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): August 2, 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))

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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. [ ]

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**Item 2.02 Results of Operations and Financial Condition.**

On August 2, 2017, TransEnterix, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the second quarter ended June 30, 2017. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 2, 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 transcript of the conference call is furnished herewith as Exhibit 99.2.

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

**Item 9.01 Financial Statements and Exhibits.**

99.1 Press release, dated August 2, 2017
99.2 August 2, 2017 conference call script

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**SIGNATURES**

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

TransEnterix, Inc.

*August 4, 2017*

*By: /s/ Joseph P. Slattery*

*Name: Joseph P. Slattery*
*Title: EVP and CFO*

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Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release, dated August 2, 2017 |
| 99.2 | August 2, 2017 conference call script |

**Exhibit 99.1**

**August 2, 2017**

# TransEnterix, Inc. Reports Operating Results for the Second 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 second quarter of 2017.

**Recent Highlights**

-The Company sold a Senhance™ Surgical Robotic System to Saitama Medical University International Medical Center
-The Company submitted its 510(k) application for the Senhance Surgical Robotic System to FDA
-The Company raised approximately $23.2 million through an equity financing

-The Company refinanced its debt, securing up to $17.0 million in debt financing

-In July, the Senhance platform was used in the first-ever robotic micro-laparoscopic surgeries using 3mm instruments
-In July, the Novadaq Pinpoint Fluorescence Imaging system was used in conjunction with the Senhance platform

“We are very pleased with the progress we made during the quarter on our key strategic priorities, including the steps taken towards achieving 510(k) clearance for the Senhance by the end of 2017,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “We are also encouraged by the continued momentum in clinical utilization in Europe, and now globally with our sale in Japan. In addition, we have been able to leverage the open architecture of the Senhance to incorporate cutting edge technologies into the platform, setting a new standard for minimally invasive robotic surgery.”

**Commercial and Clinical Update**
In the second quarter, the Company sold a Senhance Robotic Surgery System to the Saitama Medical University International Medical Center located in the Saitama Prefecture in the Greater Tokyo region. The Senhance System was purchased in Japan under a physician import license, which allows cutting-edge medical devices to be directly purchased by Japanese physicians. Japan is the second largest market for medical devices as well as robotic assisted surgery devices. The Senhance does not have broader market approval for sale in Japan.

As of June 30, 2017, the Company had eight Senhance systems installed in France, Germany, Italy, the United Kingdom, and Japan. Within these eight hospitals, 21 surgeons performed surgery in the second quarter across gynecology, colorectal, general surgery, urology, and thoracic specialties**.**

In July, the Senhance platform was used in the first-ever robotic micro-laparoscopic surgeries utilizing 3mm instruments. Cases were performed at multiple clinical sites and included ovarian cystectomies, endometrial excisions, total laparoscopic hysterectomies, bilateral salpingo-oophorectomies and cholecystectomies. The Company expects to fully launch its 3mm instruments in the fourth quarter in CE Mark countries.

In July, the Novadaq PinPoint Endoscopic Fluorescence Imaging System was used in conjunction with the Senhance platform in multiple general surgical and gynecologic procedures. The open architecture of the Senhance platform allowed us to rapidly integrate this system so that surgeons can benefit from utilizing this leading fluorescence imaging technology.

**Financial Highlights**
For the three months ended June 30, 2017, the Company reported revenue of $1.6 million, primarily related to the sale of one Senhance during the quarter.

For the three months ended June 30, 2017, total operating expenses were $15.4 million, as compared to $80.7 million in the three months ended June 30, 2016. The prior year quarter included approximately $67.4 million of non-recurring impairment charges.

For the three months ended June 30, 2017, net loss was $14.7 million, or $0.11 per share, as compared to $80.1 million, or $0.70 per share, in the three months ended June 30, 2016.

