

# TRANSENERIX INC.

## **FORM 8-K** (Current report filing)

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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):

November 9, 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 November 9, 2016, TransEnterix, Inc., a Delaware corporation (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2016. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on November 9, 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated November 9, 2016
99.2	November 9, 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.

*November 14, 2016*

TransEnterix, Inc.

By: */s/ Joseph P. Slattery*

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*Name: Joseph P. Slattery*

*Title: EVP and CFO*

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated November 9, 2016
99.2	November 9, 2016 conference call script

## **Exhibit 99.1**

**November 9, 2016**

### **TransEnterix, Inc. Reports Operating Results for the Third 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 third quarter of 2016.

#### **Recent Highlights**

On July 29, 2016, the Company closed its first sale of the Senhance™ Surgical Robotic System (formerly known as the ALF-X System) to Humanitas Hospital, a research and teaching hospital partnered with Humanitas University Medical School, located in Milan, Italy.

On October 4, 2016, the first radical hysterectomy for cervical cancer utilizing the Senhance system was performed by gynecologic surgeon Dr. Salvatore Gueli Alletti at the Policlinico A. Gemelli Foundation in Rome, Italy.

On November 8, 2016, the Company announced that it has partnered with Getz Healthcare, a leading pan-Asian distributor of medical devices and equipment. Getz will be the exclusive distribution partner for the Senhance system in the Australian and New Zealand markets.

Today, the Company announced the installation of a Senhance system at Imperial College, in partnership with Imperial College London and St. Mary's Hospital. The Senhance system will be utilized within Imperial College's Minimally Invasive Surgery program in general, bariatric and colorectal surgery.

“We are pleased with our recent progress, which included the first sale of a Senhance system and the continued development of our commercial pipeline,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We remain enthusiastic about the potential of Senhance, and will continue to invest in global commercial expansion, including partnering with additional influential institutions to establish clinical reference sites.”

#### **Financial Highlights**

The company reported revenue of \$1.5 million for the three months ended September 30, 2016, representing the sale of one Senhance system and related instruments and service, net of deferred revenue.

Total operating expenses were \$14.0 million for the three months ended September 30, 2016, as compared to \$13.6 million in the three months ended September 30, 2015.

Net loss was \$12.9 million, or \$0.11 per share, for the three months ended September 30, 2016, as compared to \$13.9 million, or \$0.16 per share, in the three months ended September 30, 2015.

The Company had cash, cash equivalents and restricted cash of approximately \$52.9 million as of September 30, 2016. The Company expects its existing cash, cash equivalents and restricted cash to fund operations into the fourth quarter of 2017.

#### **Conference Call**

TransEnterix, Inc. will host a conference call on Wednesday, November 9, 2016 at 4:30 PM ET to discuss its third quarter 2016 operating and financial results. To listen to the conference call on your telephone, please dial (888) 455-2238 for domestic callers or (719) 325-2237 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 is also developing 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](http://www.transenterix.com).

## Forward Looking Statements

This press release includes statements relating to our 2016 third quarter financial 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 and when we will prepare a 510(k) submission for the Senhance Surgical Robotic System, whether our commercialization plans and the development of our pipeline will be successful, whether we will continue to invest in global commercial expansion, including partnering with additional influential institutions to establish clinical reference sites and whether existing cash, cash equivalents and restricted cash will fund operations into the fourth 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 third 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.

