UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 5, 2015

TransEnterix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-19437	11-2962080
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
635 Davis Drive, Suite 300, Morrisville, North Carolina		27560
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: 919-765-8400

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 2.02 Results of Operations and Financial Condition.

On November 5, 2015, TransEnterix, Inc., a Delaware corporation (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2015. A copy of the press releases is furnished herewith as Exhibit 99.1.

Also on November 5, 2015, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results. A copy of the script of the conference call is furnished herewith as Exhibit 99.2.

The information included herein and in Exhibit 99.1 and Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit
No. Description
99.1 Press release, dated November 5, 2015
99.2 November 5, 2015 conference call script

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TransEnterix, Inc.

November 9, 2015

By: Joseph P. Slattery

Name: Joseph P. Slattery
Title: EVP and CFO

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Exhibit Index

Exhibit No.	Description
99.1	Press release, dated November 5, 2015
99.2	November 5, 2015 conference call script

Exhibit 99.1

Nov 5, 2015

TransEnterix, Inc. Reports Operating Results for the Third Quarter 2015

RESEARCH TRIANGLE PARK, N.C., — (BUSINESS WIRE) — TransEnterix, Inc. (NYSE MKT: TRXC), a medical device company that is pioneering the use of robotics to improve minimally invasive surgery, today announced its operating and financial results for the third quarter of 2015.

Operating Highlights

- Completed Acquisition of the Surgical Robotics Division of SOFAR S.p.A.
- Remain on Track for Expected Second Quarter 2016 Launch of SurgiBot
- Expanded Global Leadership Team with the Appointment of Three Senior Executives

“The third quarter was transformational for TransEnterix. We acquired the surgical robotics division of SOFAR in September, which positions us as a global surgical robotics company,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We are now focused on achieving FDA clearance for the SurgiBot and preparing for commercialization, as well as building the infrastructure to support the commercial launch of the ALF-X Surgical Robot in multiple countries that accept CE Mark.”

For the three months ended September 30, 2015, the Company reported research and development expenses of $7.1 million, sales and marketing expenses of $0.4 million, general and administrative expenses of $1.8 million, and acquisition-related costs of $4.0 million. Operating expenses were primarily associated with the development of the SurgiBot System. On September 30, 2015, the Company’s cash and cash equivalents totaled $52.9 million. Complete financial statements, including the acquisition of the Surgical Robotics Division of SOFAR S.p.A, will be presented in the Company’s Form 10-Q for the third quarter of 2015.

Global Leadership Team Expansion

Three senior executives have recently been appointed to our global leadership team:

- Paul Ziegler was named Vice President of Sales in August 2015. Mr. Ziegler joins the company with over 11 years of medical device experience including managing capital and clinical sales in the surgical robotics industry. He most recently served as Regional Vice President of Sales at Intuitive Surgical, Inc. (Nasdaq: ISRG) and will lead our sales efforts in the United States;
- Anthony Fernando was appointed Vice President International Development in August, 2015. Mr. Fernando joins the company with over 15 years of experience driving business growth through innovation in healthcare companies. He most recently served as Vice President of Innovation and Technology within the international group of Stryker Corporation (NYSE: SYK). Mr. Fernando is currently leading the integration of the Surgical Robotics Division of SOFAR;
- Steven Boudrez was recently appointed Vice President of Sales, Europe. Mr. Boudrez joins the company with nearly 20 years of medical technology sales experience, including 12 years in international sales leadership positions at Intuitive Surgical, Inc. He will lead our sales efforts in Europe.

“Paul, Anthony and Steven are key additions to TransEnterix’ global leadership team,” said Mr. Pope. “Collectively, these executives bring over 40 years of significant global medical device expertise along with in depth knowledge of surgical robotics and a proven track record of delivering sustained growth.”

Conference Call

TransEnterix, Inc. will host a conference call on Thursday, Nov 5, 2015 at 8:30 AM ET to discuss its 2015 third quarter operating and financial results. To listen to the conference call on your telephone, please dial (888) 417-8465 for domestic callers or (719) 325-2494 for international callers approximately ten minutes prior to the start time. Management will refer to a presentation that is available for download on the Company’s website. To download the presentation or to access the live audio webcast or archived recording, use the following link http://ir.transenterix.com/events.cfm. The replay will be available on the Company’s website.

