

TRANSENERIX INC.

FORM 8-K (Current report filing)

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Address	635 DAVIS DRIVE SUITE 300 MORRISVILLE, NC 27560
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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, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2017, TransEnterix, Inc., a Delaware corporation (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2017. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on May 10, 2017, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated May 10, 2017
99.2	May 10, 2017 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 12, 2017

By: /s/ Joseph P. Slattery

Name: Joseph P. Slattery

Title: EVP and CFO

Exhibit Index

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99.1	Press release, dated May 10, 2017
99.2	May 10, 2017 conference call script

Exhibit 99.1

May 10, 2017

TransEnterix, Inc. Reports Operating Results for the First Quarter 2017

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 2017.

Recent Highlights

-On February 23, 2017, the Company sold a Senhance Surgical Robotic System to St. Marien-Krankenhaus Siegen, a large multi-specialty hospital, establishing the hospital's robotic surgical program

-In April 2017, the Company submitted its 510(k) application for the Senhance Surgical Robotic System to FDA

-The Company established its fourth European Clinical Leadership site in Hamburg, Germany

-On April 28, 2017, the Company raised approximately \$23.2 million through an equity financing

-On May 10, 2017, the Company refinanced its debt, securing up to \$17.0 million in debt financing

-As a net result of the combined financings, the Company expects to be able to fund its operations into the second quarter of 2018

“We are very pleased with the progress we have made thus far in 2017, including the submission of our Senhance 510(k) application” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We will continue to build upon the strong foundation we’ve established to drive growth in Europe, and continue to expect FDA clearance for the Senhance in 2017.”

Clinical Update

In April, the Company established its fourth European Clinical Leadership Site at the University of Hamburg-Eppendorf, in Hamburg, Germany. The Company now has seven Senhance systems installed between France, Germany, Italy and the United Kingdom. Within these seven hospitals, 18 surgeons are trained and performing surgery across gynecology, colorectal, general surgery, urology and thoracic specialties .

Financial Highlights

For the three months ended March 31, 2017, the Company reported revenue of \$1.9 million, primarily related to the sale of one Senhance during the quarter.

For the three months ended March 31, 2017, total operating expenses were \$16.5 million, as compared to \$15.0 million in the three months ended March 31, 2016.

For the three months ended March 31, 2017, net loss was \$15.4 million, or \$(0.13) per share, as compared to \$12.9 million, or \$(0.12) per share, in the three months ended March 31, 2016.

On April 28, 2017, the Company announced the pricing of a public offering of common stock and warrants. Initial proceeds from the deal were approximately \$23.2 million, net of fees and expenses.

On May 10, 2017, the Company entered into a loan and security agreement with Innovatus pursuant to which Innovatus has agreed to make certain term loans in the aggregate principal amount of up to \$17.0 million, with the funding of the first \$14.0 million tranche expected to occur upon satisfaction of customary funding conditions. The Company will be eligible to draw on the second tranche of \$3,000,000 upon achievement of certain milestones, including clearance for commercialization of Senhance by the U.S. Food and Drug Administration (“Senhance Clearance”). The Company is entitled to make interest-only payments for twenty-four months so long as it meets certain milestones, including Senhance Clearance by May 30, 2018. The loans will mature on the earlier of (i) the fourth anniversary of the initial funding date or (ii) twenty-four (24) months following the failure to achieve such interest-only milestones. This loan and security agreement includes customary warrant coverage and is secured by all of the Company's, and its domestic and material foreign subsidiaries', assets. The Company fully repaid its term loans with Silicon Valley Bank and Oxford Finance LLC on May 10, 2017. Proceeds will be used for general corporate and working capital purposes.

The Company had cash, cash equivalents and restricted cash of approximately \$23.5 million as of March 31, 2017. As a net result of the recent equity and debt financings, the Company expects to be able to fund its operations into the second quarter of 2018.