The Company had cash, cash equivalents and restricted cash of approximately $36.2 million as of June 30, 2017. In the second quarter, the Company completed an equity offering with approximately $23.2 million in net proceeds, and refinanced its debt. With these funding actions, the Company expects to fund its operations into the first 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, the Company will receive another $25.0 million, which the Company expects will fund its operations into late 2018.

**Conference Call**
TransEnterix, Inc. will host a conference call on Wednesday, August 2, 2017 at 4:30 PM ET to discuss its second quarter 2017 operating and financial results. To listen to the conference call on your telephone, please dial (888) 852-6561 for domestic callers or (719) 325-2281 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 second 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 of our Senhance 510(k) submission by the end of 2017; whether our commercialization plans and the development of our pipeline will be successful; whether TransEnterix will fully launch its 3mm instruments in the 2017 fourth quarter in CE Mark countries; whether existing cash and cash equivalents will fund operations into the first quarter of 2018; and whether the Company is able to fund its operations into late 2018 resulting from the exercise of its Series A Common Stock Warrants. 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue | $ 1,584 | $ — | $ 3,530 | $ — |
| Cost of revenue | 972 | — | 2,306 | — |
| Gross profit | 612 | — | 1,224 | — |
| Operating Expenses | | | | |
| Research and development | 5,070 | 6,364 | 11,925 | 14,749 |
| Sales and marketing | 3,749 | 1,306 | 7,472 | 2,989 |
| General and administrative | 2,719 | 2,895 | 5,768 | 5,134 |
| Amortization of intangible assets | 1,687 | 1,786 | 3,323 | 3,603 |
| Change in fair value of contingent consideration | (774) | 944 | 453 | 1,800 |
| Change in fair value of warrant liabilities | 2,326 | — | 2,326 | — |
| Issuance costs for warrants | 627 | — | 627 | — |
| Inventory write-down related to restructuring | — | 2,565 | — | 2,565 |
| Restructuring and other charges | — | 3,085 | — | 3,085 |
| Goodwill impairment | — | 61,784 | — | 61,784 |
| Total Operating Expenses | 15,404 | 80,729 | 31,894 | 95,709 |
| Operating Loss | (14,792) | (80,729) | (30,670) | (95,709) |
| Other Expense | | | | |
| Interest expense, net | (622) | (489) | (956) | (1,067) |
| Other (expense) income | (40) | 95 | (100) | 95 |
| Total Other Expense, net | (662) | (394) | (1,056) | (972) |
| Loss before income taxes | $ (15,454) | $ (81,123) | $ (31,726) | $ (96,681) |
| Income tax benefit | 741 | 992 | 1,599 | 3,637 |
| Net loss | $ (14,713) | $ (80,131) | $ (30,127) | $ (93,044) |
| Other comprehensive income (loss) | | | | |
| Foreign currency translation gain (loss) | 5,430 | (2,286) | 6,563 | 1,510 |
| Comprehensive loss | $ (9,283) | $ (82,417) | $ (23,564) | $ (91,534) |
| Net loss per share — basic and diluted | $ (0.11) | $ (0.70) | $ (0.24) | $ (0.85) |
| Weighted average common shares outstanding — basic and diluted | 132,386 | 114,319 | 127,052 | 109,290 |

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

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | $ 29,741 | $ 24,165 |
| Accounts receivable, net | 1,665 | 621 |
| Inventories | 9,464 | 7,883 |
| Interest receivable | 13 | 12 |
| Other current assets | 7,231 | 5,335 |
| Total Current Assets | 48,114 | 38,016 |
| Restricted cash | 6,419 | 10,425 |

