
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):

March 3, 2016

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 March 3, 2016, TransEnterix, Inc., a Delaware corporation (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2015. The press release is furnished herewith as Exhibit 99.1.

Also on March 3, 2016, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results. The Company had issued a press release on February 18, 2016 to announce the scheduling of the conference call. The transcript 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 March 3, 2016

99.2 Transcript of conference call held on March 3, 2016

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.

March 8, 2016

By: *Joseph P. Slattery*

Name: Joseph P. Slattery
Title: EVP and CFO

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated March 3, 2016
99.2	Transcript of conference call held on March 3, 2016

TransEnterix, Inc. Reports Operating Results for the Fourth Quarter and Full Year 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 fourth quarter and full year 2015.

Full Year 2015 Operating Highlights

- Completed Acquisition of the ALF-X® System from SOFAR S.p.A.
- Submitted 510(k) Application to the FDA for the SurgiBot™ System
- Raised \$58.3 Million in Net Proceeds from Equity and Debt Transactions
- Strengthened Global Leadership Team with the Appointment of Senior Executives

“2015 was a transformative year for TransEnterix, as we are now positioned as a global surgical robotics company. In 2016, our focus will shift from product development to commercial execution,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We will continue building the infrastructure to support the commercialization of the ALF-X in multiple countries that accept CE Mark, and we remain focused on achieving FDA clearance for the SurgiBot by the end of March, 2016, and preparing for a U.S. commercial launch.”

Financial Highlights

For the three months ended December 31, 2015, the Company reported research and development expenses of \$8.6 million, sales and marketing expenses of \$1.7 million, general and administrative expenses of \$2.2 million, amortization of intangible assets of \$1.6 million, and acquisition related costs of \$0.2 million. Operating expenses were primarily associated with the commercialization of the ALF-X and the development of the SurgiBot.

For the full year ended December 31, 2015, the Company reported research and development expenses of \$29.7 million, sales and marketing expenses of \$2.9 million, general and administrative expenses of \$7.8 million, amortization of intangible assets of \$2.2 million, and acquisition related costs of \$4.2 million. Operating expenses were primarily associated with the acquisition of the ALF-X and the development of the SurgiBot.

ALF-X Business Update

In the fourth quarter, the Company completed integration of the Surgical Robotics Division of SOFAR S.p.A. The commercialization team for the ALF-X was significantly expanded and now is comprised of 10 employees. The Company initiated digital marketing campaigns targeted at surgeons and hospital administrators across Europe and the Middle East. The Company participated in seven medical symposia, including four where the ALF-X was on-site for surgeon demonstrations. In addition, sales activities were commenced in targeted markets in Europe.

2016 Priorities and Expectations

During 2016, the Company will continue to expand its sales and service infrastructure for the ALF-X System in Europe and the Middle East. Following SurgiBot FDA clearance, the Company intends to expand its U.S. sales and service infrastructure, develop training sites and work with key opinion leaders to gain clinical experience on SurgiBot. The Company plans to submit a 510(K) application to the FDA for the ALF-X system in the fourth quarter of 2016 and capitalize on the U.S. market opportunity in 2017 with a dual-platform portfolio.

Cash Outlook

The Company had cash and cash equivalents of approximately \$38.4 million as of December 31, 2015, and approximately \$47.1 million as of February 29, 2016. The Company expects its existing cash and cash equivalents to fund operations through the end of 2016. Pursuant to the disclosure requirements of the NYSE MKT Company Guide Section 610(b), the Company is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission expected to be filed on or about March 3, 2016, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to the Company's ability to continue as a going concern.

Conference Call

TransEnterix, Inc. will host a conference call on Thursday, March 3, 2016 at 4:30 PM ET to discuss its fourth quarter and full year 2015 operating and financial results. To listen to the conference call on your telephone, please dial (888) 505-4369 for domestic callers or (719) 457-0820 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 the 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 fourth quarter and full year 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 prepare for a U.S. launch; whether we will be able to successfully commercialize the SurgiBot System and the ALF-X System,

and whether the Company's existing cash and cash equivalents will fund operations through 2016. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K and our other filings we make with the SEC. 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.

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TransEnterix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2015	2014	2015	2014
Sales	\$ —	\$ 134	\$ —	\$ 401
Operating Expenses				
Cost of goods sold	—	435	—	1,095
Research and development	8,558	5,984	29,669	27,944
Sales and marketing	1,694	404	2,855	1,727
General and administrative	2,224	985	7,831	5,741
Amortization of intangible assets	1,596	126	2,185	503
Change in fair value of contingent consideration	(400)	—	(400)	—
Acquisition related costs	228	—	4,231	—
Total Operating Expenses	13,900	7,934	46,371	37,010
Operating Loss	(13,900)	(7,800)	(46,371)	(36,609)
Other Expense				
Interest expense, net	(604)	(279)	(1,601)	(1,043)
Total Other Expense, net	(604)	(279)	(1,601)	(1,043)
Loss before income taxes	\$(14,504)	\$(8,079)	\$(47,972)	\$(37,652)
Income tax benefit	925	—	1,024	—
Net loss	\$(13,579)	\$(8,079)	\$(46,948)	\$(37,652)
Other comprehensive loss				
Foreign currency translation loss	\$ (2,737)	\$ —	\$ (3,166)	\$ —
Comprehensive loss	\$(16,316)	\$(8,079)	\$(50,114)	\$(37,652)
Net loss per share — basic and diluted	\$ (0.13)	\$ (0.13)	\$ (0.59)	\$ (0.64)
Weighted average common shares outstanding — basic and diluted	100,145	63,171	79,628	58,714

