TRANSENTERIX 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): March 6, 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))

Top of the Form

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2017, TransEnterix, Inc., a Delaware corporation (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2016. The press release is furnished herewith as Exhibit 99.1.

Also on March 6, 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. The Company had issued a press release on February 21, 2017 to announce the scheduling of the conference call. The transcript of the conference call is furnished herewith as Exhibit 99.2.

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

Item 9.01 Financial Statements and Exhibits.

Exhibit No. Description
99.1 Press release, dated March 6, 2017
99.2 Transcript of conference call held on March 6, 2017

Top of the Form

SIGNATURES

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

TransEnterix, Inc.

March 8, 2017

By: /s/ Joseph P. Slattery

Name: Joseph P. Slattery
Title: EVP and CFO

Top of the Form

Exhibit Index

Exhibit No.	Description
99.1	Press release, dated March 6, 2017
99.2	Transcript of conference call held on March 6, 2017

Exhibit 99.1
March 6, 2017

TransEnterix, Inc. Reports Operating Results for the Fourth Quarter and Full Year 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 fourth quarter and full year 2016.

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.

We expanded our Clinical Leadership Program to three sites, which now includes installed systems in France, Italy and the United Kingdom.

On January 5, 2017, the Company received an additional € 5 million investment, or approximately $5.2 million, from SOFAR S.p.A.

On December 15, 2016, the Company entered into a common stock purchase agreement, providing the Company with up to $25 million over 36-months from date of execution.

"We are pleased with the significant progress we made during the year in establishing a strong foundation for Senhance commercialization," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We are excited about the opportunity to leverage that foundation to drive growth in Europe and other regions, and look forward to the submission of our Senhance 510(k) and anticipated approval in 2017."

Financial Highlights

For the three months ended December 31, 2016, the Company reported revenue of $53 thousand, consisting of the recognition of deferred and services revenue associated with existing placements.

For the three months ended December 31, 2016, total operating expenses were $14.4 million, as compared to $13.9 million in the three months ended December 31, 2015.

For the three months ended December 31, 2016, net loss was $14.0 million, or $(0.12) per share, as compared to $13.6 million, or $(0.13) per share, in the three months ended December 31, 2015.

For the full year ended December 31, 2016, the Company reported revenue of $1.5 million, representing the sale of a Senhance system, net of deferred revenue, as well as the recognition of deferred and service revenue associated with existing placements.

For the full year ended December 31, 2016, total operating expenses were $124.1 million, including primarily non-cash charges for goodwill impairment of $61.8 million and restructuring charges of $5.6 million taken in the second quarter of 2016, as compared to $46.4 million in the full year ended December 31, 2015.

For the full year ended December 31, 2016, net loss was $120.0 million, or $1.07 per share, as compared to $46.9 million, or $0.59 per share, in the full year ended December 31, 2015.

The Company had cash, cash equivalents and restricted cash of approximately $34.6 million as of December 31, 2016. The Company expects its existing cash, cash equivalents and restricted cash to fund operations into the fourth quarter of 2017. Pursuant to the disclosure requirements of the NYSE MKT Company Guide Section 610(b), the Company is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2016, included in the Company's Annual Report on Form 10-K filed expected to be filed with the Securities and Exchange Commission on or about March 6, 2017, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to the Company's ability to continue as a going concern.

Conference Call
TransEnterix, Inc. will host a conference call on Monday, March 6, 2017 at 4:30 PM ET to discuss its fourth quarter and full year 2016 operating and financial results. To listen to the conference call on your telephone, please dial (888) 724-9516 for domestic callers or (913) 312-0978 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 fourth quarter and full year 2016 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 when we will file the 510(k) submission for the Senhance Surgical Robotic System, whether the Senhance 510(k) will be approved by the FDA 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 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 for the year ended December 31, 2016, which we expect to file shortly, 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 Balance Sheets
(in thousands, except share amounts)

(unaudited)

	December 31, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$ 24,165	$ 38,449
Accounts receivable, net	621	76
Inventories	7,883	6,625
Interest receivable	12	6
Other current assets	5,335	3,987
Total Current Assets	38,016	49,143
Restricted cash	10,425	—
Accounts receivable, net of current portion	266	—
Inventories, net of current portion	—	709
Property and equipment, net	5,772	4,408
Intellectual property, net	37,090	46,898
In-process research and development	15,920	16,511
Goodwill	68,697	130,869
Other long term assets	63	64
Total Assets	$ 176,249	$ 248,602
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 3,984	$ 4,450
Accrued expenses	8,206	7,395
Contingent consideration – current portion	10,502	12,500
Notes payable — current portion, net of debt discount	7,997	6,727
Total Current Liabilities	30,689	31,072
Long Term Liabilities		
Contingent consideration – less current portion	12,298	11,000
Notes payable — less current portion, net of debt discount	4,995	12,990
Net deferred tax liabilities	10,397	16,263
Total Liabilities	58,379	71,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at December 31, 2016 and 2015, respectively; 115,781,030 and 100,180,872 shares issued at December 31, 2016 and 2015, respectively; and 115,687,351 and 100,149,453 shares outstanding at December 31, 2016 and 2015, respectively	115	100
Additional paid-in capital	426,609	363,280
Accumulated deficit	(302,844)	(182,864)