| | | |
|---|---|---|
| Accounts receivable, net of current portion | — | 266 |
| Property and equipment, net | 6,404 | 5,772 |
| Intellectual property, net | 37,170 | 37,090 |
| In-process research and development | 17,276 | 15,920 |
| Goodwill | 70,310 | 68,697 |
| Other long term assets | 146 | 63 |
| Total Assets | $ 185,839 | $ 176,249 |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Accounts payable | $ 2,219 | $ 3,984 |
| Accrued expenses | 8,221 | 8,206 |
| Contingent consideration – current portion | 6,918 | 10,502 |
| Notes payable — current portion, net of debt discount | — | 7,997 |
| Total Current Liabilities | 17,358 | 30,689 |
| Long Term Liabilities | | |
| Contingent consideration – less current portion | 11,108 | 12,298 |
| Notes payable — less current portion, net of debt discount | 12,896 | 4,995 |
| Warrant liabilities | 11,041 | — |
| Net deferred tax liabilities | 9,614 | 10,397 |
| Total Liabilities | 62,017 | 58,379 |
| Commitments and Contingencies | | |
| Stockholders' Equity | | |
| Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2017, and December 31, 2016; 148,538,492 and 115,781,030 shares issued at June 30, 2017 and December 31, 2016, respectively; and 148,536,356 and 115,687,351 shares outstanding at June 30, 2017 and December 31, 2016, respectively | 148 | 115 |
| Additional paid-in capital | 455,853 | 426,609 |
| Accumulated deficit | (332,971) | (302,844) |
| Treasury stock at cost, 2,136 and 93,679 shares at June 30, 2017 and December 31, 2016, respectively | (2) | (241) |
| Accumulated other comprehensive income (loss) | 794 | (5,769) |
| Total Stockholders' Equity | 123,822 | 117,870 |
| Total Liabilities and Stockholders' Equity | $ 185,839 | $ 176,249 |

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2017 | 2016 |
| Operating Activities | | |
| Net loss | $ (30,127) | $ (93,044) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities: | | |
| Depreciation | 1,142 | 1,052 |
| Amortization of intangible assets | 3,323 | 3,603 |
| Amortization of debt discount and debt issuance costs | 43 | 99 |
| Stock-based compensation | 3,679 | 2,477 |
| Inventory write-down related to restructuring | — | 2,565 |
| Non-cash restructuring and other charges | — | 2,551 |
| Goodwill impairment | — | 61,784 |
| Deferred tax benefit | (1,580) | (3,657) |
| Loss on extinguishment of debt | 308 | — |
| Change in fair value of warrant liabilities | 2,326 | — |
| Change in fair value of contingent consideration | 453 | 1,800 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (487) | — |
| Interest receivable | 39 | (13) |
| Inventories | (862) | (3,983) |
| Other current and long term assets | (1,473) | (213) |
| Accounts payable | (1,909) | (2,497) |
| Accrued expenses | (390) | (60) |
| Net cash and cash equivalents used in operating activities | (25,515) | (27,536) |
| Investing Activities | | |
| Purchase of property and equipment | (1,397) | (517) |
| Purchase of intellectual property | (398) | — |
| Net cash and cash equivalents used in investing activities | (1,795) | (517) |
| Financing Activities | | |
| Payment of debt | (13,343) | (3,078) |
| Proceeds from issuance of debt and warrants | 13,196 | — |
| Proceeds from issuance of common stock and warrants, net of issuance costs | 29,193 | 57,637 |
| Taxes paid related to net share settlement of vesting of restricted stock units | (168) | (130) |

| | | |
|---|---|---|
| Proceeds from exercise of stock options and warrants | — | 165 |
| Net cash and cash equivalents provided by financing activities | 28,878 | 54,594 |
| Effect of exchange rate changes on cash and cash equivalents | 2 | (92) |
| Net increase in cash, cash equivalents and restricted cash | 1,570 | 26,449 |
| Cash, cash equivalents and restricted cash, beginning of period | 34,590 | 38,449 |
| Cash, cash equivalents and restricted cash, end of period | $ 36,160 | $ 64,898 |
| Supplemental Disclosure for Cash Flow Information | | |
| Interest paid | $ 368 | $ 713 |
| Supplemental Schedule of Noncash Investing Activities | | |
| Transfer of inventory to property and equipment | — | $ 1,823 |
| Issuance of common stock as contingent consideration | $ 5,227 | — |
| Relative fair value of warrants issued with debt | $ 300 | — |

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**Exhibit 99.2**
**Company: TRANSENTERIX**
**Conference Title: Second Quarter 2017 Financial & Operating Results Conference Call**
**Conference ID: 3028012**
**Moderator: Mark Klausner**
**Date: August 2, 2017**

Operator: Good afternoon, ladies and gentlemen, and welcome to the TransEnterix Second 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 Westwood Partners. Please go ahead, sir.