TransEnterix, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts)

(unaudited)

	Year Ended	
	December 31,	
	2015	2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 38,449	\$ 34,766
Accounts receivable, net	76	133
Inventories	3,923	—
Interest receivable	6	1
Other current assets	6,689	740
Total Current Assets	49,143	35,640
Inventories	709	—
Restricted cash	—	250
Property and equipment, net	4,408	3,120
Intellectual property, net	46,898	2,241
In-process research and development	16,511	—
Goodwill	130,869	93,842
Other long term assets	64	18
Total Assets	\$ 248,602	\$ 135,111
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 4,450	\$ 1,768
Accrued expenses	7,395	1,769
Contingent consideration – current portion	12,500	—
Notes payable — current portion	6,727	610
Total Current Liabilities	31,072	4,147
Long Term Liabilities		
Contingent consideration – less current portion	11,000	—
Net deferred tax liabilities	16,263	—
Notes payable — less current portion, net of debt discount	12,990	9,175

Total Liabilities	71,325	13,322
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2015 and 2014; 100,180,872 and 63,182,806 shares issued at December 31, 2015 and December 31, 2014, respectively; and 100,149,453 and 63,182,806 shares outstanding at December 31, 2015 and December 31, 2014, respectively	100	63
Additional paid-in capital	363,280	257,642
Accumulated deficit	(182,864)	(135,916)
Treasury stock at cost, 31,419 and 0 shares at December 31, 2015 and December 31, 2014, respectively	(73)	—
Accumulated other comprehensive loss	(3,166)	—
Total Stockholders' Equity	177,277	121,789
Total Liabilities and Stockholders' Equity	\$ <u>248,602</u>	\$ <u>135,111</u>

TransEnterix, Inc.
Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Year Ended	
	December 31,	
	2015	2014
Operating Activities		
Net loss	\$ (46,948)	\$ (37,652)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,248	807
Amortization of intangible assets	2,185	503
Amortization of debt discount and debt issuance costs	142	83
Stock-based compensation	3,311	1,840
Loss on disposal of property and equipment	34	86
Deferred tax benefit	(1,024)	—
Change in fair value of contingent consideration	(400)	—
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	133	55
Interest receivable	(5)	67
Inventories	(1,928)	701
Other current and long term assets	(1,974)	(170)
Restricted cash	250	125
Accounts payable	1,096	(36)
Accrued expenses	5,371	363
Net cash and cash equivalents used in operating activities	(38,509)	(33,228)
Investing Activities		
Proceeds from sale and maturities of investments	—	6,191
Proceeds from sale of property and equipment	—	25
Payments for acquisition of a business	(25,000)	—
Purchase of property and equipment	(1,234)	(2,174)
Net cash and cash equivalents (used in) provided by investing activities	(26,234)	4,042
Financing Activities		
Payment of debt	—	(2,877)
Proceeds from issuance of common stock, net of issuance costs	58,331	52,433
Proceeds from issuance of debt, net of debt discount	9,887	4,291
Taxes paid related to net share settlement of vesting of restricted stock units	(73)	—
Proceeds from exercise of stock options and warrants	259	91
Net cash and cash equivalents provided by financing activities	68,404	53,938
Effect of exchange rate changes on cash and cash equivalents	22	—
Net increase in cash and cash equivalents	3,683	24,752
Cash and Cash Equivalents, beginning of period	34,766	10,014
Cash and Cash Equivalents, end of period	\$ <u>38,449</u>	\$ <u>34,766</u>
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 973	\$ 904
Supplemental Schedule of Noncash Investing and Financing Activities		
Issuance of common stock warrants	\$ 97	\$ 54
Contingent consideration related to acquisition	\$ 23,900	\$ —
Issuance of common stock related to acquisition	\$ 43,677	\$ —

TRANSENERIX, INC.

Moderator: Mark Klausner

March 3, 2016

3:30 pm CT

Operator: Please standby. Good afternoon, ladies and gentlemen, and welcome to the TransEnterix 2015 Fourth Quarter and Fiscal Year 2015 Financial and Operating Results 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: Thanks. Good afternoon and thank you for joining us for TransEnterix's fourth quarter and full year 2015 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, 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 we 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 business, I encourage you to review the company's filings with the Securities and Exchange Commission, including the Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and the Form 10-K for the year ended December 31, 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. I'd like to add my welcome to our fourth quarter and full year 2015 call. I'll be referencing what slide I'm on to help you follow along.

