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

February 26, 2019
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 February 26, 2019, 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, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on February 26, 2019, 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 fourth quarter and full year ended December 31, 2018. The Company had issued a press release on February 12, 2019 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 February 26, 2019

99.2 February 26, 2019 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: February 27, 2019

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

Exhibit 99.1

TransEnterix, Inc. Reports Operating and Financial Results for the Fourth Quarter and Full Year 2018

February 26, 2019 at 6:55 AM EDT

RESEARCH TRIANGLE PARK, N.C.—(BUSINESS WIRE)--Feb 26, 2019— 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 fourth quarter and full year 2018.

Recent Highlights

- Sold five Senhance Systems globally in the fourth quarter in 2018
- Total revenue of $7.5 million in the fourth quarter of 2018
- Received U.S. FDA clearance for Senhance Ultrasonic System subsequent to the end of the 2018 fourth quarter
- Received U.S. FDA clearance for 3mm diameter instruments
- Received CE Mark for articulating instruments and submitted its application for U.S. FDA 510(k) clearance during the fourth quarter
- Received Taiwanese FDA approval for the Senhance System instruments in the fourth quarter of 2018
- Closed acquisition of substantially all of the assets of MST Medical Surgery Technologies Ltd., an Israel-based medical technology company

“2018 was a transformative year for TransEnterix, as we continued to drive the global commercial adoption of the Senhance System – both in terms of expanding our installed base as well as expanding the applicability of the Senhance System by increasing its indications for use, expanding the variety of instruments available with the Senhance System, and expanding into new geographies by receiving additional regulatory clearances,” said Todd M. Pope, President and CEO of TransEnterix. “In 2019, we see a significant opportunity to leverage all of the progress we made in 2018 to continue to grow the adoption of the Senhance System globally.”

Commercial and Clinical Update

In the quarter ended December 31, 2018, the Company sold five Senhance Systems, with three sold in EMEA (Europe, Middle East, and Africa), one in the U.S., and one in Asia.

Instrument Portfolio Expansion

Ultrasonic Instrument System

On October 1, 2018, the Company announced that it had received a CE Mark for its Senhance Ultrasonic Instrument System, and during the fourth quarter this system was commercially launched in CE Mark countries. Advanced energy devices, including ultrasonic devices, represent some of the most versatile and critical tools for surgeons in minimally invasive surgery. These instruments deliver controlled energy to effectively ligate and divide tissue, and minimize thermal injury to surrounding structures.

On January 15, 2019, the Company announced it had received FDA 510(k) clearance for its Senhance Ultrasonic System.

3mm Diameter Instrument Set

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.

Articulating Instruments

The Company received CE Mark for its 5mm diameter articulating instruments during the fourth quarter of 2018.

The Company submitted its application for FDA 510(k) clearance for its 5mm diameter articulating instruments during the fourth quarter of 2018.

Expansion of Geographic Regulatory Approvals

The Company received Taiwanese FDA approval for the Senhance System instruments during the fourth quarter. This follows the approval of the Senhance System in the second quarter of 2018.

Acquisition Agreement with MST

On October 31, 2018, the Company announced the closing of the acquisition of 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 System to deliver digital laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability. The acquisition also provides immediate access to an established R&D center in Israel with a core team of experienced engineers.

Fourth Quarter Financial Highlights

For the three months ended December 31, 2018, the Company reported revenue of $7.5 million as compared to revenue of $3.4 million in the three months ended December 31, 2017. Revenue in the fourth quarter of 2018 included $6.3 million in system sales, $820 thousand in instruments and accessories, and $383 thousand in services.

For the three months ended December 31, 2018, total net operating expenses were $20.1 million, as compared to $17.8 million in the three months ended December 31, 2017.

For the three months ended December 31, 2018, net loss was $6.4 million, or $0.03 per share, as compared to a net loss of $76.2 million, or $0.40 per share, in the three months ended December 31, 2017.

For the three months ended December 31, 2018, adjusted net loss was $14.7 million, or $0.07 per share, as compared to an adjusted net loss of $14.1 million, or $0.07 per share in the three months ended December 31, 2017, after adjusting for the following charges: change in fair value of warrant liabilities, amortization of intangible assets, change in fair value of contingent consideration, acquisition-related costs and SurgiBot sale gain/loss. Adjusted net loss is a non-GAAP measure. See the reconciliation from GAAP to Non-GAAP Measures below.

The Company had cash and cash equivalents and short term investments of approximately $72.9 million as of December 31, 2018. On October 23, 2018, Hercules Capital, Inc. funded the second tranche of $10.0 million under the Hercules loan agreement. The Company believes that it has sufficient cash and additional debt proceeds under the current agreement to fund the business into late 2020.