Treasury stock at cost, 93,679 and 31,419 shares at December 31, 2016 and 2015, respectively	(241)	(73)
Accumulated other comprehensive loss	(5,769)	(3,166)
Total Stockholders' Equity	117,870	177,277
Total Liabilities and Stockholders' Equity	$ 176,249	$ 248,602

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

(unaudited)

	Year Ended December 31, 2016	Year Ended December 31, 2015
Operating Activities		
Net loss	$ (119,980)	$ (46,948)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,942	1,248
Amortization of intangible assets	6,967	2,185
Amortization of debt discount and debt issuance costs	177	142
Stock-based compensation	5,033	3,311
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	2,556	—
Goodwill impairment	61,784	—
Deferred tax benefit	(5,562)	(1,024)
Change in fair value of contingent consideration	482	(400)
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	(1,041)	133
Interest receivable	(6)	(5)
Inventories	(6,647)	(4,630)
Other current and long term assets	(1,528)	728
Accounts payable	(356)	1,096
Accrued expenses	1,112	5,371
Net cash and cash equivalents used in operating activities	(52,386)	(38,759)
Investing Activities		
Payment for acquisition of a business	—	(25,000)
Purchase of property and equipment	(1,361)	(1,234)
Net cash and cash equivalents (used in) provided by investing activities	(1,361)	(26,234)
Financing Activities		
Payment of debt	(6,902)	—
Payment of contingent consideration	(1,182)	—
Proceeds from issuance of common stock, net of issuance costs	58,029	58,331
Proceeds from issuance of debt, net of debt discount	—	9,887
Taxes paid related to net share settlement of vesting of restricted stock units	(168)	(73)
Proceeds from exercise of stock options and warrants	166	259
Net cash and cash equivalents provided by financing activities	49,943	68,404
Effect of exchange rate changes on cash and cash equivalents	(55)	22
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,859)	3,433
Cash, cash equivalents and restricted cash, beginning of period	38,449	35,016
Cash, cash equivalents and restricted cash, end of period	$ 34,590	$ 38,449
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 1,289	$ 973
Supplemental Schedule of Noncash Investing Activities		
Transfer of inventory to property and equipment	$ 3,198	—
Issuance of common stock warrants	—	$ 97
Contingent consideration related to acquisition	—	$ 23,900
Issuance of common stock related to acquisition	—	$ 43,677

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

(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenue	$ 53	$ —	$ 1,519	$ —
Cost of revenue	38	—	1,069	—
Gross profit	15	—	450	—
Operating Expenses				
Research and development	7,513	8,558	29,273	29,669
Sales and marketing	3,588	1,694	9,151	2,855
General and administrative	2,886	2,224	10,813	7,831
Amortization of intangible assets	1,655	1,596	6,967	2,185
Change in fair value of contingent consideration	(1,218)	(400)	482	(400)
Inventory write-down related to restructuring	—	—	2,565	—
Restructuring and other charges	(21)	—	3,064	—
Goodwill impairment	—	—	61,784	—
Acquisition related costs	—	228	—	4,231
Total Operating Expenses	14,403	13,900	124,099	46,371
Operating Loss	(14,388)	(13,900)	(123,649)	(46,371)
Other Expense				
Interest expense, net	(390)	(604)	(1,889	(1,601)
Other (expense) income	(30)	—	35	—
Total Other Expense, net	(420)	(604)	(1,854)	(1,601)
Loss before income taxes	$(14,808	$(14,504)	$(125,503)	$(47,972)
Income tax benefit	816	925	5,523	1,024
Net loss	$(13,992)	$(13,579)	$(119,980)	$(46,948)
Other comprehensive gain (loss)				
Foreign currency translation gain (loss)	(4,802)	(2,737)	(2,603)	(3,166)
Comprehensive loss	$(18,794)	$(16,316)	$(122,583)	$(50,114)
Net loss per share — basic and diluted	$ (0.12)	$ (0.13)	$ (1.07)	$ (0.59)
Weighted average common shares outstanding - basic and diluted	115,151	100,145	112,185	79,628

Exhibit 99.2

Company: TransEnterix
Conference Title: Fourth Quarter and Fiscal Year 2016 Financial and Operating Results call

Moderator: Todd M. Pope

Date: Monday, 6 th March 2017
Conference Time: 15:30 CT

Operator :

Good afternoon ladies and gentlemen, welcome to the TransEnterix Fourth Quarter and Fiscal Year 2016 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' 4th Quarter and full year 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 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 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, 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 and welcome to our fourth quarter and full year conference call. On today's call Joe will provide a financial update, then I'll provide an update on the progress we are making on our key strategic priorities, including a commercial update on the Senhance surgical robotics system. We will then open up the line for questions. Joe.