We'll start with slide 4, and it really reviews 2015. We had a terrific year in 2015 for TransEnterix. It was a transformational year for us. We really grew into a global surgical robotics company. We're building a compelling product portfolio of both technology and economics that really differentiate ourselves from other surgical robotics platforms. Some of our top highlights were, one, we acquired the ALF-X Surgical Robotic System in the back half of 2015. With our SurgiBot, we submitted our 510(k) application to the FDA, and we certainly strengthened our leadership team across the board and in multiple geographies.

Slide 5, takes a look at three of our key hires.

On the left, Paul Ziegler, who has come on as our vice president of sales. Paul has 13 years of healthcare experience. His prior nine before joining TransEnterix was in the surgical robotics space with Intuitive and prior to that he was with Johnson & Johnson Ethicon. He's been a great addition to our team and hit the ground running across the United States.

Anthony Fernando is our Chief Technology Officer. Anthony has 15 years of healthcare experience. Prior to coming to TransEnterix, he was with Stryker based in Singapore. He ran their global innovation and R&D for their international markets and prior to that he was with Becton Dickinson and PerkinElmer also based in Singapore. Anthony and his family have recently moved back to Research Triangle Park, North Carolina to be here at our headquarters even though he has global experience and global responsibility for our company.

And next Steven Boudrez — Steven is our Vice President of Sales for Europe. Another great background, 20 years of healthcare experience; 13 years prior to joining TransEnterix in surgical robotics; 12 of those at Intuitive and prior to coming to us, he was with Medtech with the ROSA System.

So, those three have really strengthened our leadership team, not only on the technology side, but also in our commercial efforts which we're really beginning to focus on.

So move on to slide 6, we take a look at a few of our accomplishments and certainly one of the cornerstones for 2015 for us was the acquisition of ALF-X Surgical Robotics Platform. For some of you that are new to our story, I want to talk to you a little bit about the platform, it is a multi-port robot and the surgeon does sit at a console. One of the hallmarks of products that are developed by TransEnterix is we mimic laparoscopy.

We know that in U.S. and Europe alone there is over 6 million laparoscopic procedures done every year — that compares with less than a 1/2 million robotic procedures. So, laparoscopic surgery is the dominant form of minimally invasive surgery and we think when you build robotic platforms that leverage those skill sets, the training hurdle is lower and adoption is faster.

This system also has Haptic feedback. Surgeons for the first time with their robotic platform are going to be able to feel when they interact with tissue, when they interact with vessels or bones. When they're suturing they're going to be able to feel the right amount of tension to place on a knot and the early feedback around is Haptic feature has been tremendous.

We also have the ability to offer enhanced vision, primarily an eye tracking software. Surgeons now don't have to disengage with their instruments to move the camera, they can control their left hand, the right hand and they control the camera with the movement of their eyes.

This for the first time allows surgeons to be able to move all three robotic arms simultaneously. And again, the surgeons have told us, this is a tremendous advantage as they look to broaden the number of procedures and the different types of procedures they do with robotics.

We have a broad instrument offering. We have over 20 instruments that already have CE Mark and are approved, that includes wristed instrumentation. These instruments are reusable, which allows us a very different per-procedure profile. Our economic model to the hospital is drastically more affordable than what they've been offered today and this is some of the early feedback that has again driven a lot of high-interest around this platform.

So, we move on to slide 7, focus a little bit on our other platform, the SurgiBot. In the second quarter of 2015, we filed our 510(k) which was a big undertaking, it was a very extensive and comprehensive filing. We felt very good about it. As planned, we knew we'd hear back from the FDA with some of their feedback and questions, which we did in the Q3. And we've been taking the last quarter or two to really build up our answers to their question.

We've had a very proactive relationship with the FDA — very good — that continues to this day. And in the first quarter of 2016 we finalized our response and sent it back to the FDA. We built eight complete systems of the SurgiBot and over 1200 instruments in support of this mission. So we really felt like we got good experience with our manufacturing.

And we continue to expect Q1 FDA clearance which would be later this month. I just have to say as I step back and look at 2015, it was a tremendous year for the company. We really hit all of our targets that we set out to and then we took on a new one with the acquisition of ALF-X and that's turned out to be tremendous. So we're really proud of 2015 and super excited as we turn the page to look toward 2016.

And with that, I'm going to turn it over to our Chief Financial Officer, Joe Slattery for a financial review.

Joe Slattery: Thanks Todd. First, I'd like to add my welcome to those of you today on the call. This is a very exciting time for TransEnterix. We are approaching some meaningful milestones: SurgiBot clearance and first ALF-X sale. As Todd will discuss in a few minutes, we have been in the field with the ALF-X now for just a few short months and the reception has been overwhelmingly positive.

Given our increasing profile and the exciting Robotics market, we have recently attracted a great deal of new investor interest in the company. And I expect that many of you may be first time participants on our quarterly call. So before I go through the financials, I'd like to take a little time to discuss some topics that come up frequently when we receive investor e-mails and phone calls.

In February, we made two filings with the SEC to register shares issued in prior private placement transactions: our 2013 pipe financing and the 2015 acquisition of the SOFAR ALF-X platform. Both of these filings were made to satisfy contractual obligations to register the shares for resale, which is common practice in private placement transactions.

