
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):

May 10, 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 May 10, 2016, TransEnterix, Inc., a Delaware corporation (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2016. A copy of the press releases is furnished herewith as Exhibit 99.1.

Also on May 10, 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. 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 May 10, 2016

99.2 May 10, 2016 conference call script

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.

May 13, 2016

By: *Joseph P. Slattery*

Name: Joseph P. Slattery

Title: EVP and CFO

Exhibit Index

Exhibit No.	Description
99.1	Press release, dated May 10, 2016
99.2	May 10, 2016 conference call script

May 10, 2016

TransEnterix, Inc. Reports Operating Results for the First Quarter 2016

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 first quarter of 2016.

Financial Highlights

For the three months ended March 31, 2016, the Company reported total operating expenses of \$15.0 million, including research and development expenses of \$8.4 million, sales and marketing expenses of \$1.7 million, and general and administrative expenses of \$2.2 million. Total operating expenses increased from \$9.8 million in the three months ended March 31, 2015, primarily as a result of increased investment in the development and commercialization of the ALF-X and other costs related to the ALF-X platform.

The Company had cash and cash equivalents of approximately \$53.5 million as of March 31, 2016, and approximately \$75.0 million as of April 30, 2016. The Company expects its existing cash and cash equivalents to fund operations through the third quarter of 2017.

SurgiBot 510(k) Update

As previously announced, the Company received a Not Substantially Equivalent (“NSE”) letter from the U.S. Food and Drug Administration (“FDA”). The Company expects to have further discussions with the FDA, but currently believes that a new 510(k) submission would be required to obtain clearance. The Company has evaluated the operational and financial feasibility of pursuing 510(k)s for SurgiBot and ALF-X concurrently, and has decided to reprioritize its near-term regulatory efforts and focus on the ALF-X 510(k) submission. As a result, in the 2016 second quarter, the Company has taken actions to reduce headcount and investment related to the SurgiBot.

ALF-X Business Update

In the first quarter, the Company continued to strengthen the ALF-X commercialization team, increasing direct sales headcount by three since our March 3, 2016 investor update, including anticipated new hires starting through July 1, 2016. Ten additional hospitals have participated in hands-on training events, bringing the total since beginning the commercial launch to eighteen hospitals. The Company has also executed on its plan to expand commercialization through distribution, adding distributor partners in Europe and the Middle East. The Company has also begun evaluating distribution partners for Asia. The Company continues to expect to submit a 510(k) application to the FDA for the ALF-X in the fourth quarter of 2016.

“We were surprised and disappointed with the outcome of our SurgiBot 510(k) submission and expect to gain further clarity from the FDA on its response,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We remain enthusiastic about the significant opportunity for ALF-X and are continuing to invest in our commercialization efforts and preparing for our ALF-X 510(k) submission.”

Conference Call

TransEnterix, Inc. will host a conference call on Tuesday, May 10, 2016 at 4:30 PM ET to discuss its first quarter 2016 operating and financial results. To listen to the conference call on your telephone, please dial (888) 427-9419 for domestic callers or (719) 457-1035 for international callers and reference TransEnterix Call approximately ten minutes prior to the start time. 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 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 ALF-X has been granted a CE Mark but is not available for sale in the US. The company is also working on the development of the SurgiBot System, a single-port, robotically enhanced laparoscopic surgical platform. The SurgiBot System is not yet available for sale in any market. For more information, visit the TransEnterix website at www.transenterix.com.

Forward Looking Statements

This press release includes statements relating to our 2016 first quarter financial results, the ALF-X® System, the SurgiBot™ 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 be able to gain greater clarity from the FDA on its response to our 510(k) submission on the SurgiBot System and whether the Company’s existing cash and cash equivalents will fund operations through the third quarter of 2017. 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 filed on March 3, 2016, our other filings we make with the SEC and our Form 10-Q for the 2016 first quarter expected to be filed on or before its 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.