Joe Slattery :

Thanks Todd. So the three months ended December 31, 2016 the company reported revenue of $53,000 consisting of deferred and services revenues associated with existing placements. R&D expenses in the quarter decreased to approximately $7.5 million as compared to the prior year period at $8.6 million; primarily from the timing of work conducted to prepare FDA submissions. The marketing expenses in the quarter increased to approximately $3.6 million from approximately $1.7 million in the prior year period; primarily related to head-count growth and other expenses from our commercial expansion in Europe. General and administrative expenses in the quarter increased to approximately $2.9 million from approximately $2.2 million in the prior year period; primarily due to expansion in support of our European commercial investment. Net loss for the quarter was $14 million, or 12 cents a share, compared to a net loss of $13.6 million, or 13 cents per share in the prior year period.

Before moving on to the balance sheet I'd like to discuss two events that occurred since our last call in November and the associated impact on our financials. In December we announced the execution of a common stock purchase agreement with Lincoln Park Capital Fund. This equity facility gives us the right, in our sole discretion, to raise up to $25 million through sales of common stock to Lincoln Park over three years.

Since the execution of the agreement we have raised approximately $4.9 million at a weighted average discount to transaction date closing price of 4.1%. Also in January we announced an agreement with Sofar S.P.A., from whom we purchased a Senhance platform in 2017, with a combination of stock, upfront cash and deferred cash. This new agreement related to the € 10 million deferred payment from that transaction, which, subject to our meeting one of several milestones, would have been payable, most likely during 2017. The new agreement converted half of that amount into stock and deferred the other half to be due on the later of December 31, 2017 or the achievement of one of the triggering milestones. We currently anticipate making this € 5 million payment on December 31, 2017 given that one of the triggering milestones is FDA clearance of the Senhance, which we anticipate before year end.

Moving on to the balance sheet, we finished the fourth quarter with cash, cash equivalents and restricted cash of approximately $34.6 million. Quarterly cash flows from operations was $15 million in the quarter. Including the restricted cash, we believe that our current cash can fund our operations into the fourth quarter of 2017 and, assuming we draw down the remaining Lincoln Park commitment, we will be able to fund our operations, including the Sofar payment I just mentioned, beyond the expected Senhance FDA clearance later this year and into 2018.

We have primarily relied on raising capital through equity offerings and will continue to need to raise additional capital in the form of equity sales to fund our investments in commercializing the Senhance platform. We have an additional $38 million available, excluding the amount currently reserved for our existing financings, under two shelf registration statements, both of which expire in 2017. In order to allow us to access the public financing markets in the future, we intend to file a new shelf registration statement with the SEC in the coming weeks as a matter of good housekeeping. As a reminder, we have an extended period of time to sell shares under a shelf registration and that any such filing does not represent a signal that we will be issuing equity imminently. I will now turn the call back over to Todd, Todd.

Todd Pope :

Thank you Joe. As a reminder, our key strategic priorities are as follows: continue to commercialize the Senhance platform in CE mark countries through a

combination of direct resources and distributors; partner with leading hospitals and surgeons through our clinical leadership program; obtain US regulatory 510K clearance for the Senhance system; and leverage the open architecture of the Senhance platform.

Before covering our commercial and regulatory progress, I would like to provide an update on our clinical leadership program and open architecture strategy. We introduced the clinical leadership program in the fourth quarter, the goals of which are, (1) partner with leading institutions and surgeons to establish clinical reference sites in target markets; (2) meaningfully expand the utilization of the Senhance system across multiple procedures and specialties; and (3) generate clinical data to support our long-term growth strategy. In addition to these key goals, these clinical partnerships will enable us to host prospective surgeons and hospital executives for surgery observation and training.

Complementing our first clinical leadership site in Italy, we have recently installed systems in the United Kingdom and France. Earlier in the year we began performing clinical cases at Imperial College in the UK and we recently announced our first surgical cases in France at CHU Saint-Étienne. The mixture of cases being performed at each of our clinical leadership sites continues to expand as we have now performed upper GI cases in addition to colorectal and GYN, which reflects the broad applicability of the Senhance system. Although it is early, these clinical leadership sites are providing some immediate value and we expect to establish a fourth and final European clinical leadership site in another strategic geography in the near term. Later in the call I will share some specific learnings from these new clinical leadership sites, together with our overall commercial progress.

Another key priority going into 2017 was 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 the robotics program, while permitting rapid technology expansion in between our major upgrade cycles.

We have completed the validation to utilize 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 Fluorescent Imaging System enables surgeons to visualize tissue profusion and anatomical structures. These technologies provide important information to the surgeon in many of the procedures that can be performed with the Senhance system. Customer reaction to this new capability has been extremely positive and this differentiates us from the competition, not only in terms of offering choice by leveraging hospitals' existing investments but also in terms of our philosophy as a company to work collaboratively within our customers' own eco-system.

In addition to continuing to expand the Senhance compatibility with additional vision and imaging systems, we are also co-developing advanced energy devices and expanding our differentiated laparoscopic instrument suite in collaboration with companies that offer unique and differentiated technologies. This is a key component to our open architecture strategy – to integrate new technology on the Senhance platform, while maintaining the direct relationship with the customer.