The standard form of the registration statement required by the SEC requires us to label the shareholders as "selling shareholders," so it tends to create some confusion that shares are being sold imminently, but these filings do not necessarily indicate an intent to sell.

In fact, most of these shares have been able to be resold for some time under rules that provide for sale of unregistered shares known as Rule 144. And the great majority of the shareholders have maintained or in some cases increased their share ownership of the company since the time of their sale eligibility. We have enjoyed tremendous support from our early investors, current board members and SOFAR, and we anticipate this support to continue.

We've also pursued a public financing vehicle and commonly referred to as an at-the-market equity offering, or an ATM. An ATM is designed to allow companies to opportunistically access equity capital markets, particularly during periods of high volume or volatility, and allows us to pursue raising equity at a lower overall cost of capital because the fee structure is lower and pricing discounts common with fully marketed financings are avoided.

In February 2015, we implemented an ATM program to raise up to \$25 million, which represented 14% of our market cap at the time of the filing. Over the course of almost a year, we raised the \$25 million at an average price of \$3.24 a share, while over the same period, our weighted average share price was under \$3 a share, which shows how this program worked to minimize dilution while raising needed capital for our business.

Through this initial ATM, we also attracted new institutional investors who are now some of our more significant investors. After we had fully utilized the 2015 ATM, in February, we commenced a new ATM offering to raise up to \$43.6 million over time, which represented 9% of our market cap at the time of filing, lower than the 14% in the prior ATM.

The amount of this ATM was aligned with the remaining capacity under one of our existing shelf-registration statements. Overall, we continue to think that having an ATM facility in place provides us with flexibility in terms of the timing of future equity offerings and provides us an opportunity to minimize the dilutive impact of our overall funding requirements as the success of our last ATM program has shown.

Under the ATM, we are under no obligation to sell any shares; the timing, frequency and terms of any sales orders are entirely at our discretion. We have primarily relied on raising capital through equity offerings and we'll continue to need to raise additional capital in the form of equity sales to fund our investments in commercializing our robotic platforms.

We have an additional \$18 million available under our other shelf-registration statement. In order to allow us to access the public financing markets in the future, we expect that we would make a filing with the SEC to increase the size of this shelf-registration. As a reminder, we have an extended period of time to sell shares under a shelf-registration and that any such filing does not represent a signal that we will be issuing equity in the near term.

Now, let me turn to the financial review on slide 9.

For the three months ended December 31, 2015, we reported research and development expenses of \$8.6 million, sales and marketing expenses of \$1.7 million, and general and administrative expenses of \$2.2 million. Operating expenses were primarily associated with the commercialization of the ALF-X and the development of the SurgiBot.

For the full year ended December 31, 2015, the company reported research and development expenses of \$29.7 million, sales and marketing expenses of \$2.9 million, general and administrative expenses of \$7.8 million. Operating expenses were primarily associated with the acquisition of the ALF-X and the development of SurgiBot.

On December 31, 2015, the company's cash and cash equivalents totaled \$38.4 million. And as of February 29, 2016, earlier this week, we had approximately \$47 million in cash, which we expect will fund our cash requirements through the end of 2016.

Now, I would like to turn the call back over to Todd.

Todd Pope: Thank you, Joe. I'm going to start on slide 11 here with our ALF-X update. As Joe said, some of you are new to our call and some to our story, so I want to make sure you get a good update on the product that we acquired in the back half of last year.

So — our integration — on our last call we shared with you that we had a six month timeframe to complete our integration. We are five months into that, and we are finalized with that. We feel great about the diligence that we made going in, and our integration is finalized, and our confidence is high.

Some of the confirmations that we received going through this integration finalization - first, the market interest for ALF-X is very high. Our platform is reliable, stable and robust. It's been in development for quite some time, it had a CE Mark, it's got good human clinical experience.

Our manufacturing is solid and scalable, we have plans for the coming years continued to invest in commercial infrastructure and we want to make sure our manufacturing doesn't hold us back. And we've made great strides in our confidence there.

And we certainly inherited a great engineering team from the SOFAR company, and we've made a couple of significant adds to that. So we feel great about that. On our background — on commercial prior to TransEnterix acquiring the platform — the prior activity for the system was really focused on clinical experience. They wanted to get a couple of systems out at SOFAR and get different specialties doing a surgery on there to see how their results were, get some both publication and podium presence, and they did that. The trade show participation was limited and we at TransEnterix inherited no sales or marketing infrastructure. So we've been building that up from scratch.

The next slide talks a little bit about what we have done in a very short period of time. It talks about our team today and we feel very good about it. As we talked about our Vice President of Sales, Steven Boudrez in Europe, we have hired a Director for the EU distribution market.

As you know, a lot of times in Europe, distributors will be the preferred way to a channel for medtech companies and some countries will be best served with direct. So distribution will be very important — hire someone that has extensive distribution experience with very successful high-growth med-tech companies. So he's on-board and making a great progress early.

We are going to go direct and we've hired someone to cover the France and Switzerland market. We've hired someone to cover the UK and Benelux market that will be starting shortly. And we've also brought people on sales leadership capacity in the Middle East, which we expect is going to be a big market for us and Asia.