Conference Call

TransEnterix, Inc. will host a conference call on Tuesday, February 26, 2019 at 8:00 AM ET to discuss its fourth quarter and fiscal year 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 6086178 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 current regulatory and commercialization plans for the Senhance Surgical System, as well as 2018 fourth quarter and full year results and plans for 2019 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 will be able to leverage all of the progress we made in 2018 to grow the adoption and purchase of the Senhance System globally; whether the clearance of the 3 millimeter diameter instruments will allow the Senhance System to be used for microlaparoscopic surgeries; whether the addition of MST's technology, IP portfolio and R&D team will support and accelerate TransEnterix's vision to leverage its Senhance System to deliver laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability; and whether TransEnterix has sufficient cash and additional debt proceeds under the current agreement to fund the business into late 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, including the Form 10-K for the year ended December 31, 2018 expected to be filed prior to its filing deadline. 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenue	$ 7,524	$ 3,398	$ 24,102	$ 7,111
Cost of revenue	5,635	3,500	16,171	6,727
Gross profit (loss)	1,889	(102)	7,931	384
Operating Expenses (Income)				
Research and development	6,439	5,175	21,823	21,989
Sales and marketing	7,901	5,536	25,736	17,536
General and administrative	3,865	3,587	13,854	12,275
Amortization of intangible assets	2,624	2,714	10,868	7,858
Change in fair value of contingent consideration	(1,092)	800	(1,011)	2,026
Issuance costs for warrants	—	—	—	627
Acquisition related costs	302	—	647	—
Gain from sale of SurgiBot assets, net	75	—	(11,840)	—
Reversal of transfer fee accrual	—	—	(2,994)	—
Total Operating Expenses (Income)	20,114	17,812	57,083	62,311
Operating Loss	(18,225)	(17,914)	(49,152)	(61,927)
Other Income (Expense)				
Change in fair value of warrant liabilities	10,118	(58,521)	(14,320)	(83,734)
Interest income	418	184	1,400	308
Interest expense	(810)	(862)	(4,208)	(2,443)
Other income (expense)	1,235	(6)	1,126	(300)
Total Other Income (Expense), net	10,961	(59,205)	(16,002)	(86,169)
Loss before income taxes	$ (7,264)	$ (77,119)	$ (65,154)	$(148,096)
Income tax benefit	823	963	3,377	3,300
Net loss	$ (6,441)	$ (76,156)	$ (61,777)	$(144,796)
Other comprehensive loss				
Foreign currency translation (loss) gain	(1,039)	1,282	(3,690)	10,797
Comprehensive loss	$ (7,480)	$ (74,874)	$ (65,467)	$(133,999)
Net loss per share – basic and diluted	$ (0.03)	$ (0.40)	$ (0.30)	$ (0.97)
Weighted average common shares outstanding – basic and diluted	215,144	190,648	207,199	148,744

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

	December 31, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 21,061	$ 91,217
Short-term investments	51,790	—
Accounts receivable, net	8,560	1,536
Inventories	10,941	10,817
Interest receivable	26	80
Other current assets	9,205	9,344
Total Current Assets	101,583	112,994
Restricted cash	590	6,389
Property and equipment, net	6,337	6,670
Intellectual property, net	39,716	52,638
In-process research and development	10,747	—
Goodwill	80,131	71,368
Other long term assets	203	192
Total Assets	$ 239,307	$ 250,251
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 4,433	$ 3,771
Accrued expenses	9,619	10,974
Deferred revenue – current portion	1,733	1,088
Deferred gain from sale of SurgiBot assets	—	7,500
Contingent consideration – current portion	72	719
Deferred consideration – MST Acquisition	5,962	—
Notes payable – current portion, net of debt discount	—	4,788
Total Current Liabilities	21,819	28,840
Long Term Liabilities		
Deferred revenue – less current portion	109	—
Contingent consideration – less current portion	10,565	11,699
Notes payable – less current portion, net of debt discount	28,937	8,385
Warrant liabilities	4,636	14,090
Net deferred tax liabilities	4,720	8,389
Total Liabilities	70,786	71,403
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at December 31, 2018 and December 31, 2017; 216,345,984 and 199,282,003 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	216	199
Additional paid-in capital	676,373	621,261
Accumulated deficit	(509,406)	(447,640)
Accumulated other comprehensive income	1,338	5,028
Total Stockholders' Equity	168,521	178,848
Total Liabilities and Stockholders' Equity	$ 239,307	$ 250,251

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

	Twelve Months Ended December 31,	
	2018	**2017**
Operating Activities		
Net loss	$ (61,777)	$ (144,796)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Gain from sale of SurgiBot assets, net	(11,840)	—
Depreciation	2,420	2,486
Amortization of intangible assets	10,868	7,858
Amortization of debt discount and debt issuance costs	725	510
Amortization of short-term investment discount	(351)	—
Stock-based compensation	9,039	7,078
Non-employee warrant awards	—	838
Deferred tax benefit	(3,377)	(3,300)
Loss on extinguishment of debt	1,400	308
Change in fair value of warrant liabilities	14,320	83,734
Change in fair value of contingent consideration	(1,011)	2,026
Reversal of transfer fee accrual	(2,994)	—
Changes in operating assets and liabilities (net of effect of acquisition):		
Accounts receivable	(7,225)	(381)
Interest receivable	54	23
Inventories	(2,145)	(2,981)
Other current and long term assets	(325)	(3,348)
Accounts payable	767	(531)
Accrued expenses	2,134	2,093
Deferred revenue	825	1,088
Net cash and cash equivalents used in operating activities	(48,493)	(47,295)
Investing Activities		
Purchase of short-term investments	(55,439)	—
Proceeds from maturities of short-term investments	4,000	—
Payment for acquisition of a business	(5,800)	—
Proceeds related to sale of SurgiBot assets, net	4,496	7,500
Purchase of property and equipment	(770)	(1,566)
Purchase of intellectual property	—	(425)
Proceeds from sale of property and equipment	32	—
Net cash and cash equivalents (used in) provided by investing activities	(53,481)	5,509
Financing Activities		
Payment of notes payable	(15,305)	(13,343)
Proceeds from issuance of debt and warrants, net of issuance costs	28,507	13,005
Payment of contingent consideration	(770)	(7,181)
Proceeds from issuance of common stock and warrants, net of issuance costs	279	77,579
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	12,403	34,479
Net cash and cash equivalents provided by financing activities	26,452	104,371
Effect of exchange rate changes on cash and cash equivalents	(433)	431
Net (decrease) increase in cash, cash equivalents and restricted cash	(75,955)	63,016
Cash, cash equivalents and restricted cash, beginning of period	97,606	34,590
Cash, cash equivalents and restricted cash, end of period	$ 21,651	$ 97,606
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 1,730	$ 899
Supplemental Schedule of Noncash Investing and Financing Activities		
Transfer of inventories to property and equipment	$ 2,160	$ 1,258
Transfer of property and equipment to inventories	$ 637	$ —
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	$ 23,774	$ 78,359
Transfer of in-process research and development to intellectual property	$ —	$ 17,913
Cashless exercise of warrants	$ 4,272	$ 149
Issuance of common stock related to acquisition	$ 8,300	$ —
Deferred consideration – MST acquisition	$ 5,962	$ —