About TransEnterix

TransEnterix is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options. The company is focused on the development and commercialization of the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform, and the commercialization of ALF-X®, a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology such as haptic feedback and eye tracking camera control. The SurgiBot System is not yet available for sale in any market. The ALF-X has been granted a CE Mark but is not available for sale in the US. For more information, visit the TransEnterix website at www.transenterix.com.

Forward Looking Statements

This press release includes statements relating to initial third quarter 2015 results and the SurgiBot System, the ALF-X® System and our current regulatory and commercialization plans for these products. These statements and other statements regarding our future plans and goals constitute “forward looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations, including whether we will achieve clearance for the SurgiBot System from the FDA and launch the SurgiBot in the 2016 second quarter, and whether we will be able to successfully commercialize the SurgiBot System and the ALF-X

System. For a discussion of the most significant risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Quarterly Report on Form 10-Q filed on August 6, 2015, our other filings we make with the SEC and our Form 10-Q for the 2015 third quarter expected to be filed on or before the due date. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contact:
Westwicke Partners
Mark Klausner, 443-213-0501
transenterix@westwicke.com
or
Media Contact:
TransEnterix, Inc.
Mohan Nathan, 919-917-6559
mnathan@transenterix.com

Source: TransEnterix, Inc.

TRANSENTERIX, INC.

Moderator: Mark Klausner
November 5, 2015
7:30 am CT

Operator: Please standby. Good morning ladies and gentlemen and welcome to the TransEnterix 2015 third quarter conference call. As a reminder, this conference call is being webcast live and recorded.

It is now my pleasure to introduce your host, Mr. Mark Klausner of Westwood Partners. Please go ahead sir.

Mark Klausner: Good morning and thank you for joining us for TransEnterix's third quarter conference call. Joining us on today's call are TransEnterix's President and Chief Executive Officer, Todd Pope and its Executive Vice President and Chief Financial Officer, Joe Slattery.

I would like to remind you that this call is being webcast live and recorded. A replay of the event will be available following the call on our Web site. To access the webcast, please visit the Events link in the IR section of our Web site, www.TransEnterix.com.
In addition, on today's call, management will be referring to a presentation that is available for download in the investor relations section of the company's Web site.
Before I begin, I would like to caution listeners that certain information discussed by management during this conference call, are forward looking statements covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.
Actual results could differ materially from those stated or implied by our forward looking statements, due to risks and uncertainties associated with the company's business. The company undertakes no obligation to update information provided on this call.
For a discussion of risks and uncertainties associated with TransEnterix's business, I encourage you to review the company's filings with the Securities and Exchange Commission, including the quarterly report on Form 10-Q filed on August 6, 2015 and the Form 10-Q for the quarter ended September 30, 2015, expected to be filed shortly.
With that, it's my pleasure to turn the call over to TransEnterix's President and Chief Executive Officer, Todd Pope.

Todd Pope: Thank you Mark and welcome to our third quarter call. We've made tremendous progress this quarter. We've completed the acquisition of the Surgical Robotics Division of SOFAR.