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

	Three Months Ended		2015
	2016	March 31,	
Operating Expenses			
Research and development	\$ 8,385		\$ 7,484
Sales and marketing	1,683		375
General and administrative	2,239		1,855
Amortization of intangible assets	1,817		125
Change in fair value of contingent consideration	856		—
Total Operating Expenses	14,980		9,839
Operating Loss	(14,980)		(9,839)
Other Expense			
Interest expense, net	(578)		(281)
Total Other Expense, net	(578)		(281)
Loss before income taxes	\$ (15,558)		\$ (10,120)
Income tax benefit	2,645		—
Net loss	\$ (12,913)		\$ (10,120)
Other comprehensive gain			
Foreign currency translation gains	3,796		—
Comprehensive loss	\$ (9,117)		\$ (10,120)
Net loss per share — basic and diluted	\$ (0.12)		\$ (0.16)
Weighted average common shares outstanding — basic and diluted	104,260		\$ 63,745

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

	March 31, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	\$ 53,511	\$ 38,449
Accounts receivable, net	79	76
Inventories	3,615	3,923
Interest receivable	12	6
Other current assets	7,069	6,689
Total Current Assets	64,286	49,143
Inventories	1,028	709
Property and equipment, net	5,921	4,408
Intellectual property, net	46,892	46,898
In-process research and development	17,191	16,511
Goodwill	132,394	130,869
Other long term assets	64	64
Total Assets	\$ 267,776	\$ 248,602
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 3,140	\$ 4,450
Accrued expenses	6,663	7,395
Contingent consideration – current portion	13,300	12,500
Notes payable — current portion	7,493	6,727
Total Current Liabilities	30,596	31,072
Long Term Liabilities		

Contingent consideration – less current portion	11,056	11,000
Net deferred tax liabilities	14,210	16,263
Notes payable — less current portion, net of debt discount	11,057	12,990
Total Liabilities	66,919	71,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at March 31, 2016 and December 31, 2015; 109,457,941 and 100,180,872 shares issued at March 31, 2016 and December 31, 2015, respectively; and 109,386,396 and 100,149,453 shares outstanding at March 31, 2016 and December 31, 2015, respectively	109	100
Additional paid-in capital	396,098	363,280
Accumulated deficit	(195,777)	(182,864)
Treasury stock at cost, 71,545 and 31,419 shares at March 31, 2016 and December 31, 2015, respectively	(203)	(73)
Accumulated other comprehensive income (loss)	630	(3,166)
Total Stockholders' Equity	200,857	177,277
Total Liabilities and Stockholders' Equity	\$ 267,776	\$ 248,602

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

	Three Months Ended	
	March 31,	
	2016	2015
Operating Activities		
Net loss	\$(12,913)	\$(10,120)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	565	265
Amortization of intangible assets	1,817	125
Amortization of debt discount and debt issuance costs	52	27
Stock-based compensation	1,428	899
Deferred tax (benefit) expense	(2,645)	—
Change in fair value of contingent consideration	856	—
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	—	80
Interest receivable	(6)	—
Inventories	(1,735)	—
Other current and long term assets	(132)	143
Accounts payable	(1,391)	510
Accrued expenses	(765)	(143)
Net cash and cash equivalents used in operating activities	(14,869)	(8,214)
Investing Activities		
Purchase of property and equipment	(153)	(155)
Net cash and cash equivalents used in investing activities	(153)	(155)
Financing Activities		
Payment of debt	(1,219)	—
Proceeds from issuance of common stock, net of issuance costs	31,391	1,783
Taxes paid related to net share settlement of vesting of restricted stock units	(130)	—
Proceeds from exercise of stock options and warrants	8	196
Net cash and cash equivalents provided by financing activities	30,050	1,979
Effect of exchange rate changes on cash and cash equivalents	34	—
Net increase (decrease) in cash and cash equivalents	15,062	(6,390)
Cash and cash equivalents, beginning of period	38,449	34,766
Cash and cash equivalents, end of period	\$ 53,511	\$ 28,376
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 373	\$ 187

Supplemental Schedule of Noncash Investing Activities
Transfer of inventory to property and equipment

\$ 1,823

\$ —

For TransEnterix, Inc.

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or

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TRANSENERIX, INC.

Moderator: Mark Klausner

May 10, 2016

3:30 pm CT

Operator: Please standby, we're about to begin. Good afternoon ladies and gentlemen and welcome to the TransEnterix 2016 First Quarter Financial and Operating Results conference call.

As a remainder, this conference is 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 afternoon and thank you joining us for TransEnterix first quarter 2016 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.