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 December 31, 2018	Three Months Ended December 31, 2017	Twelve Months Ended December 31, 2018	Twelve Months Ended December 31, 2017
Net loss (GAAP Measure)	$ (6,441)	$(76,156)	$(61,777)	$(144,796)
Adjustments				
Gain from sale of SurgiBot assets, net	75	—	(11,840)	—
Amortization of intangible assets	2,624	2,714	10,868	7,858
Change in fair value of contingent consideration	(1,092)	800	(1,011)	2,026
Acquisition related costs	302	—	647	—
Reversal of transfer fee accrual	—	—	(2,994)	—
Change in fair value of warrant liabilities	(10,118)	58,521	14,320	83,734
Loss on extinguishment of debt	—	—	1,400	308
Adjusted net loss (Non-GAAP Measure)	$(14,650)	$(14,121)	$(50,387)	$ (50,870)

(Unaudited, per diluted share)	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Twelve Months Ended December 31, 2018	Twelve Months Ended December 31, 2017
Net loss per share (GAAP Measure)	$ (0.03)	$ (0.40)	$ (0.30)	$ (0.97)
Adjustments				
Gain from sale of SurgiBot assets	0.00	—	(0.06)	—
Amortization of intangible assets	0.01	0.01	0.05	0.05
Change in fair value of contingent consideration	(0.01)	0.00	0.00	0.01
Acquisition related costs	0.00	—	0.00	—
Reversal of transfer fee accrual	—	—	(0.01)	—
Change in fair value of warrant liabilities	(0.04)	0.32	0.07	0.57
Loss on extinguishment of debt	—	—	0.01	0.00
Adjusted net loss per share (non-GAAP Measure)	$ (0.07)	$ (0.07)	$ (0.24)	$ (0.34)

The non-GAAP financial measures for the three and twelve months ended December 31, 2018 and 2017 provide management with additional insight into the Company's results of operations from period to period without non-recurring and non-cash charges, 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 or upon exercise 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 statement of operations and comprehensive loss for the twelve months ended December 31, 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 statement of operations and comprehensive loss for the twelve months ended December 31, 2017.

Source: TransEnterix, Inc.

For TransEnterix, Inc.

Investors:

Mark Klausner, +1-443-213-0501

invest@transenterix.com

or

Media:

Joanna Rice, + 1-951-751-1858

joanna@greymattermarketing.com

Exhibit 99.2

Company: TRANSENTERIX, INC.
Moderator: Mark Klausner
Date: February 26, 2019

PRESENTATION

Operator

Good afternoon, ladies and gentlemen. Welcome to the TransEnterix Fourth Quarter and Full Year 2018 Financial and Operating Results Conference Call. As a reminder, this conference call is webcast live and recorded. It is now pleasure to introduce your host Mr. Mark Klausner of Westwicke Partners. Please go ahead, sir.

Mark Klausner - *Westwicke Partners, LLC – Managing Partner*

Good afternoon, and thank you for joining us for the TransEnterix fourth quarter conference call. Joining us on today's call are 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 including guidance related to the number of Senhance Systems expected to be sold in the first quarter of 2019, 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, 2018, to be filed this week.

During this call, we will also present certain non-GAAP 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 non-cash and other expenses that are not indicative of the company's core results.

Management uses non-GAAP measures to compare our performance relative to forecast and strategic plans to benchmark our performance externally against competitors and for certain compensation decisions.

Reconciliations from U.S. GAAP to 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 fourth quarter 2018 conference call. We will begin today's call by providing a high level overview of our fourth quarter performance followed by a review of the progress we made during 2018. I will then turn the call over to Joe to provide a financial overview, after which I will discuss our priorities for 2019.

Starting with our fourth quarter performance. In the fourth quarter we sold five systems – three in the EMEA region, one in the U.S. and one in Asia. We were very pleased with our results during the quarter.

Notably, this was the first quarter in which we sold at least one system in each of the three geographic regions. Starting in EMEA region, we sold three systems. One was a direct sale to an end user hospital in Switzerland and the other two were sales to end user hospitals by distributors.

The direct sale in Switzerland was our first sale in Switzerland to Moncucco Clinic Lugano, which is the largest hospital in the Ticino Canton. And they have already begun performing procedures in general surgery, with plans to expand the use to multiple specialties.

Turning to the U.S., we sold a Senhance to Hackensack Meridian Health at Pascack Valley, which is part of a large hospital system including thirteen hospitals in New Jersey. This represents an important expansion into a key geography with a major health care system.

We're pleased to be partnering with leading surgeons within this hospital to offer patients access to advanced minimally invasive surgery in general surgery and gynecology. Now that training is complete, we anticipate these surgeons to perform their first cases in the coming weeks.

We also had one sale in Asia to Fu Jen Catholic University Hospital in Taiwan. This sale comes on the heels of our fourth quarter Taiwanese FDA approval, and is our second sale in Taiwan.

These initial systems can serve as locations for surgical observations and training to support growth in Asia.

Shifting gears to our strategic priorities. At this time last year, we discussed the following strategic priorities for 2018 to continue to drive the adoption of Senhance.