Before we turn to a commercialization update, I am pleased to announce that we have hired Wouter Donders as our new General Manager for Europe. He most recently served as Vice President of Europe for EndoStim, a neuromodulation technology company. Wouter has deep laparoscopic surgery experience, having also served as Vice President of Sales and Marketing at Gyrus, a company focused on advanced vessel sealing. In his role at TransEnterix Wouter will be responsible for all aspects of the commercial business in Europe, including sales, marketing, training and customer service. Wouter has a solid track record of launching new and differentiated medical technology products into markets with established players, and successfully building teams to drive adoption and sales growth. With Wouter's leadership, our existing European sales team, led by our Vice President of Sales, Steven Boudrez, and a growing number of sales and clinical professionals across Europe, we believe we are very well positioned to capitalize in 2017 on the investments that we made last year.

Now I would like to provide an update on our commercial progress. We recently announced the sale of the Senhance system to St. Marien-Krankenhaus, a large multi-specialty hospital in Siegen, Germany. They chose the Senhance platform for its robotic precision, advanced visualization and haptic technology. They view the Senhance as offering the latest technology with attractive per procedure economics. Given that this was a traditional system sale, with a purchase price in line with the competition's latest offering, we are pleased to see this strong validation of our value proposition. Their initial focus is on general and gynecologic surgery and their plan is to expand their utilization to other specialties over time.

With respect to hospital targeting, our first two sales are demonstrating our attractiveness to hospitals, both with and without existing robotics programs. Our Italian hospital customer preferred the Senhance for colorectal applications in a head-to-head evaluation of the Senhance against the competition, resulting in this hospital expanding its robotics program by adding a Senhance system. Prior to Senhance being on the market, our German customer never seriously contemplated robotics, given the high procedure cost. While these are early reactions from a small set of customers, they are common themes throughout all of our customer interactions and they will be particularly important as we expand into markets with a large number of existing surgical robotics like the United States.

While we are still in the early stages of commercialization, a key component of our strategy is to expand system placements and drive clinical experience. We are developing a more balanced pipeline and our capital sales team is now spending a higher percentage of its time on converting the mature opportunities into sales. We are encouraged by the level of pipeline maturity at this stage of our commercialization, given the current tenure of the team has an average of two to three quarters.

As we continue to engage with potential customers, we are finding that a number of hospitals are interested in the Senhance due to its unique value proposition. However, they do not have the capital reserve to make a purchase in the current fiscal year. In certain situations, where we see high value and a long-term partnership with an institution, we have offered operating leases or other economic arrangements that will allow the hospital to immediately implement a Senhance surgical program.

Now I'd like to conclude this commercial update by sharing my perspectives on learnings from the past few months. In general, we are experiencing a tremendous amount of interest as the second player to enter the market after nearly two decades with a single incumbent. What is most encouraging is that our differentiation in terms of features, benefits, value proposition and open architecture is resonating with surgeons and hospital executives. Since our last call, our clinical activity has increased substantially. At that time we had two active customer sites in one country – we now have four active customer sites in three countries, with eight surgeons regularly performing cases. In March we expect to begin surgeries in Germany, after we complete installation and training at St. Marien-Krankenhaus. We are also seeing the realization of important aspects of our value proposition through our growing European clinical experience.

Our unique ability to increase a surgeon's sense of security through the use of haptic feedback has been cited by surgeons as a critical safety benefit of Senhance. This commentary has been consistent, particularly from colorectal, GYN oncologists and upper GI surgeons as they all have to navigate critical organs

and vessels in each of their surgeries.

Another aspect of our value proposition that is consistently being validated is our ability to convert traditional laparoscopic procedures to robotics. For example, general surgery and gynecology are two specialties that have been significantly under-penetrated by robotics, especially in Europe, due primarily to the significantly higher procedure costs versus laparoscopy. We continue to discover that procedure cost is the number one reason hospitals have either not yet invested in robotic surgery, or have taken steps to limit regular usage of the robot in their institution. In February, at Imperial College, we began performing cholecystectomies in addition to other more complex cases. This procedure has historically been difficult to penetrate with robotics given the high procedure cost incurred with other systems. It has been encouraging to see surgeons scheduling Senhance cases for the most commonly performed surgeries, without pressure from administration to constrain their robotic usage.

Our other recent learnings confirm our expectation that laparoscopic surgeons get comfortable very quickly given our familiar laparoscopic motion and feel and that Senhance set up and OR times are similar to traditional laparoscopy after the first set of clinical cases. We are now routinely conducting two cases in a single day on the same system, including complex procedures such a total hysterectomies, with extensive lymph node dissections, oophorectomies, along with simple ovarian cystectomies and cholecystectomies.

Having demonstrated excellent surgical outcomes and having addressed the historical robotic challenges of higher costs and incremental procedure time, our new surgeon users are commenting on the value of ergonomics as they consider converting more and more of their laparoscopic procedures to robotics. As a result, we are beginning to see the potential to change the game in robotics in terms of defining what high-volume looks like. For example, one of our surgeons is already performing four to five cases per week after their first case occurred in early February. As system use at this hospital has expanded to additional surgeons that are currently being trained, we can envision utilization rates that are much higher.

Turning to the US regulatory process for the Senhance; we are in the final stages of completing our submission and expect to file the Senhance 510K with the FDA before our next quarterly earnings call, which we will host in early May. We remain on track to meet our goal of achieving a 2017 clearance. Overall we're extremely confident about the future of TransEnterix. I am encouraged by our early commercial traction in Europe and enthusiastic about our prospects for this year. In addition we are well on our way towards a Senhance FDA submission, which we believe will lead to an FDA clearance in 2017. We will now open the line up for questions.

