UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

November 8, 2018
Date of Report (date of earliest event reported)

TransEnterix, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**0-19437**	**11-2962080**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

635 Davis Drive, Suite 300
Morrisville, North Carolina
(Address of principal executive offices)

919-765-8400
(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company □

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

Item 2.02 Results of Operations and Financial Condition

On November 8, 2018, TransEnterix, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the third quarter ended September 30, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on November 8, 2018, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results for the third quarter ended September 30, 2018. The Company had issued a press release on October 24, 2018 to announce the scheduling of the conference call. 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

(d) Exhibits.

99.1 Press Release, dated November 8, 2018

99.2 November 8, 2018 conference call script

SIGNATURES

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

TransEnterix, Inc.

Date: November 13, 2018

/s/ Joseph P. Slattery
Joseph P. Slattery
EVP and Chief Financial Officer

Exhibit 99.1

TransEnterix, Inc. Reports Operating and Financial Results for the Third Quarter 2018

November 8, 2018 at 4:05 PM EDT

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Nov 8, 2018-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced its operating and financial results for the third quarter 2018.

Recent Highlights

- Total revenue of $5.4 million, including the sale of four Senhance™ Systems in the third quarter
- Acquired the technology assets and IP of MST Medical Surgery Technologies
- Received FDA 510(k) clearance for 3mm diameter instruments
- Received CE Mark approval for Senhance™ Ultrasonic Instrument System

“We are proud of the progress we made during the third quarter, as we continued to drive adoption of the Senhance System by executing on our sales and marketing strategy and continuing to develop the capabilities of the Senhance System to deliver on our vision of digital laparoscopy,” said Todd M. Pope, President and CEO at TransEnterix. “We are focused on driving the global adoption of the Senhance System by increasing the applicability of the system for a wider range of surgeons, patients and geographies.”

Commercial and Clinical Update

In the quarter ended September 30, 2018, the Company sold four Senhance Systems, with one sold in the U.S. and three in the EMEA (Europe, Middle East, and Africa) region.

On October 11, 2018, the Company received FDA 510(k) clearance for 3 millimeter diameter Senhance System instruments, as well as additional 5 millimeter Senhance System instruments. The clearance of the 3 millimeter diameter instruments will allow the Senhance System to be used for microlaparoscopic surgeries, enabling surgeons to operate through smaller incisions considered virtually scarless for patients, supporting the Company's mission of advancing minimally invasive surgical capabilities within digital laparoscopy.

On October 1, 2018, the Company announced that it had received a CE Mark for its Senhance Ultrasonic Instrument System. As previously announced, the Company continues to expect to commercially launch the Ultrasonic Instrument System in CE Mark countries in the fourth quarter of 2018.

Acquisition Agreement with MST

On September 23, 2018, the Company announced that it had entered into an agreement to acquire substantially all of the assets of MST Medical Surgery Technologies Ltd. ("MST"), an Israel-based medical technology company. MST is a leader in the field of surgical technology, having developed a software-based image analytics platform powered by advanced visualization, scene recognition, artificial intelligence, machine learning and data analytics.

The addition of MST's technology, IP portfolio, and R&D team will support and accelerate TransEnterix's vision to leverage its Senhance Surgical System to deliver digital laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability. In addition, the acquisition will provide immediate access to an established R&D center in Israel with a core team of experienced engineers. The closing of the MST transaction occurred on October 31, 2018

Third Quarter Financial Highlights

For the three months ended September 30, 2018, the Company reported revenue of $5.4 million as compared to revenue of $183 thousand in the three months ended September 30, 2017. Revenue in the third quarter of 2018 included $4.3 million in system sales, $867 thousand in instruments and accessories, and $237 thousand in services.

For the three months ended September 30, 2018, total net operating expenses were $13.1 million, as compared to $14.9 million in the three months ended September 30, 2017.

For the three months ended September 30, 2018, net loss was $20.2 million, or $0.10 per share, as compared to a net loss of $38.5 million, or $0.26 per share, in the three months ended September 30, 2017.

For the three months ended September 30, 2018, adjusted net loss was $12.7 million, or $0.06 per share, as compared to an adjusted net loss of $13.0 million, or $0.09 per share in the three months ended September 30, 2017, after adjusting for the following non-cash charges: change in fair value of warrant liabilities, reversal of transfer fee accrual, amortization of intangible assets, change in fair value of contingent consideration, acquisition-related costs and SurgiBot sale gain/loss.

The Company had cash and short term investments of approximately $81.4 million as of September 30, 2018. On October 23, 2018, Hercules Capital, Inc. funded the second tranche of $10,000,000 under the Hercules loan agreement. The Company continues to believe that it has sufficient cash and additional debt proceeds under the current agreement to fund the business through 2020.

Conference Call

TransEnterix, Inc. will host a conference call on Thursday, November 8, 2018 at 4:30 PM ET to discuss its third quarter 2018 operating and financial results. To listen to the conference call on your telephone, please dial (844) 804-5261 for domestic callers or (612) 979-9885 for international callers and reference conference ID 9991627 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 digitizing the interface between the surgeon and the patient to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options in today's value-based healthcare environment. The Company is focused on the commercialization of the Senhance™ Surgical System, which digitizes laparoscopic minimally invasive surgery. The system allows for robotic precision, haptic feedback, surgeon camera control via eye sensing and improved ergonomics while offering responsible economics. The Senhance Surgical System is available for sale in

the US, the EU and select other countries. For more information, visit www.transenterix.com.