Maximize the effectiveness of our commercial sales infrastructure, expand the portfolio of instruments available for use with Senhance, broaden the indications for use with Senhance and continue to achieve regulatory clearances in key geographies. We made tremendous progress in each of these strategic priorities, taking each one in order:

First, maximize the effectiveness of our commercial sales infrastructure. 2018 represented a major shift in our commercial efforts, as it was the first full year where we had Senhance approvals both in U.S. and Europe, and late in the year we achieved Taiwanese FDA approval as well.

As a result, we focused on managing the effectiveness of our commercial sales infrastructure across the organization, which shifted from operating primarily in Europe to one that is now focused on driving the adoption of Senhance in three major geographic regions and multiple countries.

We took a major step in that direction with the hiring of Eric Smith as Chief Commercial Officer in September. This was 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 both internal and external, with a focus on adoption and clinical excellence.

The addition of this position has had strong positive impact on our global sales and marketing organization, as well as our ability to effectively leverage our global momentum and share best practices across all three geographies.

One of the key accomplishments of 2018 was the establishment of our U.S. based commercial sales team to support the approval of Senhance. We initially launched the sales force with fifteen sales reps.

We felt this was the appropriate sized sales force to handle the challenge of bringing a new product to market with a focus on key high volume laparoscopic surgeons and hospitals. We feel very good about the position we put ourselves in throughout the year to drive long term growth in the U.S.

We are confident in the robustness of our pipeline generated by this team. And as we continue to expand our footprint throughout the U.S., we will evaluate the location and timing of additional hires.

Outside the U.S., our growing installed base of Senhance Systems and the successful clinical uptake is generating a high level of demand. To capitalize on this demand in the EMEA region, we took the opportunity to evaluate an increased use of distributors to optimize our success from the commercial organization.

We continue to see increased effectiveness by utilizing distributors due to their deep understanding of the local landscape when working with complex sales and hospitals in various geographies throughout EMEA.

Our second strategic priority was to expand the portfolio of instruments available for use with Senhance. Our ability to move quickly in adding instruments is one of the benefits of our open architecture strategy for this Senhance platform.

Competing robotic systems are closed or vertically integrated, requiring hospitals to utilize only technology offered by the robotic system manufacturer regardless of the technology preference of the surgeon or the current capital equipment owned by the hospital.

With our open architecture strategy, we can rapidly integrate today's leading technologies for use with our platform which allows hospitals to leverage existing and new investments for use in their robotics program. In 2018, we made great strides to show the potential of this open architecture strategy.

As we continue to strive to make Senhance more broadly applicable to surgeons, we focused on aggressively expanding our instruments offering to allow Senhance to be used in more high volume procedures. This was done while also accommodating the instrument and technology preferences of surgeons and hospitals.

Our portfolio expansion initiatives focused around three groups of instruments: 3-millimeter microlaparoscopy instruments; articulating instruments; and advanced energy instruments. In October, we received FDA 510(k) clearance for 3-millimeter diameter microlaparoscopy instruments.

The clearance of the 3-millimeter instruments represents a first in robotic assisted surgery. There is growing adoption in the 3-millimeter manual laparoscopic instruments. In addition to reduced scarring, smaller incisions, offer the potential for less pain and lower narcotic use after surgery.

The Senhance's digital interface addresses the challenge of manually controlling these small instruments. Our 3-millimeter instruments, coupled with 5-millimeter endoscopes from our vision system partners, each represent a new standard in robotic surgery.

Another portfolio expansion initiative in 2018 was for articulating instruments. During the fourth quarter, in line with expectations, we received CE Mark approval for 5-millimeter articulating instruments and we submitted our application for FDA 510(k) clearance.

Our most important instrument portfolio expansion initiative in 2018 was the Senhance ultrasonic, an advanced energy instrument. Advanced energy devices are some of the most versatile and critical tools for laparoscopic surgeons.

They are used in a high percentage of cases across a wide range of procedures. Because of this, it's often viewed as one of the most important instruments for laparoscopic surgeons.

We believe the addition of the ultrasonic instrument offering is significant and broadens the attractiveness of digital laparoscopy with this Senhance platform for surgeons across the globe.

In October, we received CE Mark approval for our ultrasonic instrument and subsequent to the end of the fourth quarter we received FDA 510 (k) clearance. The majority of our EU and U.S. accounts have received and begun to use ultrasonic with Senhance.

The clinical feedback from this device has been excellent, with many surgeons utilizing the instrument to perform complex dissections in general surgery, colorectal, bariatric, gynecology and urology with speed and safety.

Several additional product enhancements occurred in 2018, including compatibility with two additional vision systems as well as a 4K monitor capability, in addition to the existing 3DHD on the Senhance. We now have compatibility with virtually all of the market leading laparoscopic visualization systems and continue to expand these offerings.

Shifting gears to expanding indications for use. In the fourth quarter of 2017, when we received FDA clearance for Senhance, this system was initially approved for laparoscopic colorectal and gynecologic surgery, which provided immediate access to over 1.5 million surgeries in the U.S.

While this was a tremendous achievement, there still remained important procedures in additional surgical specialties that we believed would be key for the adoption of Senhance in the U.S.

In May of 2018, we received FDA clearance for expanded indications for hernia and gallbladder procedures. This more than doubled our addressable market, bringing the total available procedures to over three million annually.

Our final strategic initiative was to expand regulatory clearances in key geographies. In 2018, this focused primarily around countries in Asia. In the fourth quarter and in line with expectations, we received Taiwanese FDA approval for Senhance instruments.

This was the second of two TFDA approvals required to receive a full clearance, the first of which was for the Senhance Surgical System, which was received in the second quarter of 2018.

Our other focus area was building a foundation in Japan. As we have discussed in the past, Japan is the world's second largest robotics market by country, only behind the U.S.

In 2018, we established a Japanese subsidiary to focus on the regulatory process and eventual commercial needs in this market. Outside of these key initiatives, we also wanted to continue to advance the capabilities of Senhance.