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 the 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 report Form 10-K for the year ended December 31, 2015 and the Quarterly Report Form 10-Q for the quarter ended March 31, 2016 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 first quarter 2016 conference call. On today's call, we will be reviewing a number of topics. I will start by discussing the FDA's recent decision on our subsequent regulatory plans for the SurgiBot. I will then hand it over to Joe for a financial overview and an update on our recent restructuring. We'll then turn our attention to ALF-X and wrap up before opening the line for questions.

Turning to SurgiBot, as we announced on April 20, we were notified by the FDA through an NSE or Not Substantially Equivalent letter that we did not receive 510(k) clearance for the SurgiBot. We were certainly surprised and extremely disappointed by this response, given the extensive history of interactions with the agency as well as our belief that we submitted a robust 510(k) application.

For the last three years, we've had numerous interactions with the FDA in planning and completing the SurgiBot 510(k) submission. In 2013 we held our first pre-submission meeting and proposed our approach in terms of predicate device, indications for use, and preclinical testing plan.

In March of 2014, we filed a pre-submission to the FDA and received their written feedback in June of 2014. With this feedback, we moved forward with the submission plan that we were confident was fully aligned with the FDA's guidance and expectations.

In June of 2015, we submitted our 510(k) application, which was an extensive compilation of documentation and testing results. As is typical in the 510(k) process, within 60 days, we received a request for additional information from the FDA called an AI, and immediately undertook the actions necessary to respond to their request. The 510(k) process gives the company up to six months to respond to an AI. And we submitted our response in February 2016.

In total, over the course of the submission we provided over 11,000 pages of requested material to the FDA. After a total of 138 days of FDA review, we received the NSE for the SurgiBot. The reason stated by the FDA for this decision included items that we believe we had adequately addressed through the interactive period.

Since receiving the NSE, we've been analyzing the FDA's response together with regulatory counsel. I personally interacted with the director of the division of surgical devices of the FDA, along with the director of the CDRH for the FDA, to request an in-person meeting to review the topics raised in the NSE, which they have agreed to, but has not yet been scheduled.

The current situation is as follows. This 510(k) file is now considered closed by the agency. We do expect further discussions with the FDA to help inform our future regulatory strategy for both SurgiBot and ALF-X. As it stands today, we believe that a new 510(k) would need to be submitted for SurgiBot.

Based on this belief, we've evaluated the operational and financial feasibility of pursuing two 510(k)s concurrently and have elected to focus our efforts on the 510(k) submission for the ALF-X. In anticipation of clearance, we have been investing substantially and continuing development and production efforts for SurgiBot.

This week we have taken significant actions to reduce infrastructure in these areas of the business. These actions put us in a stronger financial position to allow us to fully focus on ALF-X commercialization and prepare the FDA 510(k) submission for ALF-X, while also investing in expanding the capabilities of the ALF-X platform.

I will now turn the call over to Joe to review the financials.

Joe Slattery: Thanks, Todd. For the three months ended March 31, 2016, company reported total operating expenses of \$15 million, including research and development expenses of \$8.4 million, sales and marketing expenses of \$1.7 million, and general and administrative expenses of \$2.2 million.

Total operating expenses increased from \$9.8 million in the three months ended March 31, 2015, primarily as a result of increased investment in the development and commercialization of the ALF-X and other costs related to the ALF-X platform.

As Todd mentioned, earlier this week we implemented a plan to reduce headcount investment in SurgiBot production and development. These actions have resulted in an annualized reduction in salaries of approximately \$4 million.

Many of our home office R&D and regulatory personnel will continue in new roles focusing on the ALF-X 510(k) and continuing ALF-X development activities, while, overseas, our headcount and investment plans remain unchanged as we continue our focus on supporting revenue growth and advancing the platform.

We've also taken this opportunity to further integrate our US and Italy based teams to drive leadership synergies. We continue to retain key US commercial personnel who will be focused on market development activities, as we move the ALF-X through the US regulatory process, and plan to expand this investment throughout 2016.

Turning to the balance sheet, on March 31, 2016 the company's cash and cash equivalents totaled \$53.5 million. And as of April 30, we had approximately \$75 million in cash. With our current strong cash position and the cost reductions that we've undertaken, we have adequate cash on hand to fund our operations in working capital needs through the third quarter of 2017.

In the second quarter of 2016, we will incur impairment charges related to SurgiBot inventory, fixed assets and capitalized intellectual property of approximately \$46 million, which will be non-cash in nature. I'll now turn the call back to Todd, to discuss our progress with an expectation for ALF-X. Todd?