Non-GAAP Measures

The adjusted net loss and adjusted net loss per share presented in this press release are non-GAAP measures. The adjustments relate to the change in fair value of warrant liabilities, reversal of transfer fee accrual, amortization of intangible assets, change in fair value of contingent consideration, acquisition-related costs, loss on extinguishment of debt and SurgiBot sale gain/loss. These financial measures are presented on a basis other than in accordance with U.S. generally accepted accounting principles ("Non-GAAP Measures"). In the tables that follow under "Reconciliation of Non-GAAP Measures," we present adjusted net loss and adjusted net loss per share, reconciled to their comparable GAAP measures. These items are adjusted because they are not operational or because these charges are non-cash or non-recurring and management believes these adjustments are meaningful to understanding the Company's performance during the periods presented. These Non-GAAP Measures should be considered a supplement to, not a substitute for, or superior to, the corresponding financial measures calculated in accordance with GAAP.

Forward-Looking Statements

This press release includes statements relating to the 2018 third quarter results and plans for 2018 and beyond. 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 and include whether we are driving global adoption of Senhance by increasing the applicability of the system for a wide range of surgeons, patients and geographies, whether we will commercially launch the Ultrasonic Instrument System in CE Mark countries in the fourth quarter of 2018, whether the acquisition of MST’s technology, IP portfolio and R&D team will support and accelerate TransEnterix’s vision to leverage its Senhance Surgical System to deliver digital laparoscopy, and whether the Company has sufficient cash and additional debt proceeds under the current agreement to fund the business through 2020. 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, 2017, filed with the SEC on March 8, 2018 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$ 5,422	$ 183	$ 16,578	$ 3,713
Cost of revenue	4,249	921	10,536	3,227
Gross profit (loss)	1,173	(738)	6,042	486
Operating Expenses (Income)				
Research and development	4,838	4,889	15,384	16,814
Sales and marketing	5,819	4,528	17,835	12,000
General and administrative	3,686	2,920	9,989	8,688
Amortization of intangible assets	2,674	1,821	8,244	5,144
Change in fair value of contingent consideration	(1,358)	773	81	1,226
Issuance costs for warrants	—	—	—	627
Acquisition related costs	345	—	345	—
Gain from sale of SurgiBot assets, net	44	—	(11,915)	—
Reversal of transfer fee accrual	(2,994)	—	(2,994)	—
Total Operating Expenses (Income)	13,054	14,931	36,969	44,499
Operating Loss	(11,881)	(15,669)	(30,927)	(44,013)
Other (Expense) Income				
Change in fair value of warrant liabilities	(8,760)	(22,887)	(24,438)	(25,213)
Interest income	391	62	982	124
Interest expense	(685)	(563)	(3,398)	(1,581)
Other expense	(52)	(194)	(109)	(294)
Total Other (Expense) Income, net	(9,106)	(23,582)	(26,963)	(26,964)
Loss before income taxes	$ (20,987)	$ (39,251)	$ (57,890)	$ (70,977)
Income tax benefit	781	738	2,554	2,337
Net loss	$ (20,206)	$ (38,513)	$ (55,336)	$ (68,640)
Other comprehensive loss				
Foreign currency translation (loss) gain	(561)	2,952	(2,651)	9,515
Comprehensive loss	$ (20,767)	$ (35,561)	$ (57,987)	$ (59,125)
Net loss per share - basic and diluted	$ (0.10)	$ (0.26)	$ (0.27)	$ (0.51)
Weighted average common shares outstanding - basic and diluted	209,088	149,516	204,531	134,622

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

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 41,748	$ 91,217
Short-term investments	39,670	—
Accounts receivable, net	5,669	1,536
Inventories	10,242	10,817
Interest receivable	51	80
Other current assets	9,039	9,344
Total Current Assets	106,419	112,994
Restricted cash	663	6,389
Property and equipment, net	6,659	6,670
Intellectual property, net	42,925	52,638
Goodwill	70,669	71,368
Other long term assets	224	192
Total Assets	$ 227,559	$ 250,251
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 2,785	$ 3,771
Accrued expenses	7,432	10,974
Deferred revenue – current portion	1,270	1,088
Deferred gain from sale of SurgiBot assets	—	7,500
Contingent consideration – current portion	555	719
Notes payable - current portion, net of debt discount	—	4,788
Total Current Liabilities	12,042	28,840
Long Term Liabilities		
Deferred revenue – less current portion	131	—
Contingent consideration – less current portion	11,549	11,699
Notes payable - less current portion, net of debt discount	19,106	8,385
Warrant liabilities	15,044	14,090
Net deferred tax liabilities	5,624	8,389
Total Liabilities	63,496	71,403
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at September 30, 2018 and December 31, 2017; 212,631,801 and 199,282,003 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	212	199
Additional paid-in capital	664,439	621,261
Accumulated deficit	(502,965)	(447,640)
Accumulated other comprehensive income	2,377	5,028
Total Stockholders' Equity	164,063	178,848
Total Liabilities and Stockholders' Equity	$ 227,559	$ 250,251