In September, we announced the acquisition of the assets of Medical Surgery Technologies or MST, an Israel-based medtech company, focused on surgical image analytics whose technology, we believe, will meaningfully advance the benefits of digital laparoscopy to patients, surgeons in operating rooms globally.

Specifically, the key underlying technologies are, software-based image analytics powered by advanced visualization, scene cognition, artificial intelligence, machine learning and data analytics.

As I just reviewed, we made significant progress throughout the year. At the beginning of 2018, we looked quite different than we do now.

In the U.S., we had just received the FDA clearance for Senhance and we're in the very early stages of launching our commercial sales efforts. We had a limited instrument set available and indications for use within two surgical specialties.

With only one U.S. sale in 2017, we had very limited number of available reference sites in the U.S. for surgeons to observe surgery and interact with the system. Today, our total addressable market in the U.S. is double its initial size, as we have expanded our indications for use in the high volume surgical specialties.

We added two significant instrument expansions, 3-millimeter instruments and ultrasonic, and expanded our U.S. installed base from one system in Florida to six systems. We have a large addressable market opportunity.

We have added key surgeon preference instruments and made it significantly easier for surgeons in our pipeline to access Senhance in the U.S. In our international markets, we had similar transformations, both in terms of the expansion of our key instruments and the expansion into new geographies.

This dynamic shift in our product offering and geographic footprint was a key driver in our significant growth in 2018 as we expanded the applicability of Senhance to more surgeons, hospitals and patients on a global scale.

Looking at our performance for the full year, we saw significant improvement in both systems sales and revenue growth. In 2017, we sold five systems and recognized $7.1 million in revenue.

And in 2018, we sold fifteen systems and recognized $24.1 million in revenue, nearly a 240% growth. We're all very proud of what we've been able to accomplish in 2018 and the foundation we have established as we go into 2019. I'd like to now turn the call over to Joe to provide a financial review.

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

Thanks Todd. For the three months ended December 31, 2018, we reported revenue of $7.5 million dollars, comprised of $6.3 million in systems revenue from the sale of five systems, $820,000 in instruments and accessories and $383,000 in services.

Of the $7.5 million, approximately $7 million was from new installations during the quarter, reflecting average revenue per new placement of approximately $1.4 million and $500,000 in revenue from customers that purchased systems prior to the fourth quarter.

Gross margin for the fourth quarter was 25%. R&D expenses in the quarter increased to approximately $6.4 million as compared to the prior year period at $5.2 million, due primarily to increased personnel and consulting costs.

Sales and marketing expenses in the quarter increased to $7.9 million from $5.5 million in the prior year period, as we can continue to expand investment in our commercial infrastructure with a focus in the U.S.

General and administrative expenses in the quarter increased to approximately $3.9 million from approximately $3.6 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 $6.4 million, or $0.03 per share, compared to a GAAP net loss of $76 million, or $0.40 per share, in the prior year period. Adjusted net loss for the quarter was $14.7 million, or $0.07 per share, compared to an adjusted net loss of $14.1 million, or $0.07 per share, in the prior year period.

The primary adjustment from GAAP net loss relates to accounting for the change in fair value of warrant liabilities, which is driven mostly by changes in our stock price.

Cash and short term investments as of December 31, was $72.9 million. On December 28, 2018, we entered into an At-the-Market Equity Offering Sales Agreement or ATM to sell from time-to-time at our option up to $75 million of shares of common stock.

An ATM is designed to allow companies to opportunistically access equity capital markets, particularly during periods of high volume or volatility.

It allows us to pursue raising equity at a lower overall cost of capital because the fee structure is lower and pricing discounts common with fully marketed financings are avoided. Under the ATM, we are under no obligation to sell any shares. The timing, frequency and terms of any sales orders are entirely at our discretion.

During the fourth quarter, we received the $10 million second tranche of nondilutive financing relating 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 believe that our existing cash and additional debt proceeds will support the business into late 2020.

As Todd mentioned, we also closed the MST transaction in the fourth quarter. This transaction was valued at $20.3 million, and was funded with $5.8 million of 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 on or before October 31, 2019 (sic). Now I'll turn the call back over to Todd. Todd?

Todd M. Pope

Thank you. I would like to discuss our key strategic priorities for 2019. First, we will focus on driving adoption of digital laparoscopy with Senhance in the U.S.

Our experience commercializing Senhance in Europe and more recently in U.S. has given us a deeper understanding of the volume process. Surgeons in hospitals typically need to complete a system demonstration followed by preclinical labs, and finally a live surgery observation.

Until recently, surgeons and hospitals may have been able to do some of those activities in the U.S., but they would have to fly to Europe to observe live surgery. For obvious reasons, this was a hurdle to progressing accounts through the pipeline.

As a result of the greater number of installed systems in the U.S. and increased credentialing and training of surgeons, we continue to improve our ability to allow pipeline accounts to interact with this system in the U.S. and we are focused on continuing to expand this capability.

We believe that this, along with the advances in instrumentation, as well as our broader label, will help convert our U.S. pipeline at a higher pace in the second half of 2019 and beyond.

Second, implement key instrument expansions in the U.S. While we made significant strides in 2018, we still had additional opportunities to expand our instrument offerings in 2019, the first of which is the FDA approval of Senhance ultrasonic instruments which we received in January.

The second is articulating instruments, which we expect to receive FDA clearance during the fourth quarter of 2019. Third, advance the technological capabilities of Senhance through the integration of image analytics technology.

As I mentioned, previously the acquisition of MST gave us immediate access to a variety of innovations driven by augmented intelligence that we believe will meaningfully advance the benefits of digital laparoscopy to patients, surgeons and operating rooms globally.