For TransEnterix, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	\$ 1,466	\$ —	\$ 1,466	\$ —
Cost of revenue	1,031	—	1,031	—
Gross profit	<u>435</u>	<u>—</u>	<u>435</u>	<u>—</u>
Operating Expenses				
Research and development	7,011	7,048	21,760	21,111
Sales and marketing	2,574	413	5,563	1,161
General and administrative	2,793	1,762	7,927	5,607
Amortization of intangible assets	1,709	338	5,312	589
Change in fair value of contingent consideration	(100)	—	1,700	—
Inventory write-down related to restructuring	—	—	2,565	—
Restructuring and other charges	—	—	3,085	—
Goodwill impairment	—	—	61,784	—
Acquisition related costs	—	4,003	—	4,003
Total Operating Expenses	<u>13,987</u>	<u>13,564</u>	<u>109,696</u>	<u>32,471</u>
Operating Loss	<u>(13,552)</u>	<u>(13,564)</u>	<u>(109,261)</u>	<u>(32,471)</u>
Other Expense				
Interest expense, net	(432)	(436)	(1,499)	(997)
Other (expense) income	(30)	—	65	—
Total Other Expense, net	<u>(462)</u>	<u>(436)</u>	<u>(1,434)</u>	<u>(997)</u>
Loss before income taxes	\$ (14,014)	\$ (14,000)	\$ (110,695)	\$ (33,468)
Income tax benefit	1,070	99	4,707	99
Net loss	<u>\$ (12,944)</u>	<u>\$ (13,901)</u>	<u>\$ (105,988)</u>	<u>\$ (33,369)</u>
Other comprehensive gain (loss)				
Foreign currency translation gain (loss)	689	(429)	2,199	(429)
Comprehensive loss	<u>\$ (12,255)</u>	<u>\$ (14,330)</u>	<u>\$ (103,789)</u>	<u>\$ (33,798)</u>
Net loss per share — basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.16)</u>	<u>\$ (0.95)</u>	<u>\$ (0.46)</u>
Weighted average common shares outstanding - basic and diluted	<u>114,946</u>	<u>86,044</u>	<u>111,189</u>	<u>72,713</u>

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

	September 30, 2016	December 31, 2015
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 42,518	\$ 38,449
Accounts receivable, net	616	76
Inventories	2,250	3,923
Interest receivable	15	6
Other current assets	8,149	6,689
<b>Total Current Assets</b>	<b>53,548</b>	<b>49,143</b>
Restricted cash	10,353	—
Accounts receivable, net of current portion	274	—
Inventories, net of current portion	—	709
Property and equipment, net	4,614	4,408
Intellectual property, net	41,260	46,898
In-process research and development	16,972	16,511
Goodwill	69,948	130,869
Other long term assets	63	64
<b>Total Assets</b>	<b>\$ 197,032</b>	<b>\$ 248,602</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 2,596	\$ 4,450
Accrued expenses	7,246	7,395
Contingent consideration – current portion	11,325	12,500
Notes payable — current portion	7,826	6,727
<b>Total Current Liabilities</b>	<b>28,993</b>	<b>31,072</b>
<b>Long Term Liabilities</b>		
Contingent consideration – less current portion	13,875	11,000
Net deferred tax liabilities	11,971	16,263
Notes payable — less current portion, net of debt discount	7,059	12,990
<b>Total Liabilities</b>	<b>61,898</b>	<b>71,325</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock \$0.001 par value, 750,000,000 shares authorized at September 30, 2016 and December 31, 2015; 115,086,256 and 100,180,872 shares issued at September 30, 2016 and December 31, 2015, respectively; and 115,014,711 and 100,149,453 shares outstanding at September 30, 2016 and December 31, 2015, respectively	115	100
Additional paid-in capital	425,041	363,280
Accumulated deficit	(288,852)	(182,864)
Treasury stock at cost, 71,545 and 31,419 shares at September 30, 2016 and December 31, 2015, respectively	(203)	(73)
Accumulated other comprehensive loss	(967)	(3,166)
<b>Total Stockholders' Equity</b>	<b>135,134</b>	<b>177,277</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 197,032</b>	<b>\$ 248,602</b>

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

	Nine Months Ended September 30,	
	2016	2015
<b>Operating Activities</b>		
Net loss	\$(105,988)	\$(33,369)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,498	802
Amortization of intangible assets	5,312	589
Amortization of debt discount and debt issuance costs	140	89
Stock-based compensation	3,858	2,388
Common stock issued for services	116	—
Inventory write-down related to restructuring	2,565	—