Todd Pope: Thank you, Joe. As Joe reviewed, we've taken significant actions that have put us in a strong financial position to accelerate our investment in ALF-X. We are focusing this investment in two ways, and even more aggressive commercial expansion of ALF-X, and the planning and preparation for an ALF-X 510(k) submission.

With that said, I'd like to provide you an update on ALF-X. We gave our team an aggressive goal to sell a system in the Q1. Even though, we haven't closed that initial sale, we continue to expand our pipeline and our confidence continues to be emboldened through our interactions with customers.

When we last spoke on March 3, we explained that our early efforts were focused on near-term opportunities, where hospitals that had an improved budget, and we're planning on near term robotic purchase. Pursuing these situations certainly provided the potential to close one of these accounts in the first quarter.

And while these opportunities have not yet converted into a sale, most are still active deals and we continue to be engaged with them, so far so good. These hospital interactions have validated much of our thinking and we've learned some new things that reinforce our confidence.

First and foremost, our platform offers unique features and benefits that are resonating in the market. Surgeons love the independence the eye tracking camera provides. The haptic feedback restores the sense of touch that they have been without since the advent of robotics. And ALF-X allows them to be more engaged in the surgical field, which has multiple benefits.

Our ROI model in ALF-X, due to the reusability of the instruments, is also resonating with hospitals. This economic shift gives us the opportunity to expand the current market for robotics. Our conversations are starting to redefine robotics as a potential mainstay technology across many specialties in the hospital rather than limiting the applicability only to high reimbursement indications.

Finally, as we get deep in the conversations about what a hospital is looking for from a robotics company, we have repeatedly heard that they are looking for a solution that complements of their existing ecosystem rather than having to duplicate it. The ALF-X open architecture allows hospitals to utilize much of their current infrastructure and we believe that we can, over time extend the platform's capabilities by incorporating more and more advanced technologies.

We've also had some additional key learning's from interactions with these hospitals. Robotic capital sales have always required a long involved sales process, and now with two systems to consider, hospitals are having to look at their purchase decisions differently in terms of time and information that they need to process.

The old norm of deciding whether to buy a robot or not, is being replaced with the new normal that adds, which robot is the best fit for my needs. In these situations, when our ALF-X is compared with the competitor's newest technology, our features, benefits, and low per procedure cost model positions us extremely well.

We have, however, been somewhat surprised by the competitive response, which has included withdrawing their high-end platform and substituting refurbished older technology at a highly discounted price and attempted to win the deal. Over time, we remained convinced that our ability to offer the most advanced robotic technology with materially lower per procedure cost will resonate with hospitals and allow us to be successful in the market.

Now, I'd like to provide an update on the commercial and operating progress we've made since our last call and our plans going forward. On the commercialization front, we've added three additional direct sales people since our March 3 call. These new hires will start between now and June 30 and this will bring our total direct sales team to nine people.

Across most of Europe, the onboarding process can take several months, once a position is accepted. So we are pleased with both the speed at which we have developed our team as well as the caliber of people we are adding, with a solid mix of experience from large cap med device companies, as well as capital and robotics companies.

The direct team has focused more of our efforts on building our pipeline for long-term success through interactions with hospitals earlier in the decision making process, and the pipeline is starting to be more balanced across deal stages. Ten new hospitals have participated in at least one full hands-on training event since our last call.

We also highlighted in our last call, the importance of our demonstration and training capability and our plans to expand our capability with the new training site and the second quarter remain on track. We made solid progress setting up our distributor network since the March call.

At that time, we had recently hired an individual to establish our distributor network across Europe as well as a senior sales executive focused on the Middle East. As a result of their efforts, we now have added distribution partners in each of those regions.

We've also begun evaluating partners for Asia and we currently have a senior leader on the team with extensive robotics experience in that region. The Asian market requires additional regulatory work, which is typically done in partnership with distributors. So selecting the right partner is a long-term commitment that we are pursuing thoughtfully.

Needless to say the platform is driving meaningful inbound the interest. And we'll be making our selection from an excellent pool of potential distributors. Finally, although we do not expect the ALF-X to be on the US market until 2017, we received considerable surgeon interest. So we are planning to add market development resources in the US in the coming months.

Now, let me turn our planning to the ALF-X 510(k) submission. While, I mentioned earlier that upcoming interactions with the FDA will be important to confirm our regulatory strategy for ALF-X, it's important to know that this is a CE marked product with significant clinical experience. We continue to believe that will be able to compete — complete our submission to the FDA by the end of the year.