Operator :

Thank you. If you would like to ask a question at this time, please signal us by pressing star one on your telephone keypad. If you are using a speakerphone, please make sure your mute function is turned off to allow your signal to reach us. And again it's star one to ask a question. And we'll take our first question from Rick Wise of Stifel.

Rick Wise :

Good afternoon. How are you doing? Let me – Todd start us off talking about the sales force, I think you said that – can you remind us of direct sales team members, you know, out in the field in Europe and you said that they have two to three quarters of experience; how long does it take – how much experience is required to generate those initial orders? Does it take two to three, four to five, four to six – just maybe give us some perspective? And I'm going to ask just one more part of that and you can – you can talk about it all. And can you give us any color as the sales force experience has grown, any color on the pipeline and how we think about the rest of the year?

Todd Pope :
Hey thanks Rick. Yeah, as we've talked about in the past, we have a combination of both direct and distributor sales organizations; so we now have multiple reps in Germany, France and the UK and the Nordics. That's really important areas for us to go direct and then our distributor relationships are in other areas of Europe. In addition we have distributors, as we've talked about, in Asia, the Middle East, Australia and New Zealand. So as we think about your question on pipeline maturity, we still believe that most of these deals matriculate through four to six quarters, when they are first introduced to us, by the time they make a decision. And when we look at, you know, our sales force on average being out there about two to three quarters we feel like, you know, our pipeline is going to see some pretty significant maturity on the back half of the year. Certainly we had a sale in the Q3; that product had been out with the account for about a year. And then our German sale that we announced a few weeks ago were introduced to the technology in the second half of last year and that went a little quicker than usual. So each one of these deals takes a little bit of their own personality. But we feel really in line with where we wanted to be with our sales force and our pipeline. So did you have a follow-up question?

Rick Wise :
Yeah, turning to the – your comments about offering operating leases, again sort of a multi-part question, is this a new business model? Should we expect the majority of your sales going forward are going to be operating leases? And talk about maybe a little bit how you are going to finance them? Will this be a third-party partner? Does this change the path to profitability? How do we think about, you know, sales in that context?

Todd Pope :
Sure, I mean today you know our sales up to this point have been traditional, with, you know, our prices in ASP kind of being in line with the competition's latest offering. You know, for us we see sometimes a hospital has not been thinking about robotics because typically their features haven't been there that have compelled them or per procedure economics has kept them away from the purchase consideration. When we introduce Senhance they've become really excited about potentially applying robotics in their hospital where they haven't had that in the past. So in turn they haven't set aside money in that particular physical year. You can kind of juxtapose that with other accounts that have decided to buy a robot, they've budgeted for the year and we are in there competing for the business. So I wouldn't say this is going to be a – a new normal for us with operating leases; we just want to exhibit flexibility when we meet hospitals that haven't really been thinking about it but then they are excited about Senhance and want to try to get it in as soon as possible. In most of those cases we do an operating lease and we're usually looking down for their next physical year for them to put aside the budget and then go ahead and pay on a typical ASP.

To your question about third party, some of those we'll do on our own operating leases and others we can operate with a lease that either the hospital has a third party lease provider they use for other capital equipment or we can provide a partner.

Rick Wise :
Okay, and just one last one from me on the FDA, you sound pretty clear and pretty optimistic, Todd, that you're going to be able to file in the US before your next,

if I heard you correctly, before the next earnings call in early May. Maybe if you could talk about that, comment on what sounds like, you know, real confidence about that timeline and the confidence that you will get that US approval before year end – why so confident and just help us think through what's next on that front?

Todd Pope :
Yes, well you're reading me right and clear and confident is right. I mean you know since we've indicated that we're going to file by the time of our next quarterly call, you know, you can guess that we're in the final stages of putting that submission together. In January we announced that we had completed our usability studies and more recently, after that, we've now completed our validation studies.

So most of the items that remain to be completed for us are relatively low-risk and I don't believe that there's any steps remaining that would materially delay our time to submission. You have to keep in mind now that we've highlighted some of our clinical experience, we're doing surgery safely and effectively almost every day of the week and we have interacted with the FDA extensively since last summer in our pre-submissions, including being able to get the FDA in front of our system so they could actually have a demo and see it live, which was very helpful, at the American College of Surgery last year.

So we look at it that we've successfully completed all of our high and medium risk elements as far as all of our testing requirements and we feel very confident that we're not only going to file before that May call but receive approval before the end of the year.

Rick Wise :

Thank you Todd.

Todd Pope :

Thank you Rick.

Operator :

We will next take Glenn Novarro with RBC Capital Markets.

Brendan :
Yes, thanks for taking my question. This is actually Brendan on for Glenn. The first question on the pipeline, can you just talk about what geographies and types of customers you are experiencing the most success with in terms of interest for Senhance? And then which you're not maybe experiencing as much success in? And then a couple of follow-ups.