Loss on disposal of property	—	34
Non-cash restructuring and other charges	2,551	—
Goodwill impairment	61,784	—
Deferred tax benefit	(4,725)	(99)
Change in fair value of contingent consideration	1,700	—
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	(809)	133
Interest receivable	(9)	(5)
Inventories	(1,883)	(250)
Other current and long term assets	(1,290)	(248)
Accounts payable	(1,917)	984
Accrued expenses	(168)	4,127
Restricted cash	(10,353)	250
Net cash and cash equivalents used in operating activities	<u>(47,618)</u>	<u>(24,575)</u>
Investing Activities		
Payment for acquisition	—	(25,000)
Purchase of property and equipment	(878)	(728)
Net cash and cash equivalents used in investing activities	<u>(878)</u>	<u>(25,728)</u>
Financing Activities		
Payment of debt	(4,972)	—
Proceeds from issuance of common stock, net of issuance costs	57,637	58,295
Proceeds from issuance of debt, net of debt discount	—	9,886
Taxes paid related to net share settlement of vesting of restricted stock units	(130)	(3)
Proceeds from exercise of stock options and warrants	163	252
Net cash and cash equivalents provided by financing activities	<u>52,698</u>	<u>68,430</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(133)</u>	<u>—</u>
Net increase in cash and cash equivalents	4,069	18,127
Cash and cash equivalents, beginning of period	38,449	34,766
Cash and cash equivalents, end of period	<u>\$ 42,518</u>	<u>\$ 52,893</u>
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 1,019	\$ 598
Supplemental Schedule of Noncash Investing Activities		
Transfer of inventory to property and equipment	\$ 1,866	—
Issuance of common stock warrants	—	\$ 96
Contingent consideration related to acquisition	—	\$ 24,300
Issuance of common stock related to acquisition	—	\$ 43,677

## Exhibit 99.2 – November 9, 2016 TransEnterix Conference Call Script

### Operator :

Please standby. We are about to begin. Good afternoon, ladies and gentlemen, and welcome to the TransEnterix 2016 Third Quarter Financial and Operating Results Conference Call. As a reminder, 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 for joining us for TransEnterix Third Quarter 2016 Conference Call. Joining us on today's call is TransEnterix 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 section 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 discussion of risks and uncertainties associated with TransEnterix's business, I encourage you to review the company's filings with the Securities and Exchange Commission including the Form 10-K for the year ended December 31, 2015 and the Form 10-Q for the quarter ended September 30, 2016, expected to be filed shortly.

With that, it's my pleasure to turn the call over to TransEnterix President and Chief Executive Officer, Todd Pope.

### Todd Pope :

Thank you, Mark. Welcome to our Third Quarter Conference Call. On today's call, Joe will provide a financial update, then I'll provide an update on our key strategic priorities including the commercial update on the Senhance Surgical Robotic System, which we have recently rebranded from ALF-X, and a regulatory update on both SurgiBot and Senhance. We will then open up the line for questions. Joe?

### Joe Slattery :

Thanks, Todd. For the quarter ended September 30, 2016, we recognized revenue of approximately \$1.5 million as a result of the sale of one Senhance System and related instruments during the quarter, net of the associated deferred revenue. We also recognized approximately \$1 million in cost of revenue related to this sale, which primarily represented the fair value of the system after applying acquisition accounting since this system was an inventory at the time of the acquisition.

We expect to experience some unevenness in the quantity and average selling prices of units sold on a quarterly basis given the early stage of commercialization of the Senhance System. R&D expenses in the quarter were relatively flat as compared to the prior year period at \$7 million. The majority of our R&D spend during the quarter was related to conducting the testing required to make a 510(k) application to the FDA for Senhance.

Sales and marketing expenses in the quarter increased to approximately \$5.6 million from approximately \$1.2 million in the prior year period as a result of increased head count and other commercial investment, primarily in Europe related to the commercialization of the Senhance

I'll now turn the call back to Todd. Todd?