As a part of our increased investment in key areas of our business, we have made the decision to recruit a surgeon to our leadership team to strengthen our clinical, training and product development efforts. We are confident this will also allow us to put our best foot forward in our future interactions with the agency.

Before, I open up the line for questions I'd like to reiterate our strong optimism for the future of TransEnterix. Although, we acknowledge that the SurgiBot not being cleared was a huge disappointment, we believe that we are well positioned for success moving forward. We're excited about ramping up our commercialization efforts for ALF-X and gaining insight to inform our next steps on the US regulatory front.

I would now like to open up the line for questions.

Operator: Thank you. 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, press star 1 to ask a question.

We'll pause for just a moment to allow everyone an opportunity to signal. And we'll take our first question from Rick Wise with Stifel.

Rick Wise: Good afternoon, Todd. Let me start in multiple ways. But maybe, I'll start first thinking about the US and ALF-X. Maybe help us understand, discuss your confidence relative to an ALF-X 510(k) filing. When you reflect on it and after analyzing the SurgiBot FDA response, tell us what you learned or your thinking now that gives you confidence that the kind of timeline late this year filings and early '17 approval, why that's realistic?

I appreciate these are very different systems. And as you say, ALF-X is approved in Europe, but how can we — how do we think about our confidence levels on that kind of a timeline for ALF-X now in light of what happened?

Todd Pope: Thanks, Rick, for the question. You know, two parts, I'll kind of start a little bit with kind of our takeaways from our recent NSE. You know, I do think as we think about Robotically Assisted Surgical Device, the way the FDA is classifying these RASD, they're more complex and comprehensive than some 510(k). So I think in some regard the focus on the 90-day clock in the 510(k), some point can work against you in a large complicated submission.

I certainly think as we think back on our interaction over the last three years, certain things have changed, you know, with the landscape. I think there's more scrutiny on robotics. Certainly there was a public forum last summer for two days. And there's been three or four guidance documents released during that time that affects robotics products.

So I think we're a little smarter now. We certainly have those takeaways. But as we focus on your question on ALF-X, as we think about US 510(k) submission. We certainly think we are better positioned. First of all, the ALF-X has a CE Mark, had that for several years. We've got clinical data. We've got several systems out in clinical use.

We have multiple publications from multiple specialties. So we just think we are going in to the ALF-X filing in a different and stronger position than we were with SurgiBot.

Rick Wise: And I'm going to ask two more different topics and maybe others will chime in. I think there are a lot of questions to follow-up on that. But I wanted to turn to ALF-X in Europe. You've demoed in sort of 18 EU hospitals to date, 10 since the March quarter. How do we think about this? Are all 18 systems still in play? Can you talk about some of the feedback?

And I realize that it's hard to know, but we're modeling three systems, three ALF-X systems this year. Is that reasonable? Do you expect, you know, is that a reasonable expectation at this point, too conservative, too optimistic? Again, help us think through those issues.

Todd Pope: Yes, well, certainly as we talked about in our call just subsequent to your question. It is early days for us as we go out and start establishing our commercial organization. We are excited about the folks we brought in. We're bringing them in from great companies, both robotic companies and large cap med tech, so we've got a good working knowledge of Europe.

The 18 hospitals we brought in, those are hospitals that had actually come to Italy and spent two days with the system, interfacing with the system, getting hands on and seeing surgery. So I would certainly say it's fair to say that all of those accounts are in a serious process of considering purchasing a robot. I think ourselves and the competition, are kind of dealing with the new normal.

Now we've got two systems. If hospitals are considering a robotic purchase that they are trying to evaluate, trying to think about what specialties might be brought into the loop with the ALF-X that might not traditionally have been involved in the past. So, I think it's hard for us to provide guidance to your particular question, because we want to get some of these accounts closed and be able to look back and kind of get a good idea of the cadence, when we engage with these accounts, what kind of stage they're in.

And if they were already approved for a robotic purchase in 2016 and we've kind of come to them a little late in the game or they're just beginning to think about a robotic purchase, because some of the either features that we offer that allow a little more multispecialty approach or the economics brings a few other hospitals into the game that in the past haven't been thinking about it.