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

	Nine Months Ended September 30,	
	2018	**2017**
Operating Activities		
Net loss	$ (55,336)	$ (68,640)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Gain from sale of SurgiBot assets, net	(11,915)	—
Depreciation	1,876	1,816
Amortization of intangible assets	8,244	5,144
Amortization of debt discount and debt issuance costs	575	212
Amortization of held to maturity investment discount	(51)	—
Stock-based compensation	6,694	5,321
Non-employee warrant awards	—	571
Deferred tax benefit	(2,572)	(2,320)
Loss on extinguishment of debt	1,400	308
Change in fair value of warrant liabilities	24,438	25,213
Change in fair value of contingent consideration	81	1,226
Reversal of transfer fee accrual	(2,994)	—
Changes in operating assets and liabilities:		
Accounts receivable	(4,262)	886
Interest receivable	28	79
Inventories	(1,276)	(3,519)
Other current and long term assets	27	(2,454)
Accounts payable	(903)	(1,599)
Accrued expenses	(56)	207
Deferred revenue	361	—
Net cash and cash equivalents used in operating activities	(35,641)	(37,549)
Investing Activities		
Purchase of short-term investments	(39,619)	—
Proceeds related to sale of SurgiBot assets, net	4,496	—
Purchase of property and equipment	(490)	(1,488)
Purchase of intellectual property	—	(418)
Proceeds from sale of property and equipment	32	—
Net cash and cash equivalents used in investing activities	(35,581)	(1,906)
Financing Activities		
Payment of notes payable	(15,305)	(13,343)
Proceeds from issuance of debt and warrants, net of issuance costs	18,828	12,956
Payment of contingent consideration	(395)	(395)
Proceeds from issuance of common stock and warrants, net of issuance costs	279	31,546
Taxes paid related to net share settlement of vesting of restricted stock units	(1,662)	(168)
Proceeds from issuance of common stock related to sale of SurgiBot assets	3,000	—
Proceeds from exercise of stock options and warrants	11,396	5,449
Net cash and cash equivalents provided by financing activities	16,141	36,045
Effect of exchange rate changes on cash and cash equivalents	(114)	(311)
Net decrease in cash, cash equivalents and restricted cash	(55,195)	(3,721)
Cash, cash equivalents and restricted cash, beginning of period	97,606	34,590
Cash, cash equivalents and restricted cash, end of period	$ 42,411	$ 30,869
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 1,135	$ 597
Supplemental Schedule of Noncash Investing and Financing Activities		
Transfer of inventories to property and equipment	$ 2,160	$ —
Transfer of property and equipment to inventories	$ 648	$ —
Issuance of common stock as contingent consideration	$ —	$ 5,227
Relative fair value of warrants issued with debt	$ —	$ 300
Reclass of warrant liability to common stock and additional paid-in capital	$ 23,484	$ 2,289

TransEnterix, Inc.
Reconciliation of Non-GAAP Measures
Adjusted Net Loss and Net Loss per Share
(in thousands except per share amounts)
(Unaudited)

(Unaudited, U.S. Dollars, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (20,206)	$ (38,513)	$ (55,336)	$ (68,640)
Adjustments				
Gain from sale of SurgiBot assets, net	44	—	(11,915)	—
Amortization of intangible assets	2,674	1,821	8,244	5,144
Change in fair value of contingent consideration	(1,358)	773	81	1,226
Acquisition related costs	345	—	345	—
Reversal of transfer fee accrual	(2,994)	—	(2,994)	—
Change in fair value of warrant liabilities	8,760	22,887	24,438	25,213
Loss on extinguishment of debt	—	—	1,400	308
Adjusted net loss	$ (12,735)	$ (13,032)	$ (35,737)	$ (36,749)

(Unaudited, per diluted share)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss per share	$ (0.10)	$ (0.26)	$ (0.27)	$ (0.51)
Adjustments				
Gain from sale of SurgiBot assets	0.00	—	(0.06)	—
Amortization of intangible assets	0.01	0.01	0.04	0.04
Change in fair value of contingent consideration	(0.01)	0.01	0.00	0.01
Acquisition related costs	0.00	—	0.00	—
Reversal of transfer fee accrual	(0.01)	—	(0.01)	—
Change in fair value of warrant liabilities	0.05	0.15	0.12	0.19
Loss on extinguishment of debt	—	—	0.01	0.00
Adjusted net loss per share	$ (0.06)	$ (0.09)	$ (0.17)	$ (0.27)

The non-GAAP financial measures for the three and nine months ended September 30, 2018 and 2017 provide management with additional insight into its results of operations and are calculated using the following adjustments:

a) Gain from sale of SurgiBot assets relates to amounts received from Great Belief International Limited in excess of the carrying amount of the assets sold.

b) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.

c) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

d) Acquisition related costs were incurred in connection with the MST purchase agreement and consist of legal, accounting, and other costs.

e) In connection with the Senhance acquisition, the Company recorded an accrual in 2015 third quarter for potential assessment of additional transfer fees. In September 2018, the Company determined that the accrual was no longer required and reversed the accrual.

f) The Company’s Series B Warrants are measured at fair value using a simulation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected volatility, holding cost and the risk-free interest rate for the term of the warrant. The warrant liability is

revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

g) In May 2018, in connection with its entrance into the Hercules Loan Agreement, the Company repaid its existing loan and security agreement with Innovatus Life Sciences Lending Fund I, LP. The Company recognized a loss of $1.4 million on the extinguishment of notes payable which is included in interest expense on the consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2018. In May 2017, in connection with its entrance into the Innovatus Loan Agreement, the Company repaid its then-existing credit facility with Silicon Valley Bank and Oxford Finance LLC. The Company recognized a loss of $308,000 on the extinguishment of notes payable which is included in interest expense on the consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2017.