We now have two compelling platforms that we want to talk to you about today, both the ALF-X and the SurgiBot. If you'll follow me on slide 5, I want to talk to you for a moment about what we believe is the robotics surgery growth drivers in the future.
We talked to surgeons and administrators around the world. We constantly ask what will unlock the next wave of growth in robotics? There are three common themes that come back to us. First, build platforms that mimic laparoscopy.
Second, bring technology to bear that can address some of the trade-offs that surgeons are required to make when they use current robotics. And thirdly, bring compelling economic value to hospitals both with capital and per procedure cost.
We believe that SurgiBot and ALF-X were both designed to meet these needs. I want to go a little deeper into each one of those growth drivers. On slide 6, building on the success of laparoscopy. Today, traditional laparoscopy certainly remains the dominant form of minimally invasive surgery.
There are 6 million laparoscopic procedures done each year between US and Europe. And in Europe alone, there are 30 times more laparoscopic surgeries done each year, than robotics surgery. Surgeons are experienced with the approach — where to put their trocars and how to move their instruments.
Both of our platforms — ALF-X and SurgiBot, mimic laparoscopy. Next slide, there are some trade-offs that are still required when it comes to using laparoscopy. I'm going to talk about each one of those and how our platforms address those.
First and foremost, surgeons still have to rely on an assistant to control the camera. They're not in control of the vision during the procedure. Certainly both the SurgiBot and the ALF-X puts that control back in the surgeon's hands or eyes.
Challenging ergonomics — as you see on slide 7, surgeons with laparoscopies get in very difficult positions and they have to stand there for many hours in some instances. And this leads to fatigue and tremor. Robotic platforms like SurgiBot and ALF-X, can definitely address these.
And lastly, with robotics, precision movement is one of the big advantages that allows surgeons to do precise movements, especially when it comes to suturing around delicate organs and vessels. Now if we move to slide 8 we want to talk about really the second growth driver.
We believe that robotics today for all the great things that it offers, certainly some technology can be brought to market that addresses some of the current trade-offs that surgeons are asked to make. First and foremost is no haptic feedback with current robotics.
Surgeons constantly tell us that they want to be able to feel tissue when they're interacting with tissue, bone, suturing. And the SurgiBot allows that with a direct drive system, actually having your hands on the instruments that you're using. And ALF-X has haptic feedback built in.
Surgeons are truly able to feel their interactions with tissue as they go through the surgery. Next, camera movement — with current robotics surgeons have to disengage their instruments and take both of their hands to take control of the camera and move it to the next plane within the surgical field.
Certainly with SurgiBot the surgeons are allowed to do that on their own. And with ALF-X, as many of you have seen, it actually has eye tracking software that allows wherever the surgeon looks on the screen the camera will follow.
This enables the first robotic platform that can remove — that can move three robotic arms simultaneously. Also, disengagement with the surgical field — surgeons like to be involved. See who's in the surgical field and communicate easily.
SurgiBot — they are within the sterile field. And with ALF-X they have an open platform and they can see and communicate with the OR very easily.
And lastly, minimally invasiveness is important. With current robotics, the majority of the trocar sizes that are used are 8 mm.
But if you go back to traditional laparoscopy, most of those trocars are 5 mm. Our ALF-X system also has a 5 mm trocar platform which allows people less invasiveness. And lastly, ability to reposition the patient — many surgeries require the patient to be moved whether it's head up, head down.
It's very cumbersome to do that today with robotics. And we can easily do that with both of our platforms. So we feel like this second growth driver of, you know, addressing some of these trade-offs that are required today, are met very nicely by both of our platforms.
And thirdly, on slide 9, talk a little bit about the economic value. Certainly we hear from hospitals that they're concerned about both capital, acquisition cost and per procedure cost. The SurgiBot is able to have a very unique lower capital acquisition cost upfront.
And ALF-X is able to mimic the same pricing structure that hospitals currently enjoy, with traditional laparoscopy. This is important because robotics doesn't enjoy a special reimbursement code. They use current existing laparoscopic codes.
So they like to be able to try to keep as close to what they've been used with per procedure cost and laparoscopy. And we're able to do that with our ALF-X platform.
So, you know, the last three or four slides we just really wanted to review how both of these platforms address the three key significant growth drivers that we believe are going to drive the next wave of growth in robotics. Now I'm going to hand the call over to Joe Slattery.

Joe Slattery: Thank you Todd. Turning to slide 10 I'm going to go over some of the key financial highlights of the quarter.