We also on the right side of the slide, we know that when we have a pipeline of accounts that have a high interest and we have a new platform, that people aren't familiar with, professional education is very important. We need to train surgeons and we've actually hired a general and urology trained surgeon to come on staff, which has been a tremendous add for us.

We have a clinical nurse that is able to come in and be in all of our trainings both wet and dry labs. And we've hired someone to run global sales training that has over 30 years experience in the laparoscopic surgery space. We've also brought in field service folks since we are looking to commence sales pretty much right away.

We need to be able to service and we brought in folks that have a good experience in robotics. And in addition to the team we brought over from R&D, and added, our team now is 12 in the R&D platform. So, we now had a very short amount of time have 23 employees, focused exclusively ALF-X commercialization and support.

I'd just tell you, the five or six companies that all these folks came from are great ones and they bring great experience. They've come from Intuitive, J&J, Medtech, Covidien, Stryker and Medtronic. So, we felt like we have folks with deep experience and very good training grounds.

Now our marketing efforts on the next page, slide 13. We immediately after acquisition in the Q4, we went for a pretty aggressive digital and print marketing campaign. We wanted to get the word out that this platform of ALF-X was in the hands of TransEnterix.

We were able to contact over 5000 surgeons and hospital administrators across the EU and the Middle East and we really let them know about the transaction, let them know about ALF-X and certainly let them know that we were hiring and have hired sales leadership that could come out and meet with them. It has generated hundreds of high-quality leads and we've been following up with those and that's what's created our early pipeline.

We also attended quite a few conferences in the short amount of time in the last quarter and a half. We've been to the European Colorectal Congress in Switzerland. We've been to Arab Health in Dubai. And in Switzerland we were able to get over 100 surgeons on the ALF-X platform to really sit down and experience it for themselves.

Their feedback on Haptics and eye tracking was incredible and they took to it so easily because the laparoscopic skill set is high in those geographies and they really were very familiar with the movements that we have designed in. At Arab Health as you know it's the second largest healthcare meeting in the world and we got nearly 200 people with discreet test drives on the system, which really fit into a great pipeline for us.

We were at the World Congress of Endourology in London and we've also started to attend regional society meetings across those geographies. So, we not only have early interest but its meaningful interest and we're really pleased with that.

Next, how are we handling some of the pipeline interest? On slide 14, we talk a little bit about our demonstration capability. We now have two clinical sites up — one in Rome and one in Milan. The Milan site with general and colorectal cases and in Rome GYN and GYN oncology.

In the Milan area, we have capabilities for both wet and dry labs to demonstrate to surgeons that have interest in this system. As you saw on the previous slide, we've got a dedicated professional education team that can work with them in any scenario to let them experience the system which includes case visits and case observations.

We're usually hosting about two visits a week — so far in the first eight weeks of the year we brought in eight hospitals, some have been hospital systems represented. It's a two day program — they usually bring two to four surgeons that have represented multiple specialties. And we usually have at least one to two C-level executives coming on.

So they want to be on that trip, see the response of the surgeons and really take a look at moving an accelerated timeline if they're in the market for a robot. This really allows us to leverage some of these capabilities and we think it's going to allow us to get into a sales funnel much quicker than if we didn't have these capabilities.

On our commercialization efforts on slide 15, just to put a little more finer point on it, we have gone out with our direct sales efforts and had 65 different sales presentations over the first two months. There is certainly been a lot of interest from the generation that we talked about two slides ago.

For those, the majority of those are in person and the majority of those were either at the C level suite or accompanied by surgeons. We're going to continue to expand our direct footprint

in the geographies that we've talked about and as we sell units we'll also increase our clinical team, so they can be in the cases day in and day out.

One of the benefits of this system of ALF-X, it has a broad CE Mark, it's for general surgery, urology, GYN and thoracic. So we think when we get a system at a hospital there is going to be a lot of different specialties that are going to be interested in it.

And as we turn to distribution, we certainly have made a lot of progress in Italy, we're working with Spain and Portugal and certainly the Middle East and Asia will be primarily a distribution strategy for us. So I think we've made incredible progress in the early part of the year.

Some of the hospitals that have come through that we've met with both at their facility and then have come to Italy to take a look at the system. The majority of those have been private hospitals. We've really leaned toward that mix because they already have a robotics budget approved for 2016 and private hospitals are able to move a little bit quicker.

But we certainly have a good number of public hospitals that have interest. And in the public setting in Europe you have to go through a tender or a bid process and up to this point there has only been one robotic platform to send a tender out to and now we've gotten the word out that we have the ALF-X there and we are ready to place units.

So, we've started to be able to do two things. One, respond to some of the tenders that are just being created now that they know that we're in the market and we're also de novo going into some hospitals and talking to them and they hadn't considered robotics in the past primarily because of a per-procedure cost that's kept them from being interested.

With the ALF-X, we started to generate some pretty significant public hospital entries, so it just takes probably six or eight months with the tender process. So, most of the surgeons that come through are aware of robotics, they either have been trained on robotics and they're at a hospital that doesn't have one or they're currently using robotics and they're looking to increase the robotics usage.