Mark Klausner: Good afternoon, and thank you for joining us for TransEnterix's second 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 section 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'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, 2016, and the Form 10-Q for the quarter ended June 30, 2017, expected to be filed today.

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 second quarter 2017 conference call. On today's call, I will start by discussing the progression of our Senhance FDA 510(k) submission then I'll hand it over to Joe to provide a financial update. I will then discuss our commercial and clinical progress, including our recent sale in Japan, followed by an update on our U.S. market development activities. And lastly, I'll discuss our open architecture strategy, including our recently-announced breakthrough in robotic micro-laparoscopy. We will then open up the line for questions.

We continue to make good progress on our key strategic priorities during the second quarter. 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.

As we noted on our previous call, we filed the 510(k) for the Senhance system in April, in line with our expectations. We believe we submitted a high-quality, robust filing, bolstered by the inclusion of a large set of human clinical data and aided by extensive interactions with the FDA. As anticipated, we received the request for additional information, or AI, from the FDA in June, which is customary for 510(k) filings. Upon review the AI, we were pleased with the manageable scope of the feedback from the FDA.

We subsequently had an opportunity to discuss the contents of the AI in an in-person meeting with the review team and other key stakeholders involved in the review of our submission. This meeting provided us feedback that allowed us to tailor our response to the AI. As a result, we are confident that the response we will file will put us in the best possible position to achieve a clearance. We anticipate filing our response to the FDA early in the fourth quarter and continue to believe that we will achieve clearance for Senhance by the end of 2017.

I would now like to turn it over to Joe to provide a financial update before I review our other key priorities.

Joe Slattery: Thank you, Todd. For the three months ended June 30, 2017, we reported revenue of $1.6 million, primarily related to the sale of one Senhance system during the quarter. Cost of revenue was $1 million, resulting in gross profit for the quarter of $600,000. Cost of revenue included overhead and the cost of our field service organization.

R&D expenses in the quarter decreased to approximately $5.1 million as compared to the prior year period at $6.4 million, primarily due to our decision in 2016 to focus our resources on advancing the Senhance platform. Sales and marketing expenses in the quarter increased to $3.7 million from $1.3 million in the prior year period, primarily due to the expansion of our commercialization efforts in Europe.

General and administrative expenses in the quarter decreased to approximately $2.7 million from approximately $2.9 million in the prior year period. Other non-cash operating expenses were $3.9 million, which included costs associated with common stock warrants, intangibles and contingent liabilities. Net loss for the quarter was $14.7 million, or $0.11 per share, compared to a net loss of $80.1 million, or $0.70 per share in the prior year period. The prior year net loss included $67.4 million in non-cash charges related to goodwill impairment and restructuring charges.

Moving on to the balance sheet, we finished the second quarter with cash of approximately $36.2 million, of which approximately $6.4 million was restricted. In the second quarter, we completed an equity offering with over $23 million in net proceeds and refinanced our debt. We expect these funding actions to support our operations into the first quarter of 2018. The equity offering also included Series A Warrants that will expire 10 days after the announcement of a 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 undertake the transition toward focusing on U.S. commercialization. Todd?