Conference Call

TransEnterix, Inc. will host a conference call on Wednesday, May 10, 2017 at 4:30 PM ET to discuss its first quarter 2017 operating and financial results. To listen to the conference call on your telephone, please dial (888) 352-6793 for domestic callers or (719) 457-2615 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 Senhance™ Surgical Robotic System, 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 sensing camera control. The Company also developed the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform. The Senhance Surgical Robotic System has been granted a CE Mark but is not currently available for sale in the United States. For more information, visit the TransEnterix website at www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to our first quarter 2017 results, the Senhance™ Surgical Robotic System and our current regulatory and commercialization plans for this product. 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 the FDA will provide regulatory clearance on our Senhance 510(k) submission in 2017, whether our commercialization plans and the development of our pipeline will be successful, and whether existing cash, cash equivalents and restricted cash will fund operations into the second quarter of 2018. 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 for the year ended December 31, 2016, which was filed on March 6, 2017, 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.

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

	Three Months Ended March 31,	
	2017	2016
Revenue	\$ 1,946	\$ —
Cost of revenue	\$ 1,334	—
Gross profit	612	—
Operating Expenses		
Research and development	6,855	8,385
Sales and marketing	3,723	1,683
General and administrative	3,049	2,239
Amortization of intangible assets	1,636	1,817
Change in fair value of contingent consideration	1,227	856
Total Operating Expenses	16,490	14,980
Operating Loss	(15,878)	(14,980)
Other Expense		
Interest expense, net	(334)	(578)
Other income	(60)	—
Total Other Expense, net	(394)	(578)
Loss before income taxes	\$ (16,272)	\$ (15,558)
Income tax benefit	858	2,645
Net loss	\$ (15,414)	\$ (12,913)
Other comprehensive gain		
Foreign currency translation loss	1,133	3,796
Comprehensive loss	\$ (14,281)	\$ (9,117)
Net loss per share — basic and diluted	\$ (0.13)	\$ (0.12)
Weighted average common shares outstanding — basic and diluted	121,660	104,260

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

	March 31, 2017	December 31, 2016
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 13,086	\$ 24,165
Accounts receivable, net	1,828	621
Inventories	8,321	7,883

Interest receivable		10		12
Other current assets		5,601		5,335
Total Current Assets		<u>28,846</u>		<u>38,016</u>
Restricted cash		10,432		10,425
Accounts receivable, net of current portion		—		266
Property and equipment, net		5,800		5,772
Intellectual property, net		36,015		37,090
In-process research and development		16,161		15,920
Goodwill		68,984		68,697
Other long term assets		114		63
Total Assets	\$	<u>166,352</u>	\$	<u>176,249</u>
Liabilities and Stockholders' Equity				
Current Liabilities				
Accounts payable	\$	3,269	\$	3,984
Accrued expenses		7,262		8,206
Contingent consideration – current portion		6,250		10,502
Notes payable — current portion, net of debt discount		8,172		7,997
Total Current Liabilities		<u>24,953</u>		<u>30,689</u>
Long Term Liabilities				
Contingent consideration – less current portion		12,550		12,298
Notes payable — less current portion, net of debt discount		2,885		4,995
Net deferred tax liabilities		9,697		10,397
Total Liabilities		<u>50,085</u>		<u>58,379</u>
Commitments and Contingencies				
Stockholders' Equity				
Common stock \$0.001 par value, 750,000,000 shares authorized at March 31, 2017, and December 31, 2016; 123,629,689 and 115,781,030 shares issued at March 31, 2017 and December 31, 2016, respectively; and 123,629,689 and 115,687,351 shares outstanding at March 31, 2017 and December 31, 2016, respectively		123		115
Additional paid-in capital		439,038		426,609
Accumulated deficit		(318,258)		(302,844)
Treasury stock at cost, 0 and 93,679 shares at March 31, 2017 and December 31, 2016, respectively		—		(241)
Accumulated other comprehensive loss		(4,636)		(5,769)
Total Stockholders' Equity		<u>116,267</u>		<u>117,870</u>
Total Liabilities and Stockholders' Equity	\$	<u>166,352</u>	\$	<u>176,249</u>