For TransEnterix, Inc.
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Exhibit 99.2
Company: TRANSENTERIX, INC.
Conference Title: Q3 2018 TransEnterix Inc. Earnings Call
Moderator: Mark Klausner
Date: November 8, 2018

PRESENTATION

Operator

Good afternoon, ladies and gentlemen. Welcome to the TransEnterixs Third Quarter Financial and Operating Results Conference Call. As a reminder, this call is webcast live and recorded. It is now my pleasure to introduce your host, Mr. Mark Klausner of Westwicke Partners. Please go ahead, sir.

Mark R. Klausner - *Westwicke Partners, LLC - Managing Partner*

Thank you. Good afternoon, and thank you for joining us for TransEnterix's Third Quarter Conference Call. Joining us on today's call are TransEnterix's President and Chief Executive Officer, Todd Pope; and its Executive Vice President and Chief Financial Officer, Joe Slattery. I would like to remind you that this call is being webcast live and recorded. A replay of the event will be available following the call on our 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, including guidance related to the number of Senhance systems expected to be sold in the fourth quarter of 2018, as well as fourth quarter revenue, 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, 2017, and the Form 10-Q for the quarter ended September 30, 2018, expected to be filed shortly. During this call, we will also present non-GAAP information - financial information related to adjusted net loss and adjusted earnings per share. Management believes that non-GAAP financial measures, taken in conjunction with U.S. GAAP financial measures, provide useful information for both management and investors by excluding certain noncash and other expenses that are not indicative of the company's core operating results. Management uses non-GAAP measures to compare our performance relative to forecasts and strategic plans, to benchmark our performance externally against competitors, and for certain compensation decisions. Reconciliations between U.S. GAAP and non-GAAP results are presented in the tables accompanying our earnings release, which can be found in the Investor Relations section of our website. With that, it's my pleasure to turn the call over to TransEnterix President and Chief Executive Officer, Todd Pope.

Todd M. Pope - *TransEnterix, Inc. - CEO, President & Director*

Thank you, Mark, and welcome to our Third Quarter 2018 Conference Call.In recognition of those of you who may be listening to our conference call for the first time or simply haven't had the opportunity to hear how we have built TransEnterix over the past few years, our unique position in the surgical robotics industry and our strategy for driving adoption of Senhance going forward, I will spend the first portion of the call on this topic. Then, we'll transition to our performance during the quarter and an update on our key priorities for the year.In September of 2015, we acquired a technologically-advanced surgical robotics system, that is now called Senhance, from SOFAR, an Italian health care company. SOFAR's primary business was pharmaceuticals, and they intended to find a commercialization partner for their robotic platform after they had achieved CE Mark and completed clinical validation.Subsequent to the acquisition, we focused on two primary initiatives. First, establishing a commercial sales infrastructure in Europe, Middle East and Africa, or EMEA, from the ground up; and second, obtaining the FDA 510(k) clearance of the Senhance in the U.S.Our vision was to bring this innovative surgical robotics solution to a market that had been dominated by a single player and lacked alternatives for nearly two decades.The existing robotic offering brought many benefits, but also brought long set-up times, larger diameter instruments, loss of haptic feedback and higher procedure cost relative to laparoscopy. While robotic procedure growth has been strong, the applications tended to be limited to converting open procedures to robotics because the reduction in hospital stay could offset the high per procedure cost. This meant that nearly half of the surgical procedures being done worldwide still did not have an attractive robotic alternative.What excited us about the opportunity for Senhance was the unique design of the system that we believe will help revolutionize the robotics industry. The Senhance was developed to cater to laparoscopic surgeons, as there was nothing on the market purpose-built to convert laparoscopic procedures to robotics. It was specifically designed to leverage their laparoscopic familiarity and training and utilizes 5-millimeter reusable instruments similar to laparoscopy, which maintains the minimally invasive nature of laparoscopic procedures.The Senhance also brought new innovations with haptic feedback and eye-tracking camera control. Finally, because our instruments are reusable, we can provide surgeons with all of these benefits while maintaining procedure costs that are comparable to laparoscopy.Bringing a product to market with a well-established incumbent has been and continues to be a journey. Following the Senhance acquisition, with the CE Mark in hand, we initiated the commercialization of the product in EMEA in 2016.We have often stated that the hospital capital sales cycle is 4 to 6 quarters and, as a result, when building a pipeline from scratch, it can take a number of years to fully mature.

In EMEA, we are just beginning to see the benefits of our maturing pipeline, as we have gone from two system sales in 2017 to eight sold this year through the third quarter, and we now have ten commercially sold systems as well as three strategic placements that service training sites or to produce clinical data for our global regulatory submissions.In April 2017, we submitted our application for FDA clearance for Senhance. We took a strategic approach to our filing and decided to submit for initial indications for use within gynecologic and colorectal laparoscopic surgery. We targeted this specific clearance because we had significant clinical data from our sites in Europe that could be used to support our filing.In addition, GYN has significant laparoscopic volumes and colorectal procedures are complex and can benefit from the advantages of a robotics solution.We also decided to file for a 3-arm system, because our experience in EMEA suggested that the majority of surgeries were done with three arms.In October of 2017, six months after filing, we received 510(k) clearance for the system, becoming the first new entrant in the field of abdominal surgical robotics in nearly 20 years.Our initial indications of GYN and colorectal gave us immediate access to over 1.5 million annual procedures in the U.S. Obtaining FDA 510(k) clearance is a rigorous process for any device, but the hurdles are particularly high for a surgical robot, given that it has hardware, software, vision and instrument components, and the fact that the intended use of the system involves complex surgical procedures in and around critical anatomy.We have a long-term indication and product portfolio expansion strategy, which we are executing to broaden the applicability of the system to a greater number of surgeons and hospitals.We have made tremendous strides in a relatively short period of time, including, receiving clearance for expanded indications for use in May of this year for inguinal hernia repair and gallbladder surgery, which more than doubled our addressable market to over 3 million procedures.In addition, we have received FDA clearance for our 3-millimeter diameter instruments and have filed our FDA 510(k) submission for an ultrasonic energy device.In terms of our commercialization efforts in the U.S., similar to our experience in EMEA, we needed to develop the U.S. market and establish a sales infrastructure that can support the new launch and ultimately the successful adoption of Senhance, while being thoughtful on how we deploy our capital.We assembled a strong team of medical device sales reps and now have a 15-person sales force covering the eastern half of the country. Having received our FDA clearance just one year ago, we are pleased with what our team has been able to accomplish in terms of commercial sales to a