Todd Pope: Thank you, Joe. I'd like to provide an update on the commercial and clinical progress we're making in Europe as well as the steps we're taking to prepare the U.S. market for Senhance. As previously announced in July, we sold our first Senhance system in Japan during the quarter. Japan has the second highest concentration of robots, second only to the United States with over 300 systems currently installed. This purchase by Saitama Medical University International Medical Center was made under a physician import license, which allows Japanese physicians to directly purchase cutting edge medical devices not currently approved for sale by the Japanese regulatory authority.

The sale is a great example of Senhance's ability to convert hospitals from laparoscopic to robotic surgery. Professor Koyama chose the Senhance to establish a robotics surgery platform at Saitama because of the advanced features of the Senhance, including its eye-tracking camera and haptic feedback, which provide robotic precision while mimicking the movements and techniques used within traditional laparoscopy. Surgeons at Saitama

also chose the Senhance for its wide applicability across their clinical program. In fact, they've already had four surgeons from three different specialties train on Senhance with the expectation of conducting surgeries in the third quarter.

We continue to be very encouraged by the progress with Senhance clinical utilization, specifically around the number of cases, the breadth of procedures and the number of surgeons using the system. Year-to-date, approximately 250 cases have been successfully completed and we saw a significant uptick in procedure volume from the first quarter. Active surgeons rose from 12 in the first quarter to 21 in the second quarter. These are encouraging results and we expect these trends to continue. But we do not anticipate — we do anticipate fewer procedures in the third quarter as a result of typical surgeon and patient vacation patterns in Europe. We continue to highlight the potential for Senhance to rapidly convert laparoscopic to robotic procedures by sharing our progress with St. Marien Hospital in Germany, who purchased their Senhance in the first quarter of the year.

On our May call, we noted their quick adoption on Senhance, with Dr. Frank Willeke and Dr. Dietmar Stephan's team completing 30 cases within two months of system installation. St. Marien has continued their high utilization of the system, having now more than doubled that number. In addition, St. Marien has expanded outside of general surgery, having recently begun to perform GYN cases using the Senhance, including hysterectomy, ovarian cystectomy, and endometrial excision.

At this time, Senhance is showing success across a growing number of procedural areas. There have been 24 different types of procedures performed across colorectal, gynecology, general, urology, and thoracic surgery, with surgeons focusing their utilization on a variety of high volume procedures. Surgeons have performed a significant number of colectomies and colorectal procedures including sigmoids, both left and right, and lower anterior resections. These colorectal procedures in particular demonstrate the Senhance's utility in multi-quadrant abdominal procedures.

In gynecology, surgeons have performed laparoscopic hysterectomies, surgery of the tubes and ovaries, both for benign and cancerous conditions, including extensive pelvic lymph node dissection. Surgeons have also been performing inguinal hernia repair, both unilateral and bilateral as well as ventral. We have also continued to showcase Senhance in major U.S. and international medical meetings to allow clinicians to interact with the system. There were symposia in the Netherlands, Switzerland, Germany, Austria, and the U.K. in the second quarter.

Additionally, the system was featured at the large congresses of the European Association of Endoscopic Surgeons in Frankfurt and the American Society of Colon & Rectal Surgeons in Seattle. We are encouraged by the feedback that we are experiencing in the market and continue to develop our sales pipeline. As the average tenure of our European sales team is approaching four quarters, we expect to see the results of our commercialization efforts begin to drive more meaningful revenue in late 2017 and into 2018. In line with our guidance of the capital sales process in Europe takes four to six quarters.

I would now like to provide an update on our U.S. market development activities. We are continuing to build a commercial foundation in the U.S. market in line with our expectations for a Senhance 510(k) clearance in 2017. As a part of this strategy, we have materially expanded our U.S. presence and our team now consists of eight market development professionals, one focusing on IDNs and strategic accounts and seven others focusing on regional market development around the country.

As a further advancement of our market development efforts, we have selected Florida Hospital Orlando as our first U.S. Innovation Center, and have recently installed a Senhance system at their Institute for Surgical Advancement. The Senhance will be used to perform preclinical training and procedure development in cooperation with Florida Hospital surgical staff. Additionally, surgeons from the U.S. and around the world will have the opportunity to participate in robotic preclinical activities at the Innovation Center.