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

	Three Months Ended March 31,	
	2017	2016
Operating Activities		
Net loss	\$(15,414)	\$(12,913)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	532	565
Amortization of intangible assets	1,636	1,817
Amortization of debt discount and debt issuance costs	31	52
Stock-based compensation	2,139	1,428
Deferred tax benefit	(858)	(2,645)
Change in fair value of contingent consideration	1,227	856
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	(753)	—
Interest receivable	2	(6)
Inventories	(320)	(1,735)
Other current and long term assets	(251)	(132)
Accounts payable	(759)	(1,391)
Accrued expenses	(1,161)	(765)
Net cash and cash equivalents used in operating activities	(13,949)	(14,869)
Investing Activities		
Purchase of property and equipment	(501)	(153)

Net cash and cash equivalents (used in) provided by investing activities	(501)	(153)
Financing Activities		
Payment of debt	(1,966)	(1,219)
Proceeds from issuance of common stock, net of issuance costs	5,304	31,391
Taxes paid related to net share settlement of vesting of restricted stock units	—	(130)
Proceeds from exercise of stock options and warrants	—	8
Net cash and cash equivalents provided by financing activities	3,338	30,050
Effect of exchange rate changes on cash and cash equivalents	40	34
Net (decrease) increase in cash, cash equivalents and restricted cash	(11,072)	15,062
Cash, cash equivalents and restricted cash, beginning of period	34,590	38,449
Cash, cash equivalents and restricted cash, end of period	\$ 23,518	\$ 53,511
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 233	\$ 373
Supplemental Schedule of Noncash Investing Activities		
Transfer of inventory to property and equipment	—	\$ 1,823
Issuance of common stock as contingent consideration	\$ 5,227	—

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TRANSENERIX

Moderator: Todd M Pope
May 10, 2017
4:30 pm ET

Operator: Please standby. We're about to begin. Good afternoon, ladies and gentlemen, and welcome to the TransEnterix First Quarter 2017 Financial and Operating Results conference call. As a reminder, this conference call is webcast live and recorded.

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

Mark Klausner : Good afternoon, and thank you for joining us for TransEnterix first quarter 2017 conference call. Joining us on today's call is 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 website. To access the webcast, please visit the Events link in the IR section of our website, 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 Form 10-K for the year ended December 31, 2016, and the Form 10-Q for the quarter ended March 31, 2017 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.

Intro

Thank you Mark, and welcome to our first quarter 2017 conference call. We continued to make good progress this quarter on our key strategic priorities. As a reminder, these priorities are as follows: obtain U.S. regulatory 510(k) clearance for the Senhance system, partner with leading hospitals and surgeons through our Clinical Leadership Program, continue to commercialize the Senhance platform in CE Mark countries, and leverage the open architecture of the Senhance platform.

On today's call, I will start by discussing our progress towards US regulatory approval highlighted by our recent Senhance FDA 510(k) submission. Then I will hand it over to Joe to provide a financial update and discuss our recently completed equity and debt financings. Finally, I will discuss our Clinical Leadership program, our commercial and clinical progress in Europe, our US market development activities, and provide an update on the Senhance open architecture strategy. We will then open the line up for questions.

FDA Submission

I am pleased to report that we made our 510k submission for the Senhance system in April, which was in-line with our expectations. Our team worked diligently on this submission and we are pleased with the quality of what we have delivered to the FDA. We continue to expect clearance for Senhance by the end of this year, in line with our previously communicated expectations.

As those of you who that have followed Transenterix know, the Senhance system has an existing CE Mark and is being used clinically across Europe. This has allowed the company to generate a significant amount of human data through cases performed with our increasing number of installations in major European markets. While the FDA does not require human data for devices in this category, we elected to submit a large series of human data to support the filing with a high level of evidence.

In addition, we have had positive ongoing interactions with the FDA during the process of developing our submission. One of the most important takeaways from our interactions was being able to obtain clarity on the FDA's most recent guidance on usability studies. As a result of our interaction with the FDA on this topic, we were able to focus our efforts and develop robust data around usability through testing with a significant number of users representing the various types of healthcare professionals that will utilize Senhance. We were also able to refine our submission based on the other feedback we received from the FDA by utilizing the pre-submission process on topics such as human data, biocompatibility and sterilization.