So I think in 2016 we think about really laying the foundation. We're just bringing our team together in addition to our capital sales reps; we're hiring clinical sales reps; we're hiring professional education resources, training resources. We'll be opening up a few other locations that people can go and get their hands on.

So 2016 will be a good year for us to lay the groundwork. And I think by the end of the year we'll have a much better idea of the cadence of deals working through the system.

Rick Wise: Okay. And just last for me on cash for you, Todd or Joe. I think you have \$75 million, if I looked at the numbers correctly, in cash, you can feel

free to correct me. And that's good for sort of through the third quarter of '17. Talk about what you think you're going to be saving from the restructuring in the US. But you're upping your spending elsewhere, a surgeon advisor, more reps in Europe.

And help us think through, if you would, where your options are. I mean, I appreciate that if you could sell one or more ALF-X systems that is going to change this discussion profoundly over the next couple of quarters. But just help us think through where you go from here in terms of meeting your cash needs. Thank you.

Joe Slattery: Sure, Rick, it's Joe. You're correct, \$75 million as of the end of last month, April. So that gives us quite a bit of runway through third quarter of next year. You know, as you think about financing the company, clearly the most obvious catalyst for that raise is successful commercialization about ALF-X.

And I would just add that while the, you know, the anticipated filing on the ALF-X is later this year that would get us on the market in 2017. And that's the largest robotics market in the world, so we think that's going to be a key driver of a value creation.

So, you know, as we think about financing the company right now, we've got no capability with a strong balance sheet to possibly do some other things. Right now, we're paying down debt principal. And we have some opportunities there to use non-dilutive financing. I also think that when you look at our productivity in our pipeline as we get to the turn of the year, we'll be in a good position to raise ALF-X on a strong commercial story.

Rick Wise: Thanks. I'll follow up.

Operator: We'll take our next question from Glenn Novarro with RBC Capital Markets.

Glenn Novarro: Hi, guys. I'd like to ask a question on the international selling process, because you brought up a point during your prepared remarks where you talked about the competitor, Intuitive, kind of fighting back hard and using price. We've assumed in our models that ALF-X would go for somewhere about \$1.8 million.

Is that still a realistic assumption or do you have to play the pricing game too to get a couple of these sales across the finish line? Thanks.

Todd Pope: Yes, I mean, Glenn, when we think about price we really talk a lot about total cost of ownership. We think about, one, capital. And then we talk about what hospitals have to spend on a per-procedure pricing model. So, yes, the capital expectations that you mentioned are accurate. We're really competing up against kind of their top-of-the-line offering on the capital side.

What we've been getting the most positive feedback other than some of these enabling features that we talked about quite a bit, haptics and eye-tracking. Hospitals have also been thinking a look at their total cost of ownership. Did they need to buy anything extra to be able to use a robot, did they have to buy an extra bed, can they use their existing trocars; these are kind of things that with the ALF-X, they don't need any extra investment.

And then, when they look at their per procedure pricing were coming in anywhere from 60% to 70% less per procedure. So as we look at robotics in Europe, it's primarily been driven by urology and we're excited to approach that urology marketing be have a very strong offering there.

We also are starting to have some conversation that new specialties, which in turn means new hospitals, are thinking about getting into robotics, because there are different procedures that they can now envision being done with the robotic platform that don't kind of break the bank versus their current reimbursement.

So we don't feel like that capital on capital is something that we always have to go to definitely hospitals are starting to take a much more holistic view, and we've had one hospital that I will say is a high volume account. But as they look at out, six, seven years of owning a product, they feel like they can afford two ALF-Xs based on their volume, based on the per procedure savings versus one of the competitive product.

So, I think as people look at total cost of ownership is much more holistic view versus just capital on capital.

Joe Slattery: Yes, Rick, this is Joe — Glenn, this is Joe. I would just add that, you know, we don't — we haven't experienced real pressure in terms of capital pricing. You know, frankly, where we are today, we're young new company and we're, you know, the targets that we are pursuing are getting heavily counter detailed by the competition.

And, you know, ultimately our initial sales are going to be — are going to come from hospital systems who want to be leaders in fundamental change in robotics. And for them, discounting on prices not going to move the needle, it's more about showing a level of corporate commitment that we have to make sure that's an excellent experience.