The acquisition of the ALF-X technology requires us to allocate a portion of the purchase price to the net assets acquired, including an assessment of identifiable and tangible assets, as well as the recognition of goodwill.
Because in identifiable and tangible assets, such as in process R&D, are amortized, these non-cash items are expected to be material to our financial statements. With the acquisition having occurred so late in the quarter, we are currently in the process of concluding our analysis.
As a result, our complete financial statements will be provided in our Form 10-K — 10-Q to be filed next week. Today I will provide the key financial highlights of the quarter.
We recognize no revenue or cost of goods sold in the third quarter of 2015, as our efforts remain focused on the development of SurgiBot and the advancement in commercialization of the ALF-X system.
Research and development expenses were $7.1 million in the third quarter of 2015, compared with $9.1 million in the third quarter of 2014.
The decrease in R&D spend resulted primarily from decreased contract and consulting service expenses and parts and supplies related to the development of the SurgiBot system. Sales and marketing expenses were relatively unchanged at $.4 million in the third quarter of 2015 compared to $.5 million in the prior year period.
General and administrative expenses, were $1.8 million in the third quarter of 2015 as compared to $1.5 million in the prior year period. The increase was primarily due to increased personnel and stock compensation costs, partially offset by decreased public company costs.
Costs related to the acquisition of SOFAR Surgical Robotics Division, were $4 million during the quarter. Looking at the balance sheet, we finished the quarter with $52.9 million in cash and cash equivalents.
During the third quarter of 2015, our cash decreased by $18.2 million which represents approximately $8.5 million in cash used for operations, $25 million paid to SOFAR for the ALF-X system purchase, approximately $400,000 in property and equipment investment offset by the net proceeds from the issuance of common stock of $5.8 million, and proceeds from issuance of debt of $9.9 million.
We believe our current cash will fund operations into the third quarter of 2016. While this outlook represents an increase in our quarterly cash use as compared to past results. As we transition to the commercial phase, our cash will be invested in inventory and other working capital.
As our sales begin to ramp next year, we expect our quarterly operating cash requirements to decrease relatively quickly. Overall, the combination provides for much faster revenue growth, shorter time to cash flow breakeven and lower overall operating cash requirements through cash flow breakeven.
We expect to achieve breakeven in terms of cash needs, by the end of 2018. I'll now hand the call back to Todd.

Todd Pope: Thank you Joe. On slide 11 we're going to talk to you about things we've done to prepare for commercial success in third quarter. And subsequently, we've made significant progress toward commercialization of both our platforms. On slide 12 we'll talk to you a little bit about SurgiBot.

We have prepared our response for the AI and continuing to work on that, those requested from the FDA in August. And we plan to get approval in the first quarter of '16 and launch in the second quarter of '16 with the SurgiBot.
This is consistent with our timeframe that we've been communicating over the past year. We also hired Paul Ziegler to be our Vice President of Sales. Paul's got deep industry experience. This was an extensive search that we took a year in the process.
We are very excited about him joining our team. He's got extensive experience in not only medical technology but Surgical Robotics. And he spent a lot of time both on the capital sales side and clinical experience. So we're very pleased to have him leading up our sales and commercial efforts.
And he now is beginning to build out his team heading into the Q4 as we have communicated in the past. Slide 13 — we turn our attention a little bit to our ALF-X platform. As you know, we've completed that acquisition back in September. We're integrating that technology and the team.
Right now Anthony Fernando we mentioned in our press release we're very excited to have Anthony join our team. He comes from Stryker, where he was the Vice President of Innovation and technology for the international group.
At Stryker he's got a long history not only in MedTech, in technology but in international operations. So we're very happy to have him on the team and everything on our integration is on track.
We also recently this — earlier this week, announced Steven Boudrez is joining the team for our Vice President of Sales in Europe. Steven also began his career in technology with Ethicon Endo-Surgery and spent the last 13 years in surgical robotics.
He's really been involved with the surgical robotics business in Europe from the beginning and has a wealth of experience in (Rolodex) that's going to help us build our platform and our team very quickly.
And we continue to believe that our first commercial sale of the ALF-X platform will happen in the first quarter of 2016. So as we look at slide 14, We've been quite responsive to market interest, closing the deal September 21st. We've had a very busy October. We've been at the French Surgery Congress and also the Endo-Urology World Conference in London.
The American College of Surgery in Chicago. We were in Italy for two meetings both with urology and general surgeons. I'll just take a moment to comment on the American College of Surgery meeting in Chicago. Several of you were there. This was an exciting time for us. It was the first time that we had the SurgiBot in our booth on the floor of a large conference.
The traffic was really nonstop and the feedback, you know, was excellent. We continue to hear people comment on their excitement around the single port technology and surgeons' capability to operate with robotics by being in the sterile field, which is tremendous.
We also have the ALF-X there in a room off of the convention floor. We had many surgeons from CE Mark countries. The ALF-X does have an active CE Mark so we were able to bring them in and let them demonstrate the system and see it in action.
A lot of positive feedback — especially about two things continued to resonate. First, is eye tracking software for surgeons to be able to control the camera with their eyes, was very enabling.
They now will be able to operate both robotic arms, left and right and the camera arm, all simultaneously, which is new. It really opened up a lot of thought about different procedures that they feel like they can do robotically now.
And certainly the ability to have haptic feedback. Surgeons are used to having their hands be a real resonator of when they're operating in the surgical field and to be able to have that on a robotic platform was generating a tremendous amount of interest.
So our last slide, this is our vision slide. Many of you have heard us talk about that in the past. Really being focused on improving clinical outcomes in patient care through robotics. I think you can see why we're so bullish on the future of TransEnterix.
As we look back on this last quarter, since we were with you on our last call, we made a lot of progress on the SurgiBot platform. We've completed our ALF-X acquisition. We've made significant executive hires that really shore up our team and prepare us for our execution in the future.
And our line of sight in 2016 is Q1 revenue with the ALF-X platform and certainly a SurgiBot approval in 2016 revenue on that platform. So with that, we're going to turn it over to Q&A and look forward to talking with you through that process.