Todd Pope :
Sure Brendan. We really see our targets kind of bifurcating; we either have a customer that's similar to Siegen that had really not thought seriously about robotics after looking at robotics early on. One thing to be for sure, there's probably not a hospital anywhere that hasn't been called on to take a look at robotics, so they evaluated it, it didn't make sense. We come in, we have a different value proposition. We are in there talking to them about a robot that has haptic feel and that sense of security. We have eye-tracking camera control, we have a different economic per procedure model, so this gives – these accounts are very interested, in the case of Siegen, they moved very quickly over a couple of quarters to purchase the system. So we have one set of customers like that.

We have other targets in our pipeline that are similar a little bit more to Humanitas. They had a system in the hospital, primarily being utilized by urology, they were fine, they had considered other specialties in the past but really didn't feel like the value proposition was there. We introduced our technology and they said this would be a nice way to augment their current robotic capability, so we were able to sell one in and now they have newer surgeons in different specialties doing different procedures. So those are really the way that our targets have kind of bifurcated and obviously it's early but we've had a sale in both and we have, you know, a pretty rich pipeline in both so that's the way we differentiate and we're encouraged about having success in both of those customer sets.

Brendan :
Okay and then separately, can you discuss how many surgeons – I know it's still early but can you discuss how many surgeons have been trained through the clinical leadership program thus far and what are your plans for expansion of this program to additional sites in 2017? I think you mentioned a fourth site – when do you expect that to come on line?

Todd Pope :
Well we've not given out specific numbers at each hospital. I would just say for each one of our clinical leadership sites we have multiple surgeons trained and multiple surgeons doing cases at these hospitals and we have a – also a pipeline at our current clinical leadership sites where we will be training more. And there are oftentimes in different specialties that are currently doing them today. And, you know, as far as the next clinical leadership site, we expect that to come on board in the near term. So next time we're with you we'll have an update on that.

Brendan :
Okay, and then finally just in terms of the sales force, what goals do you want to achieve in 2017 with regards to the build out of the international sales force? And then on the US side should we assume you guys are adding additional US selling resources ahead of the FDA approval of Senhance? Thanks.

Todd Pope :
Yeah, as far as goals for Europe, we feel good about our footprint right now for capital sales reps. We have a pipeline that is almost a little difficult for us to service right now because oftentimes they want to come in and take a look and see the system in use. That's why we've added clinical leadership sites to alleviate a little bit of that pressure on the pipeline; so we don't really need to generate, you know, more of those, we need to focus on the ones that are maturing and closing into sales. What we are continuing to look to add is training in clinical resources because as we're starting to integrate this technology in some of our early sites, people are starting to do cases rapidly, multiple cases in a day, multiple operating days in a week and so we need the clinical sales force to be out there in these cases handling that. So that's where we're looking to augment, you know, our sales force and our team additions in Europe.

As far as the US, we're not able to be out there selling prior to approval, but we do have market development resources that we've put out in the field. We still have our Vice President of Sales, Paul Ziegler that we brought on over a year ago now, in the United States; he's still on building his team out and we're certainly out – we have a podium, a poster strategy, a trade show strategy – we're really interfacing with a lot of hospitals, not only surgeons but executives in the

US and not only at trade shows but going out and seeing them also them coming in to North Carolina to our headquarters. As hospitals are thinking about their 2017 purchases they hear that we're pretty bullish on an FDA clearance by the end of the year and they are looking to buy systems this year; so they've been engaging with us quite regularly. So yeah, I feel like we're in a good position to hit the ground running when we do get our clearance here in the States.

Brendan :

Okay, thank you.

Todd Pope :

Thank you Brendan.

Operator :

Next we'll take Greg Chodaczek with B. Riley.

Greg Chodaczek :

Thank you. Todd, just quick, on the 1588 and the PINPOINT announcements, can you talk about how that happened and let's say a hospital has a Fuji or something else, how difficult is that to use their – that system with your system?

Todd Pope :
Hi, thanks for the question Greg. Yeah, you know we're really pleased to have gotten the validation for both Stryker and Novadaq you know done in this first quarter. We really don't want to get into the specifics about each one of those deals or partnerships, but you know the implementation of our open architecture ranges from taking a product off the shelf and adapting it to the Senhance, all the way to signing a development with some of these companies that require co-development agreements. So you know, more generally the way we think about the open architecture strategy is two things really: (1) allow technology that we call surgeon-preference to be integrated with the Senhance where possible; you know, vision systems, fluorescents, vessel sealing, etc. And then secondly we're trying to be, you know, disruptive – you know, the least disruptive as we can going into a hospital operating room. They have their own eco-system and when they want to adopt a new robotics program we want to go in and leverage their best practices that are already in place. They have OR time that they want to adhere to room changeover time; they have current equipment like their own operating room beds and trocars, we're trying to let them incorporate our system without having to upset that applecart.

And then to your last question, we're going to continue to look at other technologies. We're trying to start with technologies that we hear are broadly being used in a strong surgeon preference and we've announced those first two and then we'll build out from there. So each system, I don't want to really get into characterizing difficulty or ease, but we're certainly being met with open arms from hospitals. You know, both the executive and the surgeons, when you tell a surgeon they have a surgeon preference that they currently use on their laparoscopic cases and they can use that camera with the Senhance, they are happy. And then when you tell a hospital executive that might have invested in multiple powers from a particular vendor and they can utilize that with the Senhance, they are pleased also. So we felt like this would be a real strategic advantage and early feedback is it's very positive.