Glenn Novarro: So when you're going head-to-head in some of these evaluations with Intuitive and they come in and say, well, we'll give you this price. And even though it's an older system it's going to be a lower price than what you're offering, are you saying you've lost some of these tenders or some of these bakeoff or is the evaluation just taking longer, because Intuitive is giving them something more to chew on?

Todd Pope: Yes, I would say it would be the latter, Glenn. We've not lost any tenders, the tenders take some time and we're working with quite a few of those, we've not lost any of those. You know, I would think you really hit on the real issue, it's not really that accounts have to have more to chew on a price discount.

Accounts have got in their head that they want the latest most forward leaning technology, and now when they're offered a technology that might be seven, eight years old that's refurbished they have to go back and think about clinical applications, is that going to be an offering that will really satisfy them, because that's not what they've been thinking about leading up to our entry into the market.

So, it's really just morphed into think about. I think we have to revisit with their surgeons and talk about different features, benefits, the different specialties that want to use robotics. It just becomes much more of a holistic conversation. It's not as simple as just this price versus the other.

Glenn Novarro: Okay, all right. Thanks, Todd. I'll let someone else jump in to queue. Thank you.

Todd Pope: Thanks, Glenn.

Operator: We will take our next question from Greg Chodaczek with CRT Capital.

Gregory Chodaczek: Thanks, Todd. Just a couple of quick questions. At SAGES a few months back, the sampling that we did with the surgeons who were at your booth. The two things that came — we came away with was procedure cost and the ability to use other people's scopes. So, I want to make sure that our sample is similar to what you're hearing.

So based on the current infrastructure in hospital X that just bought a 1588, you know, from Stryker or VISERA from Olympus, are hospitals talking about that being able to use that stuff or is that just a bad sample from us?

Todd Pope: Well, Greg, you know, I think your sampling is accurate. Certainly procedure cost, whether it's physicians, whether it's CEOs, CMOs, CFOs, hospital administrators in O.R., most of them are focused on procedure cost. It's usually two budgets in a hospital, you have a capital acquisition budget, but then the people in the operating room are really responsible to match up to what they spend versus current reimbursement.

And as you know, in most place in the world, there's not robotic reimbursement codes, they're really, you know, they're leveling those robotic costs versus laparoscopic reimbursement codes. So procedure cost is far and away driving the most interest. It's been described to us as it's not an attractive per procedure cost that we offer, but it's really shifting the paradigm.

Secondly, to your point, we certainly with the way the ALF-X has been designed, we have the ability to be more open platform. Certainly as we think about — when we talk to the hospitals, I mentioned in the call, we hear hospitals say, "Look, we're constantly evaluating technologies from vendors. We created our own ecosystem at a hospital.

We have advanced energy, we have optics, we have image guidance, we have cameras, we have fluorescence, we have many capital equipment purchases that we've invested based on what we think, especially the hospital, the patient and the surgeons. So when we buy a robotic platform, we don't want to have to replace every one of those. So please, as you are thinking about your development efforts, let us incorporate some of our existing technology in the robotic platform."

So we are really just beginning the role that concept out. And yes, I think you are accurate, that is generating a lot of positive momentum for us, because it's hard for one company no matter how big in established to be the best in all of those advanced technology modalities. We're going to try to let hospitals utilizes much of that within our platform as possible.

Gregory Chodaczek: And two very quick follow-up. So for instance, if someone just bought a 1588, is that plug-and-play into an ALF-X or is there something you need to do in order to get that 1588 to show up the surgeon cart, you know, imaging?

Todd Pope: Yes, for us that's something that is a relatively low bar, technologically for us. If you've seen the system and the way it's developed, we use current trocars in the trocar setup just like they would have laparoscopic surgery. And we believe we're going to be able to accommodate, you know, most people's CAM within our system in time.

Gregory Chodaczek: Okay. And, Joe, you are talking about the different budgets. And based on our numbers, it's roughly 1500 to 2000. And, you know, these are our rough numbers or estimates. Procedures to make up the cost of an ALF-X compared to another system, the da Vinci.

So, Todd, you're talking about buying, you know, people saying, well, I may be able to afford two instead of one, da Vinci, because of the price per procedure is much less. I guess, the question is, do you save that money, does that money go back into the capital budget, or is that something that stays in more of the budget for the O.R.

Todd Pope: Yes, it's the latter. It really usually goes into the operating budget of the OR. They are really under a lot of pressure. Whatever hospital you go in anywhere in the world, per procedure pricing is really a hot button for them, because there's not extra reimbursement for robotics. They're trying to fit robotics technology into current reimbursement. So that's why that's generated so much excitement for us.

