective the first time. So that's progressing as expected, and we're targeting to get an IDE approval around the middle of 2018.

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

Q

Okay. That's all I had, guys. Thanks so much.

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

A

Okay.

[indiscernible] (35:50)

Operator: There are no further questions in the queue. I'd like to hand the call back over to management for closing comments.

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

Okay. Well, thank you, everyone, for joining us on the call this afternoon and for your interest in Endologix. We look forward to seeing you at the upcoming conferences and on our fourth quarter call. Have a very good evening.

Operator: Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time and have a wonderful day.