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 surgeons to focus on the task at hand. 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.

In 2019, we will work towards the rollout of these innovative capabilities. The initial step involves additional product development followed by a submission of an FDA 510(k) application, which we expect to complete by the end of 2019.

Lastly, continue to facilitate the commercial adoption in Asia. Having recently received full TFDA approval in Taiwan, we are now free to commercialize within that geography.

We have significant interest in Taiwan, one of many markets in Asia where robotic surgery is typically an option only for patients who can pay out-of-pocket due to high procedure cost. We believe that the low per procedure cost of Senhance will make an attractive option in this market.

In Japan, we will continue to make progress on the regulatory process. This process is typically measured in years not quarters, so we will provide updates in future calls as warranted.

Turning to guidance, in the first quarter, we expect to sell two to four systems and remain confident in the depth and breadth of our pipeline, which we expect to result in solid growth throughout the rest of the year. To recap, we are incredibly excited about the future at TransEnterix.

We grew our business significantly and accomplished all of the key milestones we set out for in 2018. We sold fifteen systems globally during the year and increased revenue by approximately 240%.

We advanced our portfolio of instrument offerings to include ultrasonic and 3-millimeter. We expanded indications for use to approximately three million procedures annually in the U.S. and we entered into a new geographic territory in Asia.

In addition, 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 put ourselves in a great position to continue to drive the adoption of Senhance during 2019 and into the future. And with that I would like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from Rick Wise with Stifel.

Frederick Wise – *Stifel, Nicolaus & Company, Incorporated – Research Division, MD & Senior Equity Research Analyst*

Good Morning.

Todd M. Pope

Hi, Rick.

Frederick Wise

Let me start, Todd, and you gave a great rundown and clearly a great deal of positive things happened in ‘18. It’s hard not to start just at a high-level, sort of summing it all up as we reflect on the potential impact on ‘19 sales.

And you gave us, you framed the first quarter two to four systems, so not surprisingly a little seasonally softer there. But maybe you could talk about how we should think about the flow the rest of the year. You are saying stronger second half.

Is the pipeline so strong and the demos set up and the training so clear that you really see a clear path to that sort of acceleration into the year’s stronger second half? Maybe you could characterize the pipeline, some of these training and demo activities and just help expand on the comments that you made earlier. Thank you.

Todd M. Pope

Certainly. Yes, and the answer I want to say to your question is yes, a resounding yes. We do feel very strong about what we put in place in 2018 and how that's going to play out in 2019, as we mentioned, especially increasing momentum in the second half.

As you think about our pipeline, we've talked about it, it's robust. There is no doubt about it. We have had consistent sales over the last several quarters.

And our visibility is really improving on the type of quality deals that we have in the pipeline, so the trends are all moving in the right direction. And as you look at 2018, we were top-tier medtech growth. And we expect 2019 to be top-tier medtech growth, no doubt about it.

As you look, we put quite a few goals in front of the business and communicated those publicly for 2018 and we achieved every single one of those, so we feel good about that track record of success, parlaying into similar success in 2019.

Frederick Wise

And Todd, maybe talk about the instruments and the impacts of the instrument approvals and those about to be approved, and the impact its having on the discussion.

I mean, obviously, you said it, the energy device, the ultrasonic energy device, is the most critical, but is that literally tipping people over the edge in terms of moving from waiting to more interested? Are you, are people now more willing to talk to you? Again, maybe just help understand the impact of the instruments.

Todd M. Pope

Sure.

Frederick Wise

And ask one other part there before, sort of as part A of instruments. Part B is, should we imagine sort of separate revenue generation coming from the instruments and impacting 2019 revenues? Thanks.

Todd M. Pope

Yes. Sure let me take both of your questions in order. First of all, as far as are more people willing to talk to us. I will tell you, hands down, we have no lack of interest in the system.

When you are the first robotic system for soft tissue to be approved in nineteen years and there is so much fervor in the robotics industry, we have an increasing steady amount of inbound interest from all geographies around the world.

So, just to make the point a little bit more clear on your question, let's take a look at like two different instruments, 3-millimeter. 3-millimeter is really a first in robotics, as we talked about manual laparoscopy.

Patients and surgeons continue to drive more toward smaller instruments, because the obvious benefits that play out there. Patients have good cosmetic result and they certainly have less pain postop, the recovery, the return to normal activity is all quicker.

So there's a benefit. And then when surgeons are using 3-millimeter instruments manually or by hand in laparoscopy, it's sometimes hard to get the precision that you want with the smaller instrument in hand.

When you have that on a stable robotic arm of Senhance, your precision can really be heightened and that's really important with the smaller instrument. So that way with Senhance, you get all the benefits of less invasiveness with the smaller instrument, 3-millimeter, but you have that stability and precision of a robotic arm with Senhance.

So to answer your question, that's really more of a kind of epiphany for folks. Wow, we can have that small of instruments on a robotic platform. We'd never thought about that before, that's very exciting, people like that.

You juxtapose that to advanced energy. Advanced energy, people use advanced energy in almost the majority of their laparoscopic procedures. They at least want to have it available if they need it, so that was more of a kind of a ticket to play, if you will.

People want to have advanced energy. So we've had a lot of people that have been very interested in this system, very excited about this system. And certainly some of our pipeline surgeons have been saying, when that is available that would help push us over the line.

So, as we mentioned in the call, the majority of our placements around the world have been able to order in advanced energy and begin to utilize them and the results we're hearing back is fantastic. It's not enough just to have an approved product.

It has to perform as advertised and surgeons really liked the advanced energy. It has limited thermal spread. It doesn't have a lot of smoke in the field of view and we're getting a very strong clinical acceptance back on that. So those are really like two different takes on how instruments continue to help us for sure.