number of high-profile hospitals in the United States as well as the work we had done to develop a strong pipeline of accounts looking to add a Senhance to their hospital.Similar to EMEA, we expect this pipeline to develop into a cadence of sales in the coming quarters.

While many view us as a robotics company, we aspire to provide a greater level of value to surgeons, hospitals and patients through the development of a platform to deliver digital laparoscopy. We view digital laparoscopy as more than just robotics. It is a broad surgical solution, one that helps address many of the issues currently faced by surgeons and hospitals. These issues include OR inefficiency, surgical variability and workforce challenges. We recently introduced this concept to the public, but digitizing the interface between the surgeon and the patient in laparoscopy has long been our vision for what Senhance could be and has guided our internal decision-making process for a number of years now.At TransEnterix, we believe that digital laparoscopy has the potential to increase control and reduce surgical variability in today's value-based health care environment.Our vision for digital laparoscopy is based on the integrative platform that delivers the following key attributes: robotic manipulation, open platform architecture, intelligent scene cognition, augmented intelligence, connectivity, and operating room workflow.While the Senhance has elements that addresses many of these needs, our recently announced acquisition of MST's technology assets and IP, related to surgical image analytics, will provide material enhancements to our platform as we seek to realize the vision of digital laparoscopy.We're particularly excited about the opportunity to be the first player in the market with intelligent scene cognition and augmented intelligence by leveraging software that has demonstrated these capabilities on a device that is already CE Marked and FDA cleared.Taken all together, we've been on a deliberate journey over the past few years to become the transfer made digital laparoscopy company that we are today. We have worked to expand the applicability of Senhance to a greater number of surgeons, hospitals and patients both here in the U.S. as well as throughout EMEA region and into Asia.We continue to focus on expanding that applicability by adding new instruments and entering new geographies around the globe. At the same time, we continue to be laser focused on leveraging our global sales infrastructure to drive the adoption of Senhance.Thank you for giving me the opportunity to provide an overview of how we have built TransEnterix over the past few years, our unique position in the surgical robotics industry and our strategy for driving adoption of Senhance going forward.Now shifting gears to our quarterly business update. The company had a solid third quarter, generating $5.4 million in revenue, as the continued development of our global pipeline drove four system sales, one in the U.S. and three in the EMEA region, all of which have been

previously announced.This brings the cumulative number of commercial systems we have sold worldwide, from the time we began commercialization of the system in 2016 through the end of the third quarter, to 15. Additionally, to date, in the fourth quarter, we already have orders for two systems, and we will provide further guidance for the quarter following our financial update.Now I'd like to provide an update on the progress we made toward our key goals for 2018. As a reminder, those goals are: maximizing the effectiveness of our global commercial sales infrastructure; expanding the portfolio of instruments available for use with Senhance; expanding Senhance's indication for use; and continuing to obtain regulatory clearances in key geographies.In September, we announced that Eric Smith has been named Chief Commercial Officer, effective August 31, 2018. This is a newly created role, whose responsibility is to lead the company's global commercialization efforts, with a focus on both strategic and tactical execution efforts in sales, upstream and downstream marketing, field clinical support and training, with a focus on adoption and clinical excellence. It's been great to have Eric on the team and he certainly hit the ground running.Starting in the U.S., in the third quarter, we sold a Senhance to UPMC in Pittsburgh. UPMC is one of the largest health care providers in the country and is focused on the development and implementation of new models of accountable, cost-effective, patient-centered care.The system was installed in UPMC Magee-Womens’ Hospital, which is one of the most respected women's focused hospitals in the country. The training process has begun, and we're excited to work alongside their surgical team to begin growing their Senhance utilization.I spoke earlier of the key learnings from our European business, and we can leverage for the U.S. commercialization. And one such lesson was the need for customers to see live surgery and interact with surgeons who have become proficient with the Senhance.With our U.S. pipeline progressing nicely and many of these targets requesting case observations, we decided to invest and partner with two hospitals to launch time bound programs with specific performance objectives. This resulted in the installation of two systems, one in New York and one in Florida, and both are actively performing surgery.We've also invested in additional resources to drive mobile events and labs to increase surgeon and administrator access to Senhance while in the evaluation process. Mobile systems are now being utilized at various locations across the United States for training or surgeon evaluation. Seven specific hospital mobile programs have been executed in the U.S. since July 1, with over 30 surgeons participating.Moving to EMEA. During the third quarter, we sold three systems in the region, one of these systems was a direct sale to Máxima Medical Center, located in Veldhoven, Netherlands.