Greg Chodaczek :

Okay, and regarding reimbursement of your [inaudible] US, and what you are seeing in Europe, can you talk about what the cost per procedure, not exact numbers, but compare that to lap, compare it to your competitor? I know you have – your systems can be – or your toolkits can be used a lot more than your competitors and I'm just trying to figure out what – and I know it's early days, but the surgeons who are using them and the hospitals that are using them, how often are they using them? You know, I'm just trying to get my arms around that question.

Todd Pope :
Yeah, well it's a multi-layered question so let me take it in each part. First of all I want to remind you and everyone on the call, we do not have reimbursement codes for robotic surgery really anywhere in the world. People continue to forget that almost in all cases when a robot is used we're applying laparoscopic reimbursement codes. And in laparoscopy that's been around several decades, there's been a big conversion in many procedures to laparoscopy and with that reimbursement has been pushed down and many of the products have gone reusable. So for us we feel like to really get robotic utilization up, and let's face it, if you look across all of the procedures that are done day in and day out at hospitals around the world, robotic penetration is very low right now across the board. So we think if we offer meaningful features as we've talked about in the past, haptic, so on and so forth; coupled with tools that are reimbursed, tools that are reusable, that can match up a little bit with current reimbursement, you know, we think we can really remove some of the barriers and increase utilization. So that's what we're going out and we're being received very strongly with that.

As far as particular cost per procedure, I will just tell you that that really varies depending on if a company is selling directly or if they are selling through a distributor in different markets that occur. It really depends on what part of the world – in Asia customers are routinely, or patients are routinely asked to pay $10,000 or more out of their own pocket for robotic care, so that really fluctuates. It's hard to give you a fleet average, but I would say in general we are trying to come much closer to the cost per procedure that they experience with the current lap case and that's going to be fairly significantly under what the competition is offering on a per procedure case with robotics today.

Greg Chodaczek :

And last but not least I know this will be a quick answer, have you talked about what a potential label or what the approval could be for Senhance by the FDA?

Todd Pope :
We've not. We've not and we won't. We will have those discussions with the FDA. I mean we're not prepared to really discuss that publically, but we've got a broad label in Europe and we think our continued clinical evidence that's building is going to be very helpful in our submission.

Greg Chodaczek :

Thank you Todd.

Operator :
And next we'll move to Larry Keusch with Raymond James.

Larry Keusch :
Thanks, good afternoon everyone. I apologize I got disconnected so if I'm asking a question that's already been asked please let me know. But Todd I guess I wanted to start with just any thoughts that you may have on the sort of lessons learned in Europe over the course of the past year as it relates to sort of positioning of the system and what feedback you're hearing on pricing?

Todd Pope :
Yeah, well we touched on that a little bit but I would just say the main lessons learned for us is what does a good target account look like for Senhance; and you know, that is – we're having good success with both hospitals that have a system in place already, a robot that they want to expand clinical utilization into other specialties. And we're also really able to engage accounts that do not have a robot today. We really thought we might fall strongly on one or the other side of a good target there but we have so many hospitals that have wanted to look at implementing a system but just didn't feel like the per procedure economics worked for them or there was just too many tradeoffs to use a robot versus their current laparoscopy. So I think the one thing that we have a great opportunity to do is take a look at the number of laparoscopic procedures that are done day in and day out around the world and we think we have a robotic platform that is well positioned to convert those over to Senhance. That is not what you typically hear from robotic companies that are either on the market or thinking about coming to the market. It's typically been more looking at open procedures and taking those to robotics. So that was our initial value proposition.

And our lessons learned, to answer your question specifically is, that is resonating. We built our system on laparoscopic motion. When a surgeon sits down at our system it's very familiar; they get up to speed quickly and they see a lot of benefits that they might not see from other systems. And when you take away that pressure of per procedure economics being quite a bit more with robotics, we think that we're going to be able to get robotic utilization on a far broader number of procedures than are currently being done today. So that's our learnings, it's early; we, you know, it's early for us. We've got a handful of systems out there and a handful of countries starting to ramp up but we think that is going to be very transferrable when we get to the States.

Larry Keusch :

Got it. That's helpful. And then, just a couple of other quick ones here; obviously I heard you talk about the imaging and visualization capabilities that you are able to add to the system through the open architecture, but are there other product enhancements or expansion of the portfolio that we should be thinking about in 2017?

Todd Pope :
Well I think for sure, we believe imaging, visualization are really accelerating in the market. You know, there's a lot more players that are looking to get into that space other than the traditional ones. And even the traditional ones are starting to on-board more and more technology with their imaging. So for us we think we would like to participate in that without having to develop those products ourselves. So we're going to continue to work with leading imaging and visualization companies; when they have surgeon preference products we're hoping they can also be able to utilize those with the Senhance.

And then, as we've discussed before, vessel sealing is an important category; it's a very big market on its own and we expect to have a product out and C-mark cleared in Europe this year, so we think that's going to be an important advancement for the platform as we think about other procedures.