And we think as we roll out advanced energy and 3-millimeter to more and more of our current accounts, and let our pipeline accounts get their hands on those whether they're in a dry or wet lab or watch them to be able to be observed in surgery as we've talked about. We really think that's going to continue to accelerate the pipeline.

And then the second part of your question is, yes, anytime that you have instruments that you're able to bring, and they're preference instruments and they're not necessarily reusable, case in point the advanced energy.

That can and will add additional revenue to our bottom line. So we're excited about that. Those are instruments that in current laparoscopy or robotics, people pay a per procedure cost and we'll be able to enjoy that same benefit.

Frederick Wise

One last one for me for now, Todd. Just reflecting on your initial experience in the U.S., is there any common thread in the accounts that have bought Senhance initially or that you think are likeliest to buy in 2019?

Are these dedicated experienced robotic centers? Are these non-robotic centers today trying to get in, these all laparoscopic centers? Is there anything that we can and should understand about your early customers here in the U.S. that might help us think about the future or the near future? Thanks a lot.

Todd M. Pope

Sure. I'll take that in two parts. First of all, I would just say, one of the common threads that we felt would be similar across buying patterns is people want to go and watch surgery. They really do. They're excited about a new platform. There hasn't been a new platform in a couple of decades.

So they really do want to go watch surgery, talk to the surgeons, talk to OR staff, see how it's being used. And as we talked about, all of our sales in Europe so far have been able to go, I'm sorry, all of our sales in the U.S. haven't able to go to Europe and yet some of that validation.

But that's not really scalable. So that's why we're excited that we have systems all the way from New York down to Florida now on the eastern half of the U.S. to make that much easier.

As far as the way we look at different accounts, I would say that when people have acquired Senhance and began to use them, the hospitals are excited because they typically already have a robot in their hospitals, so they're looked at by the patients in their surrounding area as a destination for robotic surgery. And these hospitals have been excited to offer the newest robotic technology available in Senhance.

And it's really kind of risen their stature in their community of patient pull, because now they've acquired the latest and greatest robotic platform. So for them, I think, they're enjoying the benefits of their current robotic platform, but they're expanding cases with the new platform being Senhance.

And they not only feel like that's helping them the way patients view them and they're offering the latest technology, but as they recruit and try to retain surgeons, very important in this labor market even with surgeons that hospitals have a very good value prop to recruit and keep surgeons over there and having the Senhance on board has really helped that.

We've seen that across the board. So those are some of the similar threads we're seeing as we roll out the system here in the U.S. and we think that will continue.

Frederick Wise

Thank you.

Todd M. Pope

Thanks Rick.

Operator

And our next question comes from Glenn Novarro with RBC Capital Markets.

Glenn Novarro – *RBC Capital Markets, LLC – Research Division, Analyst*

Hi. Good morning guys. Todd, I wanted to follow up on articulating instruments and maybe talk about how important these instruments are to system placements in 2019, and then the FDA approval timeline, approval in the fourth quarter of '19. Why is it going to take the FDA twelve months to review your submission? Thanks.

Todd M. Pope

Yes, thanks Glenn. As we've talked about, we felt like our most important device we wanted to get approved in use was advanced energy and we have that. Certainly, articulation will add some more capabilities.

But the procedures and the surgeons that we're going after in digital laparoscopy certainly don't have as many needs for articulation. Articulation is really a feature that enables folks when they're in really tight spots anatomically.

They're having to reach whether it's really low in the pelvis or certain areas that you can't get a good angle. But in the majority of laparoscopic surgery, when you have the abdomen expanded with CO2, you have a broad working space.

And features like being able to have 3-millimeter instruments, being able to finally have haptic feedback on a robotic platform that they have not been able to have up to this point. The ability to have the newest fluorescence technology has really been a big value driver.

The ability to be able to drive the camera simultaneously with your other two robotic arms without having to stop, those are the features that are driving the most interest in our platform.

We really don't have that many people saying for the applications that you're talking to us on, we really can't do them well without articulation. That's why we really didn't prioritize it ahead of other things, like I just mentioned.

We prioritized 3-millimeter, haptic feedback, advanced energy, the ability to have separate robotic arm, so you can set up your lap trocars, just like you would in a regular lab case, the ability to control three robotic arms simultaneously. Those are all the features that we felt like as we were developing the system.

And now that we've rolled them out, they generate the most interest. We find that articulation is certainly most beneficial in certain anatomic sites and these aren't prevalent across all lap procedures.

Glenn Novarro

And then the twelve month timeline when some of your other approvals came within three to six months.

Todd M. Pope

Yes, that all just depends on how the interaction goes along with the FDA. And right now that's just the guidance we're providing as far as our articulation submission.

Glenn Novarro

And then just some quick ones here. You in the fourth quarter sold three systems in Europe, two were distributors. Have those systems been placed already in hospitals and then I had two follow ups for Joe.

Joseph P. Slattery

Yes, Glenn, this is Joe. Yes, all the sales are in the hospitals having gun cases. So we, if we were selling a system that was in transit at a distributor, we would always be transparent about that.

Glenn Novarro

And then two quick more for you Joe. You established the ATM in December. Has there been any activity in the ATM? And then to follow up on Rick's question, how should we model advanced energy sales? I'm assuming you're selling advanced energy outright, so price, how should we model advanced energy?

Joseph P. Slattery

Sure. With respect to the ATM, we haven't done any sales as of today. As far as the advanced energy, the ASP per use will be in the $400 to $500 per procedure range. Now it won't be used in every procedure that we perform. So we would estimate that would be anywhere from 30% to 50% of procedures once it gets out there.

As you know, Glenn, in these early days with the majority of our procedures being performed by growing installed base, the procedure volume is low relative to the fleet because most of the fleet has only been out there for a couple of quarters.