Máxima is a member of the cooperative association of the 20 largest Dutch teaching hospitals, who together work to guarantee the best level of health care for their patients.Máxima intends to develop a clinical program for Senhance, with a focus in general surgery, gynecology and urology, with first surgery scheduled to be performed next week.The other two systems were sold to a distributor. One of the systems was then sold to an end-user hospital in Europe, it has already begun performing surgery, and the other was retained by the distributor to be used as a demonstration system to support territory marketing and regulatory initiatives. The sale of the demo unit is a strong signal of the very high demand we have generated in EMEA.In the Asia-Pacific region, we continue to make progress in line with our expectations. In Taiwan, we continue to expect to receive Taiwanese FDA approval for Senhance instruments by the end of the year. Once we have the instruments approved, we can begin our commercialization efforts in earnest. We're currently planning on beginning surgeon training in early 2019, with our first cases expected shortly thereafter.And in Japan, where the regulatory process is extensive and can take up to three years, we continue to make good progress in our regulatory preparations. To help drive this process, as well as early development of a commercial infrastructure, we established a Japanese subsidiary earlier this year. As mentioned on our last call, the first cases were completed at Saitama Medical University during the third quarter, and we look forward to developing Saitama as a reference site to help establish Senhance in Japan.And now shifting gears to our instrument portfolio expansion initiatives.During the third quarter, we made significant strides toward the achievement of these important targets. As a reminder, these programs are: obtaining FDA clearance and launching 3-millimeter instruments in the U.S.; launching the ultrasonic energy device; and launching 5-millimeter articulating instruments.During the quarter, we filed an application for FDA 510(k) clearance for our ultrasonic energy device ahead of expectations. We continue to expect to achieve an FDA 510(k) clearance in the first quarter of 2019. Also in the third quarter, we received the CE Mark for our ultrasonic energy device. It has recently been launched this product in EMEA, with the first case just scheduled for later this month.Subsequent to the end of the third quarter, and ahead of expectations, we received the FDA clearance for our 3-millimeter instruments. We believe that the ability to perform surgery using 3-millimeter instruments represents a shift in the world of robotic surgery, one that, when combined with our digital interface, positions Senhance with digital laparoscopy to become the preferred option to treat a broader number of patients and procedures. We look forward to showcasing these 3-millimeter instruments, together with the Senhance, at the American Association of Gynecologic Laparoscopists next week in Las Vegas.

With our articulating instruments, we continue to progress in line with our previously-stated expectations. We intend to submit our 510(k) clearance for 5-millimeter articulating instruments by the end of 2018, and we expect to obtain CE Mark by the end of 2018 for these instruments.I'm also pleased to report that we closed the MST acquisition last week following the announcement of the transaction just six weeks earlier. Our Israel-based R&D team is on board, and we are in the process of harmonizing development initiatives for our global R&D team.Our initial application of the technology acquired will enable three new and unique features for the Senhance. The first prevents instruments from leaving the field of view, which is a fundamental element of laparoscopic best practice. The second permits the camera to follow instruments autonomously, which improves workflow and allows the surgeon to focus on the task at hand. And the third is a suture assist feature that recognizes when the surgeon is suturing to permit automatic zooming in and out to ensure accurate placement of sutures and simplify workflow.We expect these first three applications of the acquired technology to be available commercially in the next 4 to 5 quarters, and we have been encouraged by the broad level of excitement we have seen from surgeons' interactions with them since announcing this acquisition.Taken all together, we believe that these innovations will help accelerate the adoption of Senhance and the development of our sales pipeline.Now I'd like to turn the call over to Joe to provide a financial update. Joe?

Joseph P. Slattery - *TransEnterix, Inc. - Executive VP & CFO*

Thank you, Todd. For the three months ended September 30, 2018, we reported revenue of $5.4 million, comprised of $4.3 million in systems revenue from the sale of four systems, one of which was a demonstration system purchased by a distributor, $867,000 in instruments and accessories, and $237,000 in services.Gross margin for the third quarter was 22%. Relative to the second quarter gross margin of 42%, the decline was related to the sale of the demonstration system near our cost, as well as changes in territory mix, negatively-impacting global average selling system prices.R&D expenses in the quarter decreased slightly to approximately $4.8 million, as compared to the prior year period of $4.9 million. Sales and marketing expenses in the quarter increased to $5.8 million from $4.5 million in the prior year period, as we continue to expand our investment in our commercial infrastructure with a focus in the U.S.General and administrative expenses in the quarter increased to approximately $3.7 million from approximately $2.9 million in the prior year period, primarily due to increased headcount and consulting services to support our overall growth and geographic expansion.GAAP net loss for the quarter was $20.2 million, or $0.10 per share, compared to a GAAP net

loss of $38.5 million, or $0.26 per share, in the prior year period. Adjusted net loss for the quarter was $13.1 million, or $0.06 a share, compared to an adjusted net loss of $13 million, or $0.09 per share, in the prior year period.The primary adjustment from GAAP net loss relates to accounting for the change in the fair value of warrant liabilities, which is primarily driven by changes in our stock price. Cash and short-term investments as of September 30 was $81.4 million.Subsequent to the quarter end, we received the $10 million second tranche of nondilutive financing related to the debt agreement with Hercules Capital, bringing the total debt under this agreement to $30 million. We continue to anticipate that the third tranche of $10 million will be funded in 2019 and continue to believe that our existing cash will support the business through 2020.As Todd discussed, we also closed the MST transaction subsequent to the quarter end. This transaction was funded with $5.8 million in upfront cash, 3.15 million shares of common stock and a deferred payment of $6.6 million in either cash or stock at our election.Applying the stock price as of the closing results in a total deal value of approximately $22 million for accounting purposes.Turning to our guidance for the fourth quarter of 2018, we expect to sell between four and five Senhance systems, with total worldwide revenue in the range of $6.4 million to $7.7 million. This implies full year revenues of between $23 million and $24.4 million, representing growth of over 200% versus the prior year.Todd?