We certainly have hospitals that have both, some with robots and some that do not have them. And interestingly urologists are the typical key stakeholder in Europe. The great majority of robotic cases in Europe are urology cases.

And we believe that with some of the benefits, not only the features that we offer, but our cost profile we're going to be able to bring live different specialties in that haven't primarily been drivers of robotics interest. So we're excited about that and moving forward.

So, as we take a quick turn to 2016 going forward let's talk about on slide 18, our commercialization strategy. We certainly want to have a commercialization strategy that goes across our portfolio. We want to look at leveraging our products in the most effective way possible, our infrastructure and our capital spend.

So the first bullet speaks to, we want to continue to expand sales and service on ALF-X. We have a CE Mark. So, we have excellent early feedback and that's what we're focusing on both in Europe and in the Middle East. With the SurgiBot, following clearance, which we expect later this month, we want to expand our U.S. sales and service infrastructure.

We want to early on develop trainee sites and work with those sites to develop key opinion leaders and gain valuable clinical experience as you do any time you launch a new platform. We want to submit our 510(k) for the ALF-X in the fourth quarter of this year.

Now that we've gone through integration and done a gap analysis we feel very good about our CE Mark, the strength of the system, the stability of the system, so we feel much more bullish about our ability to file this year for a 510(k) for the ALF-X. And certainly that leads us to look into 2017 when we can really capitalize on the largest robotic market in the world which is the United States, you know, with the dual platform portfolio.

As far as our commercial ramp on 19, we're going to continue to put significant resources behind ALF-X. We should be selecting distributors soon and signing them up. As far as our demo capability in addition to what we described earlier with our wet and dry lab, we want to add a second training center a little closer to the heart of Milan near the city and that will come online in Q2.

We just don't want the ability to demonstrate this product to be any kind of bottleneck for our pipeline. And when we start placing units, selling units, we'll be able to take different hospitals and different surgeons to see cases there.

Anytime you have a new platform, there's a high need for hospitals to take a look at it, to talk to others that are using it, to use it in a lab setting and to watch procedures being done. So that's the way we're going to broaden out our capabilities there. If you turn to slide 20, with SurgiBot following our FDA clearance, our plans are as follows.

We want to hire three area sales managers shortly after clearance. As we've been talking to you, we've been interviewing for a while; we've got a tremendous pipeline of candidates; and we've got them lined up to be able to make those hires; and we want to go out and establish our commercial foundation.

It always involves developing early clinical experience, making sure that the site you sell into are willing to host other accounts and be a training site, you want to get a KOL, or a key opinion leader network, so they can go out and not only have a podium presence but a publication presence. And then we want to build a customer support infrastructure with service and the other things that go around early commercialization.

We do have a busy agenda coming out for both platforms. You see on slide 21, SAGES comes up in mid-March that's always a big meeting for our company. For the first time, we're going to have both ALF-X and SurgiBot on the floor in the booth. So this is generating a lot of early interest and we're excited about that.

In the middle of the year, we're going to be at the European Association for Endoscopic Surgery in Amsterdam. That's a European meeting and we'll have the ALF-X there. We will be at the ACS, the American College of Surgery in Washington, D.C. in mid-October. Again, we'll have both platforms there.

Obesity Week in New Orleans in early November, we are going to have the SurgiBot there. We're generating a lot of interest in single port obesity procedure. So, we'll highlight the SurgiBot there. And then, the AAGL, we'll be in Orlando in the middle part of November where again we'll have both platforms present.

So, you know, as we think about our summary, it's been quite a year. We're off to a great year in 2016, and I just wanted to remind you of a few key pillars of our growth story, surgical robotics is a significant market as it stands today. It's well over \$2 billion.

And if you triangulate analyst reports, it's projected to grow to \$10 billion or more in the next six to seven years. So a tremendous compounded annual growth rate. But that's really juxtaposed with the fact that less than 5% of surgery today is done robotically. You see there on the right in the U.S., it's about 5%, in Europe and in Asia it's less than 1%.

And why is that still low-single digit? The surgeons tell us it's primarily economically, they either did not want to make a capital investment as large as they needed to, so they look for a lower capital investment, which SurgiBot certainly fits into that. And then, per-procedure economics is probably one of the biggest drivers or one of the future drivers of robotic surgery.

Today, where there is reimbursement, it's laparoscopic reimbursement. There is not separate reimbursement for robotics. So hospitals are really having to use laparoscopic reimbursement codes. And if you don't have a platform that kind of mimics or gets close to laparoscopic reimbursement with your robot, it's going to be difficult for hospitals.

So we feel like both of our platforms are well positioned to address these trade-offs and needs. So lastly, I'd say our ALF-X commercialization is on track as we talked about, SurgiBot FDA decision expected later this month. And we are excited about that.

So with that I'm going to wrap up our comments and we will turn it over to the operator to take some of your questions. Thank you.

Operator: Thank you. 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 your mute function is turned off to allow your signal to reach our equipment. Again, that is star 1 to ask a question at this time.

And our first question will come from (Rick Wise) with Stifel.