We have also conducted demonstrations of the Senhance system with FDA personnel, which we feel will be helpful in their evaluation of our submission. These informational meetings were conducted via video conference and also hands-on at medical congresses where FDA staffers were in attendance. We believe these interactions will allow key agency personnel the ability to efficiently review our submission by minimizing the time required to initially familiarize themselves with the Senhance system.

We anticipate that we will receive questions from the FDA in June in the form of an "A.I.," or additional information request, which will put the review clock on hold until we respond. We believe that the quality of our April submission will allow us to respond in a timely manner to the FDA's questions, and continue to expect that we will achieve a clearance before year-end.

I'd now like to turn it over to Joe to provide a financial update before I discuss our progress on European commercialization and U.S. market

development.

Finance Update

Joe Slattery : Thanks Todd.

For the three months ended March 31, 2017, the company reported revenue of \$1.9 million, primarily related to the sale of one Senhance system during the quarter.

Cost of revenue was \$1.3 million, resulting in gross profit for the quarter of \$600 thousand, or a 31% gross margin. Cost of revenue includes overhead and the entire cost of our field service organization.

R&D expenses in the quarter decreased to approximately \$6.9 million as compared to the prior year period at \$8.4 million, primarily due to decreased personnel and outside product development costs.

Sales and marketing expenses in the quarter increased to approximately \$3.7 million from approximately \$1.7 million in the prior year period, primarily due to increased personnel and related costs, mostly to expand our European operations.

General and administrative expenses in the quarter increased to approximately \$3.0 million from approximately \$2.2 million in the prior year period, primarily to support our expanded operations in Europe.

Net loss for the quarter was \$15.4 million or \$0.13 a share compared to a net loss of \$12.9 million or \$0.12 per share in the prior year period.

Moving on to the balance sheet, we finished the first quarter with cash of approximately \$23.5 million, of which approximately \$10.4 was restricted cash.

As we entered 2017, our funding plans were predicated on (1) drawing down the entire \$25 million from the Lincoln Park equity facility, and (2) refinancing our debt to defer amortization of principal into the future, lower our restricted cash requirement and raise the overall amount financed. Late in the first quarter, it became clear that we might not be able to access all of the capital from the Lincoln Park facility, which would also impact our ability to refinance the debt. Therefore, we decided to complete an equity offering to allow us to continue to execute our business plan. Our goals going into the equity financing were to support the refinancing of our debt and raise sufficient capital to fund the business into the second quarter of 2018.

The equity financing that we completed in April helped us achieve these goals. We received over \$23 million in net proceeds, and, as we announced today, we also refinanced our debt, meeting our key refinancing objectives — deferring amortization of principal, lowering restricted cash, and increasing the gross amount financed.

With these funding actions, our pro forma cash as of March 31 was approximately \$48 million and we expect these funds to support our operations into the second quarter of 2018. The equity offering also included Series A warrants that will expire ten days after the announcement of an FDA clearance of the Senhance. Assuming that these warrants are exercised, we will receive another \$25 million, which we expect will extend our cash runway into late 2018. This positions us well as we transition later in the year toward focusing on US commercialization.

Because the recent equity financing fully utilized our existing shelf registration statement, today we are filing a new shelf registration statement to maintain financial flexibility, even though we do not have any plans to raise equity capital in advance of receiving a clearance from the FDA on the Senhance. As a reminder, we will have three years to sell shares under the newly filed shelf registration once made effective by the SEC.

Todd?

Commercialization Update

Todd Pope : Thanks Joe. I'd like to provide an update on the commercial and clinical progress we are making in Europe and the steps we are taking to prepare the US market for Senhance.

In these early stages of commercialization, a key component of our strategy has been to expand system placements to drive clinical experience to support our growth objectives in the back half of 2017 and into 2018 and beyond. As a part of this effort, we introduced the Clinical Leadership Program in the fourth quarter of 2016. The goals of the program are 1st — partner with leading institutions and surgeons in key geographies to establish clinical reference sites, 2nd - meaningfully expand the utilization of Senhance across multiple specialties and procedures, and 3rd — generate clinical data to support our long-term growth strategy for both regulatory and commercial success.