Todd M. Pope

Thank you, Joe. We're incredibly excited about the future here at TransEnterix. We accomplished a significant number of key milestones during the third quarter and subsequently.During the quarter, we sold four systems between the U.S. and the EMEA region, we acquired the technology assets and IP of MST, which significantly advances the capabilities of Senhance to deliver on our vision of digital laparoscopy. We received the CE Mark for our ultrasonic energy device and filed for a 510(k) here in the U.S.We believe the addition of ultrasonic energy to our product offering will open the doors to a greater number of surgeons and procedures globally.Lastly, subsequent into the quarter, we became the first company to receive a 510(k) approval for a robotically enabled 3-millimeter instrument. We have put ourselves in a great position to continue to drive the adoption of Senhance during the remainder of 2018 and into the future.And with that, I'd like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Rick Wise with Stifel. Your line is now open.

Andrew Christopher Ranieri - *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Hi Todd and Joe, it's Drew Ranieri on for Rick tonight, thanks for taking my question. But first, let me just start on the U.S. Senhance commercialization, with Senhance being FDA cleared for about a year now, you're getting to that 4 to 6 quarter sweet spot for capital sales. Can you just touch on that a little bit more? I know that you said you had a couple of orders in hand already. Were they U.S. or o-U.S.? And how should we be thinking about 2019? What do you need to do to accelerate U.S. growth?

Todd M. Pope

Drew, thanks for the question. Yes, we feel great about the pipeline. As you said, we've talked a lot about the pipeline really getting going after 4 to 6 quarters. We're coming into that, and we feel like we're right on track. Yes, there's not any one specific catalyst for a pipeline. I think when you're selling capital, there's a lot of blocking and tackling. As we look at our pipeline in the U.S., we have a lot of activity that's getting closer working its way through admin, the administration side of the hospital, after a lot of the clinical advocacy has been validated, which is very helpful for us. It means that's getting a little bit toward the back end of the pipeline. And I think when you're talking about conversations with the hospitals, any time you're able to add instruments and talk about where we're going with new technology, it always helps the clinical interest and the clinical conviction. 3-millimeter helps—we just got that approved about a month ago and are starting to roll that out clinically later this month. We're excited about ultrasonic. As we talked about, we got that approval in Europe and are beginning those cases now. And the U.S. is excited about getting that. We think that's going to be continuing to be enabling. And even though we don't like talking too much about futures, the MST technology, I think, our pipeline is really excited to see a company, even though we're a merging revenue company, making acquisitions in the space that really solidifies our future product pipeline. So, I would say, the last thing I would say is, we found that when people are going to buy piece of capital, like the Senhance, with that type of commitment, they sometimes, toward the latter part of the pipeline discussions, they want to go and watch surgery being done. And up to this point, we've been taking our U.S. pipeline over to Europe, because that's where we've had the majority of our placements and the majority of our surgeries. And that's not really scalable for the long-term. So now that we have multiple systems up and running in the U.S., and we'll continue to add to those, we think that will be another catalyst to get the sales pipeline going in 2019. So all those things cumulatively add up to putting us in a really good position. We're not going to really talk about mix for 2019, because we've not done that in the past as far as geography. But suffice to

say, we've got a lot of activity in all the areas that we're working in, U.S., EMEA and Asia-Pacific. So I appreciate the question, Drew.

Andrew Christopher Ranieri

And just one more, if I may, and I'll hop back in queue. But you touched on MST and some of the applications that are coming over the next 4 to 6 quarters. But, I know it's early, but can you just kind of give us a sense of maybe how Senhance could evolve over time with incorporating MST technology beyond these initial applications? Thank you.

Todd M. Pope

Certainly. I mean, a few of the things that we've talked about publicly in addition to what we talked about on the call here that we just highlighted—these are things that we've heard consistently from surgeons that feels like they are not as capable as they want to be in laparoscopic surgery or they could be much more efficient. One thing we have approval for, inguinal hernia, and when surgeons go in to repair hernia, they often put mesh in. They need to understand the size of the defect. And either they eyeball it from experience or they'll drop a flexible tape measure into the abdomen and they'll try to stretch it out and measure, and then they'll try to replicate those measurements and cut their mesh to the appropriate size.We can - with this technology in the future, we're going to be able to drop icons in and digitally visually measure right on the spot. This is something that the technology exists outside the operating room. Certainly, we see that on our smartphones and some of the navigation in vehicles. We want to bring that to the OR. This MST technology will enable that. And that's one of those real-world examples that when people need precise measurements quickly inter-operatively, you don't have a good way to do that now, and that's just an example, to specifically answer your question, of a few things even beyond what we talked about in the call. So we're excited about it. But most importantly, the surgeons that were previewing this are very excited about it. So they like the near-term additions we're making to the portfolio, but they really like to see that we're being active in the M&A space. But I'd also say that they've commented, that they think it's fairly impressive that we announced getting going with this deal into Q3 and have already closed it in the Q3. Sometimes hospitals or surgeons worry that companies talk about doing deals but don't actually get them executed, and I think we're showing a pretty good core competence with our Sofar acquisition of Senhance, with MST, that we're very open to look at M&A, if it makes sense, and we're going to get it acquired. So thanks for the question, Drew.