### Todd Pope :

Thank you, Joe. Before I provide an update on the quarter, I would like to update you on a few recent events. In September, we launched a new brand identity for the ALF-X, which is now known as the Senhance Surgical Robotic System or Senhance. We believe this change better aligns our branding with the key features and benefits of the system. And this change has been extremely well received by healthcare providers around the world.

We also recently announced the first radical hysterectomy with the Senhance System. A radical hysterectomy with lymph node dissection represents the highest level of complexity in major gynecologic cancer surgery. And this accomplishment highlights the system's applicability to the full-range of procedures known in complex GYN-oncology.

I would now like to outline our key strategic priorities moving into 2017 and provide an update on our progress in each of these areas. First, continue to commercialize the Senhance platform and CE Mark countries through a combination of direct resources and distributors. Second, partner with leading hospitals and surgeons through our clinical leadership program. Third, obtained US regulatory 510(k) clearance for the Senhance System, and fourth, leverage the open architecture of the Senhance platform.

First, I would like to provide an update on our commercialization efforts. We have direct reps covering Germany, France, and the United Kingdom. We also have independent sales agents complementing our team in Austria, Switzerland, and Italy. The pace of opportunities moving through the sales process continues to progress nicely. We define a qualified opportunity as a perspective account that has made the commitment to travel either to view a live surgery or to visit a demonstration site.

The number of qualified opportunities increased nearly 40% in the quarter, which is notable considering the limited number of selling days in the third quarter in Europe. It's great to see the level of pipeline maturity at this stage of our commercialization given the relatively short tenure of the team. We continue to validate that the typical sale cycle for capital equipment is four to six quarters and we feel that our current pipeline in Europe is developing in line with our expectations.

Outside of Europe, we have sales executives covering the Middle East and Asia and continue to receive inbound interest from many other regions. The significant interest in Senhance is reflected in our expanding distributor network, which now includes our recently announced distribution agreement with Getz Healthcare for Australia and New Zealand. Apart from Getz, we also have distributors in Taiwan, Kuwait, and the UAE.

The majority of these distribution agreements include minimum system purchase obligations in 2017 and/or 2018. Long-term distribution agreements are only entered into after significant due diligence from both sides and that typically takes three to four quarters. As part of our commercialization efforts, we continue to

have a strong presence at the key European and US trade shows.

In October, we demonstrated the Senhance System at the European Society of Gynecologic Endoscopy in Brussels, Belgium, the French Multidisciplinary Oncology Meeting in Marcé and at the American College of Surgery in Washington, D.C. At these meetings, we conducted over 100 hands-on evaluations with surgeons. In response to the strong inbound interest we have received for Senhance, we have hosted a number of mobile system demonstrations in major European markets, specifically London, Paris, Düsseldorf and Munich.

At these events, we conducted over 70 sessions with surgeons and hospital executives representing over 20 potential accounts. These mobile events are conducted to support our sales team by giving qualified surgeons and administrators an opportunity to conduct an in-depth hands-on evaluation of the system. These mobile demos can significantly reduce the time and expense required of the surgeons and administrators as compared to visiting our current installations.

To complement our experience in the field during the third quarter, we completed a comprehensive third-party market research initiative that included dozens of interviews with both surgeons and administrators in Europe. This study was conducted to help us clearly understand why robotic adoption has lagged behind the United States and how we can best position Senhance to unlock these opportunities.

The research confirmed that surgeons see value in the use of robotics but noted that the economics of the existing systems are a major barrier to adoption, especially in procedures outside of prostatectomy. With regards to Senhance, the surgeons that were interviewed clearly see the system as providing access to advanced technology while offering responsible economics, facts that resonate with surgeons and patients alike. They also convey the extremely high value placed on haptic feedback and together with the ability to leverage their laparoscopic expertise as key safety enhancements.