On our last call, we stated that we expected to install a Senhance at a fourth and final European clinical leadership site in a strategic geography in the near term, and I am pleased to announce that in April, we did just that. A Senhance has been installed at the University of Hamburg-Eppendorf, in Hamburg, Germany, a leading teaching in hospital with over 1,400 beds. Our Clinical Leadership Program has systems being utilized at leading institutions in Italy, the UK, France and now Germany.

As previously announced, in February we made a sale in Germany to St. Marien-Krankenhaus Siegen, a large multi-specialty hospital. St. Marien purchased the Senhance to establish a robotic surgery program that will be initially focused on general and gynecologic surgery.

We continue to be encouraged with our expanding presence in the European market. On our last call, we had four active customer sites in three countries with eight surgeons regularly performing cases. Today, that has increased to seven hospitals in four major European markets performing surgery using the Senhance. Within these hospitals, we have 18 surgeons performing cases across five specialties: gynecology, colorectal, general surgery, urology and thoracic.

The most encouraging aspects of the recent ramp in clinical utilization of the Senhance continues to be: the number of cases, the breadth of procedures and number of surgeons using the system. In addition, the Senhance's familiar laparoscopic motion has facilitated an impressive adoption curve where surgeons are transitioning to Senhance from laparoscopic surgery. Year to date, approximately 125 cases have been successfully completed using the system, which represents a substantial increase in run rates versus the fourth quarter of 2016.

An example of the conversion from laparoscopy to Senhance has been demonstrated at St. Marien Hospital, our most recent sale. The St. Marien team, led by Dr. Frank Willeke and Dr. Dietmar Stephan, began doing cases with the Senhance in March, and has already completed over 30 cases. This speaks to both the technical capabilities of the system as well as the short learning curve required of surgeons. Surgeons have been able to quickly utilize the Senhance system for a wide variety of procedures. At St. Marien, the mean time required to prepare the system for surgical operation, often referred to as "setup" or "docking time" is 10 minutes. The surgeons have noted: operative times comparable to laparoscopy, quick setup, ergonomic advantages, security of haptics and patient satisfaction as key attributes of Senhance surgery. Dr. Stephan's team has quickly adopted the system for both inguinal and ventral hernia repairs, nissen funduplications (which is a stomach wrap performed for GERD and hiatal hernia), and implantations of antireflux devices. This demonstrates the wide applicability of Senhance within a large multi-specialty hospital with a high volume of laparoscopic cases.

At St. Etienne university hospital in France, a site that has been using the Senhance since mid-February, five surgeons are now trained and using Senhance to successfully perform procedures in gynecology, colorectal, general surgery and thoracic surgery. This is important because hospital administrators consider whether the system can be widely utilized within their hospital across multiple specialties when allocating dollars towards a robotic system. We are pleased that Senhance is clearly demonstrating this capability in clinical use.

Our clinical experience is routinely being shared at major European clinical congresses, the Senhance was featured at the German Surgical Congress in Munich in March. There will also be presentations this quarter at the upcoming Swiss general surgery meeting, the Society for European Robotic Gynaecologic Surgery in France, and the European Association of Endoscopic Surgeons Clinical Congress in Frankfurt, Germany.

We are encouraged by the feedback that we are experiencing in the market and by the continuing development of our sales pipeline. We expect to start to see the results of our commercialization efforts begin to drive more meaningful revenue in late 2017 and in 2018 in line with our guidance that the capital sales process in Europe takes 4 to 6 quarters.

U.S. Market Development

I would now like to provide a brief update on our U.S. market development activities. In line with our expectation of a FDA clearance for Senhance by the end of 2017, we are continuing to build a foundation in the US market in the areas of sales, service, and training. As part of this strategy, we have exhibited and had a strong presence at relevant medical meetings in the United States. We presented the Senhance to surgeons at the SAGES meeting in March in Houston, Texas and will also be exhibiting at the upcoming American Society of Colon & Rectal Surgery in June in Seattle, Washington. In total, hundreds of surgeons and healthcare professionals have seen a demonstration and have had the opportunity to interact with the system at these and other meetings.