Larry Keusch :
Okay, and then two quick financial ones; Joe, if my numbers are right it looks like inventories in the fourth quarter rose $6 million sequentially, so if that's correct, what's driving the increase there? And then, given the timing of the installation that you're talking about in Germany, which sounds like it's going to happen sometime this month, do we – should we expect to see sort of a $1.5 to $2 million revenue contribution in the – in the 2Q or in the 1Q I should say I guess?

Joe Slattery :
Yeah, Larry, with respect to the inventory bill, that's right, we had a – you know, our primary supplier for the Senhance platform, we released a PO to support the US launch later this year and planning for the pipeline maturity that we've been talking about and so we have a pretty hefty up front. So that's going to normalize to some extent over the next couple of quarters.

And with respect to that, the Siegen sale, actually it was installed today so it will be a Q1 revenue event and, as we discussed, what we said was that the revenue was in line with other top tier offerings.

Larry Keusch :

Okay, perfect, thank you very much.

Todd Pope :

The only thing I would add Larry is, you know, if the – if the – the invoice value is usually a little bit higher than the revenue recognized because a portion is deferred over the first year to account for the warranty exposure.

Larry Keusch :

Okay, got it. Okay, perfect. Thank you very much.

Joe Slattery :

Thanks Larry.

Operator :

Next we'll move to Jeffrey Cohen with Ladenburg Thalmann.

Jeffrey Cohen :

Hi guys, just a couple of quick ones as most of my questions have been answered. So just to follow up on the Q1 recognition, so we should also then see the Sofar investment show up there in the first quarter, is that correct?

Todd Pope :

Yes, that's correct. It – Jeff it won't be in the form of cash right?

Jeffrey Cohen :
Right.

Todd Pope :
Yup.

Jeffrey Cohen :
Okay but it will show up in the first quarter. Okay and then second, just getting back to earlier discussion, Todd, when you were talking about the composition of hospitals, which we're in dialogue with as far as having current robotic programs or not; could you also give us a bit of color and some discussion as far as what type of physicians are you finding are becoming most engaged in the process, specific to our procedures and at the different facilities.

Todd Pope :
Well I would answer that about what type of physicians, I would say it's been a broad base of physician interest. So I would say that the way I like to clarify that is they are laparoscopic surgeons. You know, when we think of robotics traditionally, we've seen cases in surgeons that are doing open procedures historically and there's certainly been laparoscopic surgeons converted over to robotics but not in high numbers. So I would say for us we've really been focusing on procedures and, in turn, physicians that do a lot of laparoscopy. And so when we've been able to sit them down with Senhance, let them do labs, let them do surgery and now that we've got some placements and see their early usage, it's been pleasantly surprising to us that they're considering moving more and more of what maybe would be called some of their garden variety volume over to the Senhance. Not just trying to look for complex cases, or not just looking for cases that have high reimbursement – those have certainly benefited by robotics. But also just spending more and more of their usual OR day on the Senhance. I think when you remove some of those barriers of high cost per procedure compared to laparoscopy and you kind of level that out, then the benefits of robotics really start to shine and they start thinking about doing more and more of their cases. The benefit of that is when you start moving high volume procedures there, they really – they really get – they master the robot quicker and they feel more confident. So when they do run into larger, more complex cases they've really got a lot of cases under their belt. So it's early but that's how I'd characterize the physicians that we're calling on and that goes across, you know, physicians in all areas of upper and lower abdominal surgeries.

Jeffrey Cohen :
Okay and as far as the clinical leadership sites, there are three thus far; are you seeing a lot of engagement, both from the surgeons as well as sea-level suites as far as hospitals go? How would you characterize that and the difference in what you are seeing in Europe versus some other territories in the US?

Todd Pope :
Yes, 100%, you're never going to put a robot into a hospital without strong clinical support and strong sea-level support. It's a very – it's a very high profile decision. You're, you know, dedicating space in an OR and you're changing the way that – you know, you're operating on patients so there's a lot of stakeholders that get involved in that. So we've been very encouraged that we have value props that resonate a little differently with the clinical community versus the economic community but they both are very strong for Senhance. And we think a lot of those will be similar in the US. The way I would characterize the difference is in Europe and outside of the US there's not been as big of an adoption outside of urology, outside the United States. In the United States there's been a pretty broad adoption outside of urology and other specialties and so we're able to talk to people for the first time over in Europe about thinking about using a robot outside of urology and I think that's going to be a benefit to us in the US, we don't have to do as much of that early education in the US. They're already thinking about using it; they're just trying to understand what their options are when it comes to choice. So we won't have to spend as much of that early missionary work trying to talk to people about robotic applications outside of Urology when we get to the US, that will, I think, accelerate our capital decision process.

Jeffrey Cohen :

Super, okay thanks for taking the questions.

Todd Pope :

Okay, thank you.

Operator :

This concludes our question and answer session for today everyone. I would now like to turn the call back to Mr. Pope for closing remarks.

Todd Pope :
Thank you. I'd 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 afternoon.

Operator :
Everyone that concludes our conference call for today. Thank you all for your participation, you may now disconnect.