(Rick Wise): Good afternoon, Todd. Thanks for taking the question. Todd, and I apologize for this whole background noise, I'm in the airport. You described ALF-X reception was overwhelmingly positive, you clearly have made tremendous progress in a short time in terms of building the initial commercial infrastructure.

Can you give us some color or some more detail or granularity about how and when, you know, that infrastructure and that overwhelming excitement and interest translates into orders or backlog for sales and will we see some sales of ALF-X this year?

Todd Pope: Certainly, Rick. Thanks for your question. I appreciate you calling in on your travels. We've said in our last call that we expect first quarter to commence selling ALF-X and we reiterate that. We continue to be confident there. You know, I would say that in Europe a typical capital sales cycle is anywhere from four to five quarters.

But with some of the interest that's unique as we described in, you know, six or eight of those slides, we are really accelerating that. We are getting in with some hospitals that had already planned on buying a robot. They become aware of our system through the many different channels we talked about. And we've been brought into the process quickly here at the beginning of the year.

So, most hospitals are conditioned to make their capital purchases at the end of the quarter. We've got a month left here and we feel like to answer your questions specifically, we'll begin in the Q1 and then we will go from there.

(Rick Wise): So, again, I'm sorry to put you on the spot about this but — so, you're saying you think is very possible that we will see some actual ALF-X sales as the year progresses. And it sounds like if it happens, it's likely to be more second half or by fourth quarter.

Is there any kind of language that you can help us think about that?

Todd Pope: Yes. I think you're accurate with your questions and your suppositions. You know, one thing I will start off with is as much interest as we've had, we brought most of our commercial team on over the past couple of weeks, if not the past two months.

The interest is high. The pipeline is robust for such a short amount of time. But, we haven't sold one yet. So, we want to see when we are joined into these processes kind of late. How many of those can we actually turn to sales?

And then, the majority of our work will be continuing to build out our team, continuing to talk to hospitals about not only their urology robotics, which drives the great majority of European robotic volume, but also multi-specialty. For the first time hospitals are thinking about other specialties that up to this point the per-procedure economics had not worked with them.

So I think we will build a natural pipeline with some of those de novo specialties and de novo hospitals throughout the year, you know, hence to your back half comment. But, we're going to continue to add sales people both direct and distribution in the geographies that we highlighted.

And I think we'll continue to build our pipeline of momentum through 2016 and get on more of a natural capital sales pipeline cycle in '17 and beyond.

(Rick Wise): Yes. And just a couple of more for me. What do you need in the United States to do to file ALF-X? Is the system fully ready for filing? Are you going to change it or evolve it or offer enhance the next-gen version? Just walk us through the process there.

Todd Pope: Yes. It's a good question. As we said, the platform itself is quite stable and it has been in place for a while. So it's not a matter of changing the platform at all. But, there is a gap analysis you have to do when you have a CE Mark and you don't have a 510(k).

You have to look at all of your validation and verification studies, bio-compatibility, shipping and transit. There are many things that — some are subtle changes from CE Mark to 510(k) and others are a little bit larger. So it really is just a matter of doing that gap analysis, doing some testing, maybe a little more extensively, if the FDA requires that, or a few different tests that hadn't been done for CE Mark.

But, the fact that we do have a CE Mark, the fact that we do have good clinical cases, the fact that we have a growing publication list, we think that's all going to strengthen our submission. So that's why we felt confident today coming out and talking about filing by the end of the year with ALF-X.

I'd also say that we're just coming off of several years of working through all of this with SurgiBots, so I don't think there is a company in the world that is more equipped with near term experience try to get a system to the FDA. So all that's leading to our confidence of filing later this year.

(Rick Wise): Just my last question, now, just maybe Todd or Joe you want to address that the language in the press release about the auditor language about

going concern. And apologize again, just because I can't check from the airport. Is that new or different and maybe just to help everybody listening just for the perspective, what's that mean, should we be more concerned, you know, how do we think about your ability to deal with that? Thank you.

Joe Slattery: Sure, (Rick). It's Joe. We've actually — it's consistent with last year and the year before. It's done for any company that doesn't have enough cash to go more than a year from basically the filing date of the 10-K, or the financial statements.

So, about a year from now, so although we have enough cash to get through this year, you know, we have an equity gap in the beginning of 2017 and that gives rise to the going concern opinion. But, I'm sure you've seen more of these on companies our size than not.

(Rick Wise): Thanks.

Todd Pope: Thank you, (Rick).

Operator: Thank you. Ladies and gentlemen, our next question will come from Glenn Navarro with RBC Capital Markets.

(Glenn Navarro): Hi. Good afternoon. I had a question on SurgiBot, so approval is on track to be this quarter, end of this month. And then, Todd on the call, you commented that after the approval you will start the process of hiring reps. So, my question is on the hiring of the reps. Will these reps be on-board in April or May?

Will there be non-competes, and how quickly can they ramp-up and start selling? It sounds to me that maybe SurgiBot, is probably is in the third quarter, you have to bring on and train these reps? Thanks.

Todd Pope: Yes. Thank you, (Glenn). We are. We have been talking with quite a few candidates. We've got it narrowed down in a great line-up. We do think that the timeframe that you talked about, you know, coming on in the April/May timeframe is accurate.