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 allow hospitals to leverage existing and new investment for use in their robotics programs.

Two of the fastest-growing trends in surgery today are the use of fluorescence imaging and micro-laparoscopy using 3 millimeter instruments. In our open architecture strategy has allowed us to make tremendous progress this year incorporating these trends in the Senhance experience. In our last Investor call, we discussed our progress with incorporating two leading endoscopic fluorescence technologies, the Novadaq Pinpoint Imaging System and the Stryker 1588 AIM Platform. I'm pleased to report that the Pinpoint Fluorescence System has now been used clinically in conjunction with the Senhance platform in multiple general surgical and gynecologic procedures. To put this program's speed into perspective, we progressed from validation activities to clinical utilization of the Pinpoint in less than 6 months.

Earlier this week, we announced that we have enabled the expansion of micro-laparoscopy into robotic surgery with the Senhance, utilizing 3 millimeter instruments. These instruments allow surgeons to operate through incisions that are deemed virtually scarless for patients and in most cases do not require sutures to close. Patients continue to demand the least invasive approach to their surgery and this expansion into robotic 3 millimeter instruments provides patient benefits that up to now have not been available robotically.

We believe this will contribute meaningfully to the conversion of laparoscopic procedures to robotically-assisted procedures, potentially boosting the adoption of the Senhance globally. We expect to fully launch the 3 millimeter instruments in the fourth quarter in CE Mark countries. We believe that the Senhance's combination of haptics, eye-tracking, 3 millimeter instruments and cutting-edge fluorescence imaging, combined with our ability to offer low procedures costs, has set a new benchmark in the robotics industry.

Overall, we're pleased with the progress that had been made during the quarter on our key strategic priorities. We're also encouraged by the continued momentum in clinical utilization in Europe and now globally with our sale in Japan. In addition, we've been able to leverage the open architecture the Senhance to incorporate cutting-edge technologies into the platform. And most importantly, we continue to expect 510(k) clearance for the Senhance this year.

With that, I would like to 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, you may do so by pressing star one on your telephone keypad. If you are using your speakerphone, please release your mute function to allow your signal to reach our equipment. Once again that is star one and we'll pause for just a moment. And your first question will come from Rick Wise with Stifel.

Rick Wise: Good afternoon. Maybe starting off with a little more, Todd, on the FDA. So, based on your commentary in the call., it sounds like the interactions with the FDA have gone well and your interactions from request for more information has given you even more confidence in your ability to achieve 510(k) clearance. Can you give us any more color at all on the contents of the document or your interactions with the FDA, your meeting with

FDA and perhaps more important, do any of the questions have a lot of risk in terms of time to complete or complexity or how should we react to everything that happened so far?

Todd Pope: Certainly Rick. And hello, thank you for your question. Yes. I think you're correct, I mean we do have confidence in the clearance. I think that's really been bolstered by several things. We had a very good collaboration with the agency. Really leading up to our AI and then throughout the AI process, which has been great. We think the questions that we received are very manageable. I would say based in our prior experience with the agencies is why we really characterize the AI is manageable. And those combination of events had really come together to give us the confidence that we're going to get it clearance and we'll get it in 2017.

Rick Wise: And Todd, you're respond and again reiterating early in the fourth quarter and you still expect clearance by end of the year. But once you submit the response back, what's typically in your view, the comment would take to get that final, final response?

Todd Pope: Certainly, Rick, we look to file our response in the early fourth quarter. Up until that point, the clock's been stopped-typically this 510(k) process is a 90-day process, the first 60-days, they took to review our submission, they gave us the AI and the clock stopped. When we refile with them our response in early Q4, the clock will start again. And they like to try to get a final answer back to you within 30 days. We like to-we've seen it between 30 and 60 days. So we think if we file response in early Q4, we'll expect clearance between 30 and 60 days post that response from TransEnterix and that puts us well within the boundary of the end of the year.