Open Architecture

Another key priority in 2017 is to leverage the open architecture of the Senhance platform. Competing robotic systems are closed or vertically integrated, requiring hospitals to utilize only technology offered by the robotic system manufacturer regardless of the technology preference of the surgeon or the current capital equipment owned by the hospital.

With our open architecture strategy, we can rapidly integrate today's leading technologies for use with our platform, which allows hospitals to leverage existing and new investments for use in their robotics program.

During our last quarterly call, we announced the validation of two market leading vision and imaging systems in conjunction with the Senhance system. These technologies: the Stryker 1588 AIM platform and NOVADAQ's PINPOINT Endoscopic Fluorescence Imaging System. These technologies provide important information to the surgeon in many of the procedures that are being performed with the Senhance system. Recently, we received a CE Mark to enable both these technologies to be used in conjunction with the Senhance system and look forward to surgeons utilizing these technologies in upcoming procedures.

In summary, we achieved a major milestone with the submission of the Senhance 510(k) to the FDA. We are encouraged by the trends in clinical use in Europe which are validating our differentiated value proposition for the Senhance. In addition, we believe our recently completed equity and debt financings provide the capital to execute our business plan. We remain enthusiastic about our progress, and look forward to updating you on our next quarterly call.

Operator : 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. That's star 1. And we'll take our first question from Rick Wise with Stifel.

Rick Wise : Good afternoon everybody. Todd, clearly, you made a lot of progress this quarter. Let me just start with FDA. It's great to see the FDA filing and thank you for all the incremental color supporting your optimism on the late 2017 timing. But, help me understand a couple of things though.

I think you addressed why you are more optimistic this time because the data, because the interaction, because of the experience that they have had with live demos, etcetera. But, maybe just to take another step further and talk a little more, Todd, about how your interactions with the agency are different this time, and it's not fair to ask, but versus the SurgiBot experience, and this is still a complex filing and why you are so optimistic, basically, that you are right on track with the 2017.

Todd Pope : Certainly, Rick. Good afternoon and I appreciate your question. Just a quick recount and try to give you a little more color. We did have significant interactions with the FDA this time. One thing you realize is, 510(k)s are all in the same format, no matter how complex the submission. So one thing we did was we elected to take advantage of the pre-submission process. And when we did that, this time we broke them into three separate meetings with the FDA.

So instead of having one pre-submission meeting in process, we broke those into three, which was helpful. We were able to take things more in bite size chunks. When we did that, we certainly — I think one big difference is just because of the situation is, having a CE Mark with Senhance, we do have human data.

And although it's not required, we elected to submit human data and we submitted right at 200 cases. And we feel great about that. We have the data. The data was solid and we elected to submit that. So that's yet another big piece of our submission that continues to give us confidence.

As we highlighted in our clinical overview in Europe, we're doing surgery safely and effectively each and every day. We interacted with the FDA extensively since we started this process last summer and they continue to get updated on our progress in the field. So those are some of the things that might provide a little more color to answer your question specifically.

Rick Wise : And remind us what you hope the Senhance label will be? Will it be broad procedure applicability or more specific?

Todd Pope : Well, we've not really talked about our specific indications for use strategy. We have a CE Mark obviously and we have turned in a variety of procedures. And that's something that you typically get involved with, with the FDA, during the AI process.

Rick Wise : Turning to the quarter in Europe. I mean the \$1.9 million you say in the press release is mostly the system sale. Talk a little about the system pricing which seems like it remains quite strong and the 125 cases done in the first quarter. And maybe help us understand how to think about the kind of revenue you are generating from cases and how we think about maybe, I know it's tough to give guidance here, Joe, but maybe help us frame the rest of the year if you could.

I mean, do we think about you doing sort of a system a quarter until we get to the, I assume seasonably, typically seasonally strong fourth quarter, as you alluded to Todd. The results are more visible later in the year. Just, again, any kind of framework for the pricing, the procedure volume and how to think about guidance for the year.