Andrew Christopher Ranieri

Thanks, Todd.

Operator

Thank you. Our next question comes from the line of Jeffrey Cohen with Ladenburg Thalmann. Your line is now open.

Jeffrey Scott Cohen – *Ladenburg Thalmann & Co. Inc., Research Division - MD of Equity Research*

Hi Joe and Todd, how are you? Just a few issues I wanted to touch upon. So, you had mentioned earlier in your prepared remarks about 15-person sales force on the eastern half of the country. Could you talk now about what the U.S. commercial organization looks like, as far as capital, clinical, et. Cetera?

Todd M. Pope

Yes. The 15-person sales force that we mentioned our folks out there driving capital sales. We have ancillary forces out there on the clinical side that are driving clinical cases and being in the cases after a system is installed. And we're really focusing on the eastern half because our pipeline, as we've talked about, has generated a lot of interest. But that pipeline eventually needs to work through sites that are doing surgery day in and day out. And until we were able to get a few more systems up and going, really weren't able to handle some of the interest in the pipeline. So we've kept a relatively small, focused sales force. And I think you'll see us continue to expand and lockstep with the sales and installations that we make throughout the U.S. That's what will drive in 2019 and beyond additional headcount on capital. And when we add that capital headcount, we continue to sell, we'll follow that up with clinical sales folks in those geographies.

Jeffrey Scott Cohen

Okay, got it. And could you give us a little further color on the types of institutions or the types of interest that you're seeing amongst the U.S. facilities? And a little color there on the facilities as well as the types of potential users in as far as disciplines.

Todd M. Pope

Sure. When you talk about the different type of hospitals, there's multiple ways that you can categorize those—private, public, teaching or not, but I would say we have in our pipeline the full spectrum of interest. We have the large teaching hospitals that have a lot of interest, because Senhance is the first entered into the market, and almost 19 years in the surgical robotics for the abdominal space, so a lot of teaching institutions feel like they want to be able to be able to offer that to the people coming through their institutions. Have a lot of private institutions that are really focused on patient acquisition, and they want to be looked at on the cutting edge of technology. They're excited about a new system being out there, and that's certainly driving a lot of interest. And then, as far as the types of specialties to the latter part of your question, we're certainly seeing a lot in general surgery, GYN, colorectal and those specialties operate in a lot of different realms, obviously. So a wide variety of interest certainly in types of institutions and certainly specialties. And we saw that just coming back from Boston two weeks ago at the American College of Surgery, it was great to interact with the wide spectrum of surgeons there.

Jeffrey Scott Cohen

Perfect. Okay, and then lastly, could you give us a little more color on timeline for the articulation of some of the instruments and which of the actual instruments will be commercial in articulated format? And when those timelines may hit as far as getting them out there into the public's use?

Todd M. Pope

Well, what we've talked about is we want to submit our 510(k) for 5-millimeter articulating instruments by the end of this year, 2018. And in CE Mark countries, we're looking to obtain that CE Mark by the end of this year, in 2018. So, those are relatively near-term milestones that we continue to feel good about.

Joseph P. Slattery

As far as the instruments –typical instruments for surgery, the needle driver, grasper, those kind of things.

Jeffrey Scott Cohen

Okay. And you'll have cases later this year in Europe expected after the CE mark?

Joseph P. Slattery

We can't really schedule them until we get the CE Mark. So it's not something that we can say for sure is going to happen this year or not.

Todd M. Pope

But in the past, every time we've had approvals in a reasonable timeframe, after that, we get the orders in, we get the orders out and delivered. We get people trained up and cases followed shortly thereafter.

Jeffrey Scott Cohen

Okay, perfect. That does it for me. Thanks, guys.

Todd M. Pope

Thanks, Jeff.

Operator

Thank you. We do have a follow-up question from the line of Rick Wise with Stifel. Your line is now open.

Andrew Christopher Ranieri

Hi, Todd and Joe, back again. Just a quick question for you on guidance for the fourth quarter. I think this is the first time that you actually really gave like a revenue range for guidance. But I was just hoping to get a better sense of your insights on the Senhance ASP that's embedded in your guidance range. How should we think about the price between U.S. and the rest of world? And maybe the system breakdown as well.

Joseph P. Slattery

Sure. You can see from the range that 4 to 5, the gap between the two numbers we gave is $1.3 million. And that's—I think that's a good number to think about, what is the incremental revenue that's derived in a quarter from an additional sale. It's going to vary between one market to the next, whether it's system configuration, local pricing, whether the sale had a vision system or, say, depending on instrument selection and how many trays they acquire on their initial sale. But we feel like $1.3 million per incremental system is a moderately conservative way to look at our revenue model.As it relates to our Q3 results and our Q4 guidance, the orders have been—the orders that we've gotten in have been a little bit more than that, about $1.4. But depending on territory mix and what the configuration is, we just think it's an appropriately conservative number to focus on $1.3 million.

Andrew Christopher Ranieri

Thanks, Joe, I appreciate it.

Operator

Thank you. That concludes our question-and-answer session for today. I would now like to turn the call back to Todd Pope for closing remarks.

Todd M. Pope

Well, thanks all of you for joining us on today's call. We look forward to updating you on our progress in the next quarter. Thank you.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program. You may all disconnect. Everyone, have a great day.