Rick Wise: And it seems like, you're making some important, some meaningful investments in the U.S. in advance of FDA clearance. I'm guessing I should take that as a sign of your confidence in a positive result and clearance.

Todd Pope: Yes, we certainly were ready to make some investments but we wanted to get this point and our process with the FDA, which we are now at, so we are ramping up ahead of our clearance, we want to be able to hit the ground running, as you know the U.S. is by far the biggest robotics market globally, you know we've doubled up, we had four market development reps, we've recently hired four more, we're up to eight. One of those is just focusing on IDN and our strategic accounts and the other seven right now we've got moved around the United States really focusing on regional market development in different parts of the country. And we really continue to think about adding headcount through the end of the year. We're going to be focused on a process, hiring the best people we can, quality over quantity. But you're right — we're confident and we're making moves so we can be prepared for its approval.

Rick Wise: One interesting fact that this placing system at Florida Hospital Orlando, I know for years they've been a major robotics program, if I remember correctly. Any more color on what you'd hoped to get out of that placement there? What's the goal? What do you expect? What did you ask of them? What are they asking of you, et cetera?

Todd Pope: Certainly, Florida Hospital is certainly looked at as one of the top robotic systems in the United States and globally. And Florida Hospital Orlando has created this center, you know, focused exclusively on new surgical approaches and also how they utilize the latest technology, so we felt like it was a great place to demonstrate the capabilities of Senhance. We want to put the Senhance down there. We want to perform preclinical training, look at procedure development, and do that in cooperation with Florida Hospital surgical staff. After we get them trained up, it will also allow not only Florida Hospital staff but surgeons from around the U.S. and, where Orlando is located, really around the world, a great opportunity to come in and participate in preclinical activities at the Innovation Center, a really good preparation for our activities post-approval.

Rick Wise: Todd, can you talk a little bit more about what's going on in Europe? Obviously, a number of training centers are performing a significant number of wide range of surgeries. As you know, I spent a day in one of them and saw what's going on. Can you give us any color about the amount of visits from other hospitals? And what kind of interest, what kind of training, can you give us any concrete sense of numbers? And when we're going to start to see a real impact from that? Will we see it as soon as the fourth quarter, do you think? Or is it going to take through next year? What's happening in Europe?

Todd Pope: Yes, it's a good question, you got the benefit of being over there and seeing the system in action, and I think seeing some of the pipeline come through. Up until the second quarter we're really, most of our pipeline accounts were coming through Italy, now we've got systems up in Germany, we're able to broaden our capability to handle pipeline accounts. We're able to see different types of procedures in different types of setting. I think that diversity of experience had helped our pipeline. And, as we've said, you know we tried to match up the tenure of our sales reps, which is right at about four quarters, we've always said that we think the capital sales process in Europe usually equates to about four to six quarters.

So you're correct, as we're kind of coming in to the fourth quarter for the average of our sales reps, we think at the end of the year heading into 2018, we're going to be in a position to start taking some of those pipeline accounts and driving some more meaningful revenues. So we're excited about that, we really wanted to take, you know, the first and certainly the second quarter to continue to drive a broad array of procedures. We wanted to give that clinical validation in multiple countries in multiple specialties, and we've done that. And I think the other thing that we are really excited about doing in the second quarter, we've had so much good feedback on this concept of the open architecture, but people wanted to see us pay that off with some actual instruments and technologies that would be equipped onto the Senhance for the experience.

So as we've touched on in the call we really can ask any laparoscopist the two fastest growing areas in laparoscopy are primarily micro-laparoscopy using instruments down around 3 millimeters and then advanced imaging, especially fluorescence so you can perfuse vessels and structures. And so with us taking 3 millimeters instrumentation and fluorescence imaging with both Stryker and Novadaq, getting them validated on our system, getting regulatory approval in Europe and then start to use them clinically, we're were getting a lot of good feedback for this open architecture really kind of coming to life here this last quarter. So, we're excited about that and we certainly think that will play into benefits with our pipeline.