Our research with hospital administrators confirmed our belief that Senhance will help enable their hospital to attract patients, help enhance their leadership position as a Robotics Center of Excellence, and a system in recruiting and retaining surgeons. We believe our reusable instrumentation puts us in a strong position to offer hospitals a robotic solution that is not only cost effective, but also addresses hospital's concerns regarding the hidden cost of robotics – a point brought up in many of our interviews. Finally, our research confirmed that even with the strong value proposition, the procurement cycle is typically 12 to 18 months.

To complement our commercial investment, we have launched a new initiative called the Clinical Leadership Program. The key goals of this program are to: first, partner with influential institutions and surgeons to establish clinical reference sites and target markets, second, to thoughtfully but quickly expand the utilization of the system across multiple procedures and specialties, and third, generate clinical data that supports our long-term growth strategy.

Our first success in this program is the relationship that we announced earlier today with Imperial College of London. The Senhance System will be a part of Imperial's minimally invasive surgery program in general, bariatric, and colorectal surgery. Imperial is consistently ranked among the top universities and ranked 8th in world in both the Times Higher World University Rankings and the QS Rankings. The Imperial College Healthcare Trust is one of the leading pioneers of robotic technology in Europe. The Hamlyn Centre for Surgical Innovation is also located at this site and it is primarily focused on the following three areas of medical innovation: robotics, imaging and sensing. The Senhance Surgical Robot is precisely the kind of advanced technology that this leading institution seeks to incorporate into its practice.

In addition to the key goals mentioned above, we believe these clinical partnerships will enable us to maximize our commercial investment by expanding the number of reference accounts with clinical experience and allow us to host perspective surgeons for training and surgery observation. While we have been successful in conducting these evaluations in Milan and Rome, having only two such sites has made logistics challenging. We are excited to be able to include Imperial College as another option for surgeon evaluations and we will continue to focus on expanding this program. Our goal is to identify and establish two to three additional clinical leadership sites over the next two quarters for this program. We look forward to updating you on the progress.

Now shifting to an update on our regulatory process. Our interactions with the FDA continue to be frequent and highly collaborative. We have concluded our discussions with the FDA regarding SurgiBot and we believe that we have a clear path forward towards the future SurgiBot 510(k) clearance. Our top regulatory priority remains to submit a 510(k) for the Senhance. So even with this clarity, we intend to evaluate a SurgiBot resubmission after we have filed for Senhance clearance.

Our preparation of the Senhance 510(k) continues to progress. We have completed a series of pre-submissions and now have the agencies responses. These interactions with the FDA have allowed us to finalize our Senhance 510(k) filing approach. In our view, the most important takeaway from our series of pre-submissions is that the FDA's expectations for completing usability studies presents a very high bar. To best position ourselves for a favorable outcome of these studies for our Senhance submission, we believe we will need to increase the scope of work regarding usability. Based on this change, we now anticipate filing the Senhance 510(k) in early 2017 and we continue to expect the 2017 FDA clearance.

I'd now like to discuss the last key priority mentioned earlier, leveraging the open architecture of the Senhance platform. Competing robotics systems are closed or vertically integrated requiring hospitals to utilize only technology offered by the robotics system manufacturer regardless of technology preference of the surgeon or the hospital. With the Senhance System's open architecture, we can rapidly integrate today's leading technology for use with the platform, which allows hospitals to leverage existing and new investments for use in their robotics. The applicability of this program architecture spans from conveniences such as utilizing existing operating room beds and trocars through major investments in imaging and high-resolution video systems.

We have ongoing projects to incorporate several of today's market leading visualization, imaging, and advanced energy technologies on to the Senhance platform. And we look forward to providing more color as we progress these initiatives. Overall, we're extremely confident about the future of TransEnterix. We have continued to bolster our Senhance commercial pipeline outside of the United States, and we are well on our way towards the Senhance FDA submission, which we believe will lead to an FDA clearance in 2017.

We will now open up the line for questions.