Operator: Thank you, sir. Ladies and gentlemen if you'd like to ask a question, please signal by pressing star 1 on your telephone keypad. If you're using a speakerphone please make sure that your mute function is turned off to allow your signal to reach our equipment.

Once again, that is star 1 if you'd like to ask a question. We'll pause for just a moment to allow everyone an opportunity to signal for questions. And once again, ladies and gentlemen that is star 1. We'll take our first question from Rick Wise with Stifel.

Rick Wise: Good morning Todd. Let me — let me start off with FDA — you indicated that you've got your questions and you're preparing to respond. Just any additional color there — were the questions as expected? Do you — I mean is the response likely to be filed in the next day, week, month?

I mean obviously, your general timing you've reiterated. But just any color about where you stand there?

Todd Pope: Yes. Good morning Rick. You know, the FDA — I would characterize our interactions with them as, as expected. We had a detailed submission and the additional information requests were along the lines that we had anticipated.

So we're in close contact as you always are with the agency when you're responding. And we want to reiterate our timing that we believe a first quarter approval will be in line for us.

Rick Wise: Okay. As you indicated, you've hired two senior sales leaders. Maybe looking out over the next year, when you — based on your current thoughts and assuming US approval for a SurgiBot, what — how do we think about just in the broadest sense, the number of reps you would like to have as you exit 2016 in the US and internationally?

Again, any color or just your early preliminary perspective there.

Todd Pope: Well I would say we've got to take those, you know, in separate buckets. As far as Steven Boudrez in Europe, with the ALF-X having an active CE Mark, we'll be building out that commercial team, you know, right away.

We'll be bringing on some hires in the fourth quarter of this year and then building it from there in 2016. Certainly Paul is laying down a lot of the planning process. He will also begin to bring on people to his commercial team in the fourth quarter of this year.
And then build ahead of our anticipated launch in the second quarter.

Rick Wise: And just if I could push a little bit on that Todd, it's like so you — when we think about for each — in each geography in 12 months, maybe five to ten reps? Just I'm trying to get sort of an order of magnitude — sub-10; plus, you know, ten or just how about...

Todd Pope: Yes.

Rick Wise:...frame it a little bit?

Todd Pope: Yes. I mean I think your five to ten in each geography, is fair Rick. I mean obviously we've not sold a system in either geography. And I think a little bit of that will dictate it. But the early interest with ALF-X with an approved product. We've just been to five conferences in October. The interest is high.

So we're going to be beginning to build that team. So I think those numbers that you mentioned are accurate.