Rick Wise: And just last from me. Just, you know, continuing along with that open architecture strategy and all of these new technologies—where is it going to take you in the future? Advanced energy? Stapling? You know, what's to come? And I'll stop there, thank you.

Todd Pope: Thank you, Rick. Certainly we wanted to focus on micro-laparoscopy then imaging, I think, and the next thing we turned our attention to was vessel sealing. We think that's an important technology, advance synergy, if you will, and we want to incorporate into some of the leading technology onto the system and we plan to do that in this calendar year over in CE Mark countries. So I think it's just a real clear indication of our roadmap continuing to take important physician preference items that matter in surgery, make sure they are able to be used with the Senhance platform. So thanks for the questions Rick. Thank you.

Rick Wise: Thank you.

Operator: We will go to Jeffrey Cohen with Ladenburg Thalmann.

Jeffrey Cohen: So I guess the first question for Joe if he's on, at some point in the near future do you plan on breaking out consumables and that as a second revenue line or do you planning on the coupling everything together for the time being?

Joe Slattery: Jeff, we don't-we haven't really given any commentary on that up until now, but I think, you know, while our revenue numbers are in this range it makes the most sense the vast majority what's in there is capital.

Jeffrey Cohen: Okay, and subsequent to a potential U.S. approval, do you plan to set up a West Coast training facility besides Nicholson?

Todd Pope: We are going to start-off with Florida and we are going to kind of base geographic need – you know, now that we have reps out throughout the country, we are going to kind of gage the interest in how it comes up and kind of put the resources geographically as it makes sense.

Jeffrey Cohen: Okay, and then lastly from me, if you could further expand a little bit upon the 3 millimeter architecture and what you are seeing in the marketplace, and how you would anticipate that that may play out both in CE territories as well as potentially in the U.S.?

Todd Pope: Certainly, well, we see three millimeter — years ago, three millimeter was of great interest, but the material science just wasn't there that you can get the strength profile, the flexibility profile you needed in a smaller diameter instrument. That's come a long way and now we see many practices taking most of their minimally invasive laparoscopic surgery over to 3 millimeter in some instances. So we think it's going to have utility across a lot of specialties. Particularly in GYN, they operate oftentimes lower in the pelvis. They like to use smaller instrumentation. They like to be able to leave their patients, which what they call a scarless surgery, hardly ever closed with sutures. So, we think that's not only going to play well in Europe, but certainly in the U.S., where we're seeing 3 millimeter instruments being rapidly adopted in laparoscopy. So, to be able to put it on the Senhance platform, we're really excited about it and so our surgeons.

Jeffrey Cohen: Okay. And when you talk about full launch for our three millimeter, will all your current instrumentation be available for that sizing?

Todd Pope: Yes. The majority of all of our key manufacturers will be offered on three millimeter.

Jeffrey Cohen: Okay. And with the potential I suppose of some additional introductions as you mentioned for vessel sealing, et cetera?

Todd Pope: That's correct. Next up for us will be advanced energy, that's right.

Jeffrey Cohen: Okay. Perfect, thanks guys, that does it for me.

Todd Pope: Thank you.

Operator: And that concludes our question-and-answer session for today. I would like to turn the call back to Todd Pope for closing remarks.

Todd Pope: Thank you. We continue to be enthusiastic about the future here at TransEnterix. Looking ahead, we will continue to work diligently towards the Senhance 510(k) clearance in 2017. In addition, we will remain focused on continuing to build the momentum in clinical utilization and commercialization in Europe and continue to prepare for U.S. commercialization in order to drive revenue in 2018. Thank you for joining us today. We look forward to giving you an update on our next quarterly call.

Operator: Ladies and gentlemen that does conclude today's presentation. We do thank everyone for your participation and you may now disconnect.