**Operator:**

Thank you. Ladies and gentlemen, the question-and-answer session will be conducted electronically. If you would like to ask a question today, you may do so by pressing \*1 on your telephone keypad. If you are using your speaker phone, please release your mute function to allow your signal to reach our equipment. Again, that is \*1 to ask a question.

And we'll take your first question from Lawrence Keusch with Raymond James.

**John Shuman :** Hi, this is John Shuman for Larry. How are you?

**Todd Pope :** Hello, John.

**John Shuman :**

Hey, excellent. Congratulations on all your progress this quarter. I guess, Todd, if we could start with – you know, I guess a couple of things just regarding the distribution agreements and the minimum capital requirements there as well as, you know, the reference site in London and how we should think about, you know, that site in regards to the 12 to 18-month cycle. I'm just trying to think of, you know, over the next couple of years what the capital opportunities are there and I just have a quick follow-up for Joe after that.

**Todd Pope:**

Yeah. So thanks, John. Well, as far as the distributors, you know, we've had a lot of interest and that's really been global. So we've tried to expand our distributor network to reach those interested geographies.

And with our recent analysis distribution with Getz healthcare covering Australia, New Zealand, we're also branching out as we've talked about – into Asia with a Taiwan agreement, and then in the Middle East with Kuwait and the UAE. The more – majority of these distribution agreements do include minimum system purchases we've talked about, leading up through 17 and in 18. And even though we're not going to disclose the specific number of the minimum purchases for obvious competitive reasons, the fact that these agreements do include purchases that are minimally required from distributors, I think it reflects confidence and commitment from both us and our partners.

So we're excited about that, and I think you'll be hearing more about other distributor agreements as time goes by. And as far as your follow-up on the clinical leadership site, you know, this is a program that's new to us. We're excited about it, you know, our main goals, as we outlined in the call, are really to partner with influential institutions in target markets where we have direct representation.

Certainly want to continue to expand the utilization of the system to reach more specialties, more surgeons and more procedures. And we think it's important, whenever you're selling a system like that, to be able to generate longer-term clinical data, you know, I think it's going to feed into that.

So those are really our three main priorities for not only this system, but as we expand the program. And I'll let you follow up with Joe with another question there.

**John Shuman:**

Sure, Joe. If you could just give a little bit more color around the – you know, the pricing and the – and the expenses associated with the – with the first sale. And, you know, I think you had talked about a potential range of scenarios around the initial ASP. Just, you know, trying to get a better feel of what that might look like over, say, the first – the next couple of years.

**Joe Slattery:**

Yeah. Sure, John. Yeah, I – you know, given that we only sold one system in the quarter, we're a little sensitive to the competitive nature of the pricing, but I think what we can say comfortably is that the pricing on that sale was in line with, you know, our expectations. There's a – there is a deferred element to that, \$1.5 million in revenue, and it was actually higher than that. And on the cost side, I mentioned in the script that the cost of goods sold that we recognized was actually a marked up number associated with a purchase price allocation.

So, you know, we continue to believe, as we said in the past that our gross margin on capital will be in, you know, north of 50%. And on instrumentation, it'll be 65% or above.

**John Shuman:** Okay, great. Thank you.

**Todd Pope :** Thanks, John. We appreciate the questions.

**Operator:** From Stifel we'll hear from Rick Wise.

**Drew:**

Hi Todd and Joe, it's Drew on for Rick tonight. Congratulations on just the commercial progress you guys have made this quarter. But just to go back to the Imperial College placement, could you just talk a little bit more about that and maybe compare that to Milan? I believe Imperial was using a competitive robotic system mostly for urology procedures, but can you just talk about the Senhance placement? Was that really to expand the robotics program or was it more just to replace the competitive system?

**Todd Pope:**

Yeah. In both of those accounts, competitive systems already were in place. But as most of our, you know, targets, when we go in, we're really talking to hospitals about expanding their robotics program into specialties and procedures that they're not currently doing.