Rick Wise: Okay. And just one last one from me. Just remind us again, maybe you talk a little bit more about how you see the European opportunity, the size, I mean the — the — your early thoughts on the number of hospitals or centers you're going to target.

And I mean — I mean after all these years my impression is that your major competitor has 500 and something — approaching 600 robots in Europe. Is that the market size? Is it bigger? You know, help us think about that a little bit, as you get ready to launch or, you know, step up your launch.

Todd Pope: Sure. Well I think whenever you think about the market, right now there's just one system out there. So we're really talking about penetration from one system. And to your point, there's been great success. I believe there's over 570 units placed with the current technology in Europe.

And I think that's a good start of the market. I just think when we think about the market, you know, we just listen to feedback. We talk to hospitals. We talk to executives in hospitals and certainly surgeons. And what we hear is that they really like the features of robotics. They really do.
But they say that if there were ability to use robotic technology without some of these drawbacks today — if they were able to move the camera on their own, if they were able to easily reposition the patient without having to buy extra technology, if they were able to continue to use 5 mm trocars — if they were able to have haptic feedback, they tell us that they think the market as far as procedure adoption, will be quite larger.
Then when you couple that in Europe, especially in Europe when you tell hospitals we can take your robotic per procedure cost and have it be equal to laparoscopic surgery, that's significant. Because in many times their current robotic per procedure cost is 200% to 300% higher.
So when you add those two things together, we think about the market being a lot more procedures that could potentially be positively impacted by robotic technology.
And, you know, as we think about trying to boil that down, obviously we've not given numbers, but we think 2016 can provide meaningful revenue for our company in CE Mark countries.

Rick Wise: I appreciate that. Thanks Todd.

Todd Pope: Thanks Rick.

Operator: We'll move on to Glenn Novarro with RBC Capital Markets.

(Brandon): Yes. Thanks for taking my question. This is actually (Brandon) on for Glenn. So a couple of questions. First, remind us when — when do you expect to respond to the FDA for SurgiBot? And what is still left to do there in terms of your response?

And then how long does the FDA have to reply to your response? And what gives you confidence that the FDA will accept the submission and there won't be a second round of questions?

Todd Pope: Yes. Hello (Brandon). Thanks for the question. Typically a (510K) process is 90 days. And usually, the agency tries to respond to your first submission within 60 days. Then you have a timeframe that you can take to get all your communication with the FDA in response, in.

And then after your response goes back in, they typically respond within 30 days. And that's what makes up that 90 day period. So we are expecting a first quarter 2016 approval. And that's consistent with what we've said. So our response would be within that timeframe.
And I would say just our confidence stems from what we've highlighted in the past. We sat down personally with the FDA in 2013 and started crafting

our submission and our work. We took the extra step to do a pre-submission that we delivered March 31st of last year, to the agency.
They responded back to us formally, in writing, later that summer. Gave us feedback. And then we followed all of that guidance in learning from our interactions with the FDA to put our submission in.
And we continue to interface with the FDA regularly as they have typical questions on a submission like this. So the timeframe — that's how it lays out. And certainly our confidence is just (worn) from our close working relationship with them over the last two years.

(Brandon): Okay. And then separately, can you give us any update on the ALF-X approval timeline in the US, like when you expect to file for the approval and what indications do you expect to file for? Will it be a broad label like SurgiBot?

And then can you give us anymore clarity around when US approval may occur? Is it first half '17, second half '17?

Todd Pope: Yes. I mean right now all we're really comfortable saying is that we expect that 2017 approval. We will sit down with the agency just like we did with SurgiBot and talk about the language of the CE Mark approval. And the CE Mark approval has approvals for general surgery, GYN, urology and thoracic.

So — and we will have a, you know, a good experience in the market with the ALF-X by the time we file. So we'll sit down with the FDA and discuss all this prior to our submission and we prefer not to talk about things publicly until we've sat with them.

(Brandon): Okay. And then kind of last question for me — are there certain international markets you will go direct in versus having a distributor? And then are you close to finding distributors in any major markets? Just kind of any update there. Thanks.