Gregory Chodaczek: Great, thank you. I'll jump back in the queue.

Todd Pope: Okay.

Operator: We'll go next to Jeffrey Cohen with Ladenburg Thalmann.

Jeffrey Cohen: Hi, guys. Thanks for taking the questions. Can you hear me, okay?

Todd Pope: Yes, we can.

Jeffrey Cohen: Just two, if I may. Could you talk about if there are any ALF-X plans for Europe and C.E. Mark? And secondly, Joe, could you go through kind of the headcount and how that's been since last month and how that may look as 2016 develops toward the end of the year?

Todd Pope: Yes, Jeff, I believe your question was for SurgiBot in Europe, is that what you meant to ask?

Jeffrey Cohen: Yes, yes.

Todd Pope: Yes, right now, we're going to focus on interactions with the FDA. You know, we really had our operating rhythm set up. We've been working on our SurgiBot filing. We expected to have clearance at the beginning of this year. And then, we were going to role in to our ALF-X filing of the 510(k). So, we're going to really focus on our ALF-X 510(k) filing in the U.S. and then have the SurgiBot in the queue after that.

So we would want to go through our FDA process with the SurgiBot and then look to C.E. Mark. We really think that we've made enough progress. And we think that the work that's been done, it's best to focus on finalizing our actions with the FDA with SurgiBot before turning to a C.E. Mark.

Joe Slattery: And, Jeff, on the headcount following the actions we took earlier this week, there's no impact in Europe. We're actually up to about 30 people over there now. And we've got about 75 here in the U.S.

Jeffrey Cohen: Okay. And that should be constant for the balance of 2016 you expect?

Joe Slattery: No, what I would say is it's kind of ordinary course of business. We're investing in the business. So we're, you know, we've got seeding phase for the US market and we've got continued investment in Europe to help support the commercial rollout there.

Jeffrey Cohen: Got it. Okay. Thanks a lot for taking the questions.

Todd Pope: Thanks, Jeff.

Operator: We'll take our next question from Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson: Hi, good afternoon and thank you for taking my questions. So...

Todd Pope: Hi, Bruce.

Bruce Jackson: Hi. So, with the new strategy for ALF-X with the 510(k) can you tell us a little bit more about how you plan to structure this with the predicate device and what gives you the confidence that the ALF-X will qualify for 510(k) strategy?

Todd Pope: Yes, well, first of all, thanks for the question. It's certainly not a new strategy. This has always been our strategy. We expected SurgiBot clearance, we're going to roll right in to the ALF-X 510(k) work. So, we're continuing just as we had planned with that. That's not new.

Secondly, we're confident that it's going to be a 510(k) and nothing in our interactions have said with SurgiBot or anything else that these robotic platforms won't be a 510(k). I think as we talked about a little bit earlier, we really feel confident with our position with ALF-X. It has a C.E. Mark. It has good clinical data out there.

We've got multiple specialties doing multiple procedures with the platform with good results. So we feel strong about that. And we are excited. We've been in the process of thinking about bringing a senior leader on from the surgical community for some time. And we've decided to put those wheels into motion, so you'll be getting an update on that from us.

But we think that also will be able to allow us to put our best foot forward in front of the agency when we have a surgeon on the team with this.

Bruce Jackson: Okay. And then, I apologize if you already covered this, but how does the timeline rollout here in terms of the next meeting with the FDA? And when you think you might have some greater clarity on what they're thinking?

Todd Pope: Yes, we've — as we talked about, we've been in touch with the FDA. Our next step will be a meeting with their management hierarchy. And we think that's going to happen in the near term. That's going to be a matter of weeks, not months.

Bruce Jackson: And did you say that that meeting was scheduled already?

Todd Pope: Yes, we'll be scheduling it in the coming weeks.

Bruce Jackson: Okay, all right. That's it for me. Thank you.

Todd Pope: Okay, thanks.

Operator: That does conclude today's question and answer session. At this time, I'll return the conference to Mr. Todd Pope for any closing remarks.

Todd Pope: Thank you operator and I'd like to thank everyone again for joining us today. We look forward to updating you on our progress during our next quarterly call. Thank you.

Operator: This does conclude today's conference. Thank you for your participation. You may now disconnect.

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