And typically, they've had a good experience with the robotic program, but it's been fairly limited because of the cost barrier. So when we talk to surgeons, and especially in these two accounts, they certainly have existing robotic platforms, but they're looking to offer more of their surgeons, more of their specialties. And especially in the general surgery upper abdominal. And that's where we really were able to come in with both of these systems and really expand the current usage of their robotics.

**Drew:**

Okay. And then when we were at a surgeon event at American College of Surgeons, some presenters highlighted Senhance for really colorectal procedures. And I know you recently, as you mentioned, just the first radical hysterectomy on the system. But when we think about surgeons and hospital administrations evaluating

the system, are you finding them more focused on one specialty, or you're getting buy-in from across – or from across medical disciplines? Maybe just, like, what specialty you're seeing leading the charge to – on the purchasing decision.

**Todd Pope:**

Certainly. It was a good question, Drew. A couple of things. First of all, our CE Mark is broad. It covers general surgery, GYN, urology, and thoracic. So we have a broad opportunity to go talk to folks about, you know, robotic benefits and their specialties, especially with some of our cost benefits on a per-procedure area.

Now, a little bit of the feedback you're getting when you're talking to surgeons out there is our first two placements in Rome and Milan were primarily around GYN, GYN oncology, and colon and rectal. So some of the data that we have been able to publish coming out of that, there's been nine peer-reviewed publications around some of that data. It's looked at a variety of different things in those specialties.

So we've garnered a lot of interest in those two areas, but the system is very adaptable, and one of the things we wanted to with this clinical leadership placement at Imperial and certainly others that will come behind it will be to expose the system, not only in the colon, and rectal, and GYN where we're having great success, but other specialties in other procedures.

So you're right. That's some of your early feedback when you're hearing talks, reading papers, and talking to physicians and administrators, but we have a pretty broad mandate as far as where we're going with the system. And there's excitement across multiple specialties.

**Drew:**

Got it. And just one last question. With the distribution agreement in Australia and New Zealand, not looking for revenue numbers or anything, but, I mean, robotics has been approved in that area for over 10 years. And by my math, there's only about 40 systems in that continent that's, really, the same size as the US. I mean, can you just talk about how Senhance's position to maybe better penetrate the robotics arena in Australia and New Zealand? Maybe how you're working with those distributors? And then just maybe help us size the procedure opportunity there.

**Todd Pope:**

Yeah. Well, I'll really answer your question, and it's really not Australia-New Zealand specific. You know, as you think about robotics outside the US – and it really harkens back to the research we talked about a little bit in the call. When you think about robotic penetration, we wanted to go out and understand why that robotic adoption has been fairly low outside the US. There's been – there's been meaningful progress, but not anything like the US.

And we continue to hear a couple of key things that came up. You know, first of all, certain features that we offer with Senhance primarily haptics around safety really gives a lot of hospitals and a lot of specialties excited about more utilization of robotics. Certainly, following that up about the economics of the per-procedure, when you take a look at Europe, when you take a look at Australia, you have people that are very pleased with the robotics usage, but it's used in a very narrow area, oftentimes urology, and oftentimes there just in prostate.

So as we think about geographies that have a certain amount of robots, they've had pretty deep penetration in a very narrow area, typically urology. So as we think about general surgery, upper GI, bariatric, hepatobiliary, GYN, thoracic, and urology, we think geographies like Australia and many others have a – have a really great opportunity for, you know, further robotic penetration.

And I think the Senhance platform addresses a lot of those concerns that we think has held back the penetration a little bit.

**Drew:** Great. Thanks, guys, I'll hop back in queue.

**Todd Pope:** Thank you.

**Operator:**

And ladies and gentlemen that does conclude today's question-and-answer session. I will now turn the call back to Mr. Pope for any closing remarks.

**Todd Pope:**

Thank you very much. I would just like to conclude by saying that we're very excited about the future here at TransEnterix. And we look forward to updating you on our progress on our next quarterly call. Good evening.

**Operator:** That does conclude today's presentation. We do thank everyone for your participation.