And we really don't want to bring on anyone that has a non-compete, there's just no reason to do that. There's enough great talent out there that we don't need to cross wires with any other companies. So they won't have a non-compete issue, it's just a matter of getting them on-board, really spending some time with the system, and then getting out and beginning calling on customers.

(Glenn Navarro): And then, just as a follow-up, I wanted to follow-up on (Rick)'s question on ALF-X in the United States, the approval process. You did mention that you had a lot of experience in navigating with the FDA. Is it safe to assume you've had some early discussions with the FDA on ALF-X and that's what's giving you the confidence to file at the end of this year?

And then, should we assume a nine month approval process similar to SurgiBot? Thanks.

Todd Pope: Yes. We have not gone and had an official meeting with the FDA on the ALF-X. We want to finalize our work with SurgiBot with them and then turn our attention to that. I think from what I'm speaking of is, you know, being in the business 25 years, you know, having a lot of products go through the 510(k) process and certainly coming on the back of the SurgiBot experience, we feel like we're going to have a good solid submission. We're, you know, a good ways there and we're just going to finalize some things throughout this year to be able to file.

(Glenn Navarro): Okay. Thank you.

Todd Pope: Yes. Thank you.

Operator: Thank you. Our last question today will be from (Jeffrey Cohen) with Ladenburg Thalmann.

(Jeff Cohen): Hi, guys, thanks for taking the questions.

Joe Slattery: Hi, (Jeff).

(Jeff Cohen): If you could just, two if I might, if you could further extrapolate upon the sales organization for SurgiBot in the U.S. as far as Paul's team and the current status. Could you talk about discussions with surgeons that you've had over the past number of months and discussions with senior level executives and kind of prepping the channel for commercialization?

And secondly, could you discuss a little bit about the ALF-X instrumentation and manufacturing and where that currently stands and how that transitions goes and manufacturing for supplying an initial fleet? Thanks.

Todd Pope: Certainly, thank you (Jeff). This is Todd. Yes, as it relates to SurgiBot, as you know Paul has been on board, he has been out talking to some customers who are primarily doing recruiting. So, when those folks come onboard they will certainly have some pipeline that we talk with already, but we'll let them get out and really cultivate that on their own for sure.

As far as the ALF-X instrumentation, we remember we've got several units out in clinical experience, so that is being manufactured in Europe. We've got good experience at two sides across multiple specialties. Feel really good about not only performance reliability but the ability to scale that.

It's just much easier to be able to do a fixed instrumentation onto the ALF-X system since it doesn't have to lock into a trocar, it can be a straight insertion in. So we're really taking a lot of the typical laparoscopic instruments that surgeons are used to and expect, and they've been able to modify those for the ALF-X quite in a straight forward manner.

So, we feel really good about what we have and we certainly feel good about, you know, being able to grow with volume.

(Jeff Cohen): Thanks. And continued manufacturing of the instrumentation, you expect where?

Todd Pope: We'll keep that in Europe for now. There's a tremendous base of instrumentation very similar to in the U.S. with how orthopedics who it's all centered around a certain area. There's, similarly it's that way in Europe, a lot of good experience. We have great partners, partners that we were familiar with prior to the acquisition of manufacturing so we'll keep those relationships.

(Jeff Cohen): Okay. That does it for me. Thanks a lot for the details.

Todd Pope: Thank you.

Operator: Thank you. And next we will hear from (Bruce Jackson) from Lake Street Capital Markets.

(Bruce Jackson): Hi, thanks for fitting me in. Just a quick housekeeping question on the income statement. For 2016, are you going to be at roughly the same operating expense levels that you had in Q4 or will they maybe go up a little bit?

Joe Slattery: Yes, I would say, (Bruce), you know, just directionally, obviously, the sales and marketing expense is going to increase substantially this year compared to last year. And as far as R&D and G&A, they're, collectively they will represent about the same amount of investment in '16 versus 2015.

(Bruce Jackson): Okay, great. And then, last question, can you just give us a little bit of color about your last interaction with the FDA? Was it mostly about sort of last minute implementation type issues or, you know, what kind of topics were they interested in?

Todd Pope: Yes. As we've characterized in the past, you know, we filed, they gave us their questions in a timely manner as we expected. We responded to their questions in a timely manner as they expected. And they confirmed that they received our questions and they're working through them.

We had a good interaction with them. Any interaction over the prior, you know, month or couple of weeks have just been clarifying questions. So, everything continues to be on the path that we set out, you know, last year.

(Bruce Jackson): All right. Super. Thank you very much.

Todd Pope: All right. Thank you, (Bruce).

Operator: Thank you. And at this time, I would now like to turn the conference back to Todd Pope for closing remarks.

Todd Pope: Thank you so much. I again want to thank you for joining us for our fourth quarter and full year 2015 call. As you see, we had a great 2015 and we certainly have a dynamic year ahead of us in 2016, and we look forward to keeping all of you updated as we go along. Thank you for joining us again and have a good day.

Operator: Thank you, again, ladies and gentlemen, that does conclude our conference for today. We thank you for your participation.

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