So it won't really have a particularly meaningful impact on revenues throughout this year, probably on the order of less than a $1 million.

Glenn Novarro

Thanks Joe.

Operator

And our next question comes from Larry Keusch with Raymond James.

Lawrence Keusch – *Raymond James & Associates, Inc. – Research Division, MD*

Good morning. Todd, I was hoping that maybe you could, as you think back over 2018, did you get a sense of kind of which procedures are mostly being performed on the Senhance platform? And then also I recognized that the procedures at this point are relatively small, but could you give us some quantification how many procedures were actually done in 2018?

Todd M. Pope

Hey, Larry, thanks for the question. I would say as we step back and just kind of look at a high level as far as what type of procedures are being done, we really are starting to gravitate towards some of these higher volume laparoscopic procedures.

There is certainly a truism that everyone out there doing surgery today has been called on to see if they're interested in robotics over the last ten to twelve years, and lot of those people have made those decisions. We're going back and talking to folks about a new robotic alternative called Senhance, and we're bringing a lot of different things to the table.

And most of the things that we're bringing to the table, kind of, address some of the tradeoffs people felt like they needed to make in the past to go to some of these higher volume procedures like gallbladder and hernia. A lot of folks felt like for those type of procedures, they wanted to be able to keep their OR efficiency high.

They wanted to be able to use the cameras that they already had in their lap tower, their trocars that hospital already had on contract. They certainly wanted to put their lap trocars and the Senhance trocars in the same spot. So if they ever needed to do any type of hybrid procedure, they didn't have to add trocars.

We solved all those issues. They really liked haptic feedback, because if you're peeling the gallbladder off, the liver bed or if you're making a defect and you're trying to repair that in like a inguinal hernia, it's very important to have tactile feedback.

So all of the features that we've offered and the benefit subsequently that they provide have kind of fed into these higher volume procedures that typically have not been a good fit for traditional robotics.

So that's where each hospital that we've sold into usually already has a robot, and so we're not necessarily taking procedures from that current robotic usage pattern. We're really adding more procedures that can be done robotically because what Senhance offers.

And we think that's going to continue to play out. Not only does that allows surgeons to be able to start using a more and more robotic options with Senhance, but it also kind of helps level out block time on their current robot.

They can be used for the certain procedures that really make the most sense, and then Senhance can really pick up some of these newer alternative procedures that really haven't been thought of as a good fit for robotics. So I would think that's how we do that. And we really haven't talked about any quantity of procedures yet.

We're continuing to build our base across Asia and Europe and the U.S. And as we continue to get those systems rolled out in the future, we'll provide more details on number of procedures.

Lawrence Keusch

And just coming back to that for one moment. So is gallbladder the primary procedure or the highest volume procedure at this point or it's something else? I'm just trying to understand, again, which are the couple of procedures that Senhance is being used most frequently for?

Todd M. Pope

I would say hernia, gallbladder and GYN, that's where we see the most. The GYN procedures are the ones that really see benefit in the 3-millimeter along with hernia. When you're operating low down in towards a Pfannenstiel incision line, smaller instruments are really tolerated much better by patients.

And also it's just better to keep those small incisions low as possible and out of any sight. So I would say GYN, hernia and gallbladder is what's driving the most of our volume. And that's pretty consistent across Europe, Asia and the U.S.

Lawrence Keusch

Okay. Perfect. And then just two other quick ones. Relative to disclosure around the number of procedures, is that kind of based on when you guys get to some level of consistency or is there a threshold number that you're looking for before you start reporting that?

And then secondly, just on the IP landscape around articulating instruments. How do you think about that relative to the instruments that you expect to bring in the U.S.?

Joseph P. Slattery

Hi, Larry, it's Joe. What I would say is that with the installed base still on a low scale, that the instrument that the procedure patterns are not bubbling up to something that you'd come to a conclusion that actually describes what we see.

What I can tell you is that in some of our accounts where there aren't any number of frictions with proctoring or politics in the hospital and those kind of things, we see hospitals that have the right motivations getting quickly to ten to twenty cases a month in their first month or two. So that more describes the potential of where we can go.

Quite a few of our installations have very specific stories. For example, our sale in Japan, without reimbursement, they limit the use on the robot. So if you put it all in the mix, it sends a kind of conflicting signal on what's going on with the procedures.

Todd M. Pope

Larry, I would just say on your question articulating instruments. We have articulating instruments that are CE Mark approved and being used in Europe. So we don't have IP concerns there.

We're adding to that armamentarium with what we are looking to file and get approved in the U.S. But there's not IP concerns there. We just want to make sure that appropriate applications are identified, and that's where we roll it out.

But when we think about what we're offering with Senhance, we really standalone really focusing on converting lap and using primarily all reusable instruments, keeping our cost per procedure nearly at parity with laparoscopy. That is what continues to kind of separate us in addition to the features we've highlighted in some of the Q&A here.

When hospital administrators can sit with us and not feel the burden of their operating room per procedure cost going up three and four times versus current laparoscopy, that they still get the benefits of moving those procedures, so robotic platform with Senhance, that's from the administration side of the hospitals what's given us so much pull. Surgeons love a lot of our features, as we've talked about in the past.

But we get the most pull from administrators when they think about just the stability of their budget for robotic procedures can be with our platform with reusable instruments. So I would say that's how we think about instruments and really our value prop both clinically and to the administrators of the hospital.

Lawrence Keusch

Okay. Thank you very much.

Todd M. Pope

Thanks Larry.

Operator

Ladies and gentlemen, that concludes our question and answer session for today. I would now like to turn the call back to Mr. Pope for any closing remarks.

Todd M. Pope

Thanks all of you for joining us on the call today, and we certainly look forward to updating you on our progress in the next quarter. Thank you.

Operator

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