Todd Pope: Yes. Thanks (Brandon). Certainly as you look at like the CE Mark countries, there are certain geographies that different technologies and companies it makes sense to partner with a distributor and then certainly some it makes sense to go direct.

And we are in those discussions now. We know the markets very well. All of us kind of around the senior management table, have been involved with growing high growth MedTech companies in Europe and abroad. So we've got good relationships with the distributors.
And we are in, you know, active conversations with many distributors. And Steven, coming onboard this prior week, has 13 years of selling robotics in Europe also. So we'll be crafting that strategy and, you know, probably enlighten you more going into our next call in March of next year.

(Brandon): Okay. Thank you.

Todd Pope: Thanks (Brandon).

Operator: We'll move onto Greg Chodaczek with CRT Capital.

Greg Chodaczek: Thanks. And good morning Todd and Joe. Just a quick question — you were talking about the features and procedure costs for the ALF-X. And I guess — I'm assuming doctors like the features, hospitals like the procedure costs. Is that correct? Or they both like both?

Todd Pope: Well I would say that, you know, certainly in MedTech, I think that that environment has changed. Today, especially in the US, so many surgeons are actually employees of the hospital now that they are much more aligned with performance and compensation around the cost of their — their procedures.

So I think the days are gone of surgeons pounding their hand on the table saying what technology they want. They're involved with the economics also. So they certainly are the most keyed in on features because they're the ones using it day in and day out.
But I would say administrators and surgeons are equally invested in costs.

Greg Chodaczek: And so the — the European doctors that you saw in Chicago, were talking about procedure costs also, not just hey wow, these are great features, I want this thing?

Todd Pope: Absolutely because think about it. There's been a nice — there's been a nice growth of capital placement of robotics in Europe. But if you really dig into utilization, I rarely hear people say that they don't like operating with the robot, they like some of the technology that's brought.

But there's only a few number of procedures that really make sense that you could potentially ask a hospital to double or triple their per procedure costs and still have, you know, good utilization. So when they hear per procedure costs similar to laparoscopy they think great, this is good for my patient. I can take the benefits of robotic technology and use it across many more procedures. So, you know, that — that's what we hear when we talk to European surgeons both at ACS and certainly this last month, where we've attended that many conferences.

Greg Chodaczek: Right. And that's kind of what we're hearing with our connections, that it's a per procedure cost that kind of limits what they can use your competitor for on certain cases.

And that gets back to, can you remind me about the 5 mm tool set or instruments for the ALF-X? What do you have; what's CE Marked; why they're cheaper than your competitor? Can you go through that again please?

Todd Pope: Sure. With the ALF-X, we really wanted to try to mimic laparoscopy in the development. The majority of laparoscopic procedures today, use 5 mm trocars and 5 mm instruments. The majority of robotic procedures today, use 8 mm trocars and 8 mm instruments.

So when we were developing the ALF-X we wanted to try to have a 5 mm tool set. And today we have over 20 instruments that are approved CE Mark. The majority of those are 5 mm. There are a few that are larger.
But that's — that's the size and why we try to develop that less invasive, is typically viewed better for patient outcomes. And then lastly, the cost is fairly simple. In laparoscopy, the majority of those instruments used in traditional laparoscopy are reusable with a few of them being disposable.

With our ALF-X system the same holds true. The majority of our instruments are reusable with a few high valued instruments are disposable. And with, you know, other platforms the instruments are only able to be used a certain amount of time and then they need to be replenished.

Greg Chodaczek: Excellent. And last but not least, can I assume, and this is way out but can I assume some of the technology from ALF-X may get integrated into SurgiBot 2.0?

Todd Pope: Yes. It's a — it's a good assumption. We're certainly looking at our technology roadmap. I'd say that goes both ways. We've got some great technology with SurgiBot and some great technology with ALF-X.

And as we look at a future roadmap, we see that both platforms can share some features and benefits with one another just to strengthen our future iterations.

Greg Chodaczek: Right. Thanks Todd. Thanks Joe.

Todd Pope: Thank you Greg.

Joe Slattery: Thanks Greg.