Todd Pope : Okay. Certainly. Multifaceted question. Let me try to walk through each one of them for you. So look, I think, it's still too early for us to give formal guidance. We are early in our commercialization efforts. We're working through, what is our first full capital cycle. We'll have a lot more knowledge as we move into the back half of this year and head into 2018, certainly encouraged where our pipeline currently stands.

We are working diligently to close deals that are the most mature in our pipeline. I would say that your question about pricing is a good one. We continue to price the system comparable to the top of the line offering with today's robotics. And that continues to be well received because people take a look at capital but the thing that gets the most attention when it comes to robotic pricing is per procedure economics.

If you remember, we're really trying to focus on a larger piece of pie, which is laparoscopic surgery. The current robotic market is really focused on open procedures and look to convert those to robotics and typically when you convert an open procedure to robotics, you have a length of stay benefit that can sometimes offset a higher per procedure price.

But the larger volume of cases, upwards of 6 million in the US and Europe alone that are done laparoscopically, have not really been targeted with robotics. So as we go in and talk to these laparoscopic surgeons and certainly hospital administrators, we are really talking to them not only about the capital price but it usually comes down to if robotics hasn't been incorporated into a hospital or it hasn't been incorporated in high volume, it's due to per procedure economics.

So, with us having a reusable platform and being able to stay in the realm of pricing of their current laparoscopic procedures, it's really given them an opportunity to think about more and different procedures being done robotically and you just don't have to look any further than our current clinical experiences we talked about with Siegen, for example.

They are moving a lot of their hernia procedures that were done laparoscopically, over to Senhance. And I would say as you look at the systems that we have out there and the 125 or so cases we highlighted in the call, not one of those were taken from another robotic system.

Those were all laparoscopic cases that we have converted over. And that's a pretty strong validation of our value prop. We offer clinical benefits that are meaningful to these laparoscopic surgeons. We have the security of haptic feedback. To be able to control all three robotic arms themselves and not have to rely on someone else for the camera. To be able to have 5 mm instruments.

So that's how we really think about kind of our target market and how it feeds into pricing. Hospitals are used to buying capital equipment. They buy it every year across a broad spectrum of instruments that when you really talk about utilization of robotics at the counter OR level, it comes down to per procedure economics and we think we are getting good uptake with our model there.

Rick Wise : Yes. Let me come back to the guidance and I will move on. Todd, you talked about the rep experience and the results more visible later in the year. You must have a reasonable feeling based on the demos you have done and training session you have done, what your pipeline could look like later this year.

Can you frame that at all for us, either in the number of competitive bids or the number of presentations, or any color at all on the pipeline that you could give us to help us to think about, let's say fourth quarter and beyond? Thank you.

Todd Pope : Yes. No, Rick, I appreciate your question again. As I said earlier, I think we are still early in the process. We have not gone through one full capital sales cycle with our sales reps. The majority of them have come on in the back half of 2016. So really not been there for the four to six quarters that it usually takes to move a system through a pipeline process on capital acquisition in Europe.

So I certainly think we have reps that have at least been through that four to six quarters, we will have a much better idea of kind of closing metrics. But I am encouraged where our pipeline is. It stands well. We're continuing to work hard on those systems that are further along in our pipeline and more mature. And I think we'll have some good success as we have talked about, heading into the back half of the year.

Rick Wise : Thank you Todd.

Todd Pope : Thanks Rick.

Operator : That concludes today's question and answer session. At this time, I'll turn the conference back to Mr. Todd Pope for any additional remarks.

Todd Pope : Thank you. We continue to be enthusiastic about the future here at TransEnterix. We've completed a significant milestone by submitting a high quality 510(k) application for the Senhance system. We continue to expect the clearance by the end of 2017.

In addition, we continue to execute on our Senhance commercialization strategy in Europe and prepare to commercialize in the United States in order to drive sales growth in the second half of '17 and 2018. Thank you for joining us today. We look forward to giving you an update on our next quarterly call.

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

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