Operator: Moving on to Jeff Cohen with Ladenburg Thalmann.

Jeff Cohen: Oh hi, guys. Thanks for taking the questions.

Joe Slattery: Hi Jeff.

Jeff Cohen: Joe, could you clarify what you were talking about when you were rolling through some of the metrics on the balance sheet? I got up to — so 25 cash was paid for the ALF-X acquisition and 5.8 common; 9.9 debt issuance, is that correct?

Joe Slattery: That's right. And roughly the...

Jeff Cohen: Okay.

Joe Slattery:...rest, the remaining $8.9 million was, you know, operating of 8.5 and 400,000 of capital.

Jeff Cohen: Okay. And the — the $4 million acquisition expense — do you expect some expense to be in the fourth quarter or beyond into '16?

Joe Slattery: We — we think we have the entire expense fully accrued into the third quarter with that number.

Jeff Cohen: Okay. Got it. And Todd, you were recently talking about the — the ALF-X instrumentation. Are there any follow on R&D projects as far as any other instruments that you may be adding?

Todd Pope: I think what we've spoken about is in 2016 we will have an advance synergy platform. That's got most of our focus right now, on instrumentation development.

Jeff Cohen: Okay. Got it. And could you talk a little bit about provided we see a SurgiBot approval in the next few months, how that may play out for a CE Mark or as far as your timeframe and integration of European sales both direct and through distributors for SurgiBot?

Todd Pope: Yes. So and similar to what we've said about ALF-X, we think we're anticipating 2017 to have ALF-X approved with a (510K) and similarly with SurgiBot CE Mark in 2017.

Jeff Cohen: Okay. So activities which start shortly thereafter a US approval for a CE Mark, we should expect?

Todd Pope: Yes.

Jeff Cohen: Okay. Perfect. Thanks for taking the questions.

Todd Pope: Thanks Jeff.

Joe Slattery: Thanks Jeff.

Operator: Thank you. We'll move onto Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson: Hi. Thank you for taking my questions. If we could get some more color on the — the European launch preparations, that would be great. You're — you're making some hires, you're talking to distributors. Can you tell us a little bit more about what the anticipated revenue uptick might be?

Are there any local regulations or tender procedures that might affect the timeline?

Todd Pope: Yes. Good morning Bruce. I would say that, you know, first off all start that, you know, we have been going through an aggressive recruiting process to get our sales leadership in place.

And the hiring of Steven Boudrez which we just announced earlier this week, on Tuesday, is really that first foundational building block. We're tremendously excited. He was certainly our number one choice and we're able to be able to get him onboard and we're excited about that.
He now is just really beginning to build out his thought process on structure and team, meeting with distributors in the coming weeks and certainly meeting with a lot of customers.
So I would say that, you know, the more color and, you know, guidance for what we'll be doing in '16, will be reviewed in our next conference call.

Joe Slattery: Yes. And Bruce, it's Joe. I would just add that, you know, you — you spoke about the capital cycle and certainly the way we think about that is efforts going into the capital cycle over the next few months, are really going to, you know, show results late next year.

But we do have significant inbound interest in the system. We have already in place, a couple of clinical sites where surgeons are able to go see procedures. We've got a fully functional demo lab in Milan that's very active. Our trade show schedule has — is full and the attendance has been very high.
So there are many targets that we see that will allow us to work outside of the traditional capital environment, particularly when you're talking about

academic centers and existing placements. And we really do have an opportunity to have some nontraditional revenue.
But certainly that is going to be, you know, where we would get most of our results over the first and second quarter of next year. And, you know, our internal assumption is those will be, you know, moderate sales expectations. And then the ramp will really take place in the second half of the year.

Bruce Jackson: Yes. That's great. Thank you.

Todd Pope: Thanks Bruce.

Operator: Thank you. At this time there appears there are no further questions at this time. Mr. Pope, I'd like to turn the conference back over to you for any additional or closing remarks.

Todd Pope: Great. Thanks again for joining us today for our third quarter call. We look forward to updating you on our progress the next quarter. And thank you again.

Operator: And ladies and gentlemen that does conclude today's conference. Thank you for your participation.

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