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

August 7, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	**TRXC**	**NYSE American**

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 August 7, 2019, TransEnterix, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the second quarter ended June 30, 2019. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 7, 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 second quarter ended June 30, 2019. The Company had issued a press release on July 25, 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 August 7, 2019
99.2	August 7, 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: August 8, 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 Second Quarter 2019

Wednesday, Aug 07, 2019 04:05pm

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 second quarter of 2019.

Recent Highlights

- Total revenue of $3.6 million in the second quarter of 2019
- Received Japanese regulatory approval of the Senhance® Surgical System
- Received broad Japanese reimbursement for 98 different procedures, effective July 31, 2019
- AutoLap asset sale and equity sale to bring in a total of $47 million

“While we were disappointed with our system sales in the quarter, we are encouraged by our operational accomplishments including the monetization of the AutoLap assets and achievement of Japanese regulatory approval and broad reimbursement well ahead of our expectations.” said Todd M. Pope, President, and CEO of TransEnterix. “We are focused on improving commercial execution to drive global system sales in the second half of the year.”

Commercial and Clinical Update

In the quarter ended June 30, 2019, the Company sold one Senhance® System, in the EMEA region to an end user hospital.

On May 28, 2019, the Company announced that it received Japanese regulatory approval for the Senhance Surgical System. The Senhance Surgical System was approved by the Ministry of Health, Labor and Welfare (MHLW) for use in laparoscopy for general surgery, gynecology, and urology.

On August 1, 2019, the Company announced that the MHLW expert review panel provided reimbursement for procedures performed with the Senhance Surgical System. The reimbursement, which became effective on July 31, 2019, applies to 98 benign and malignant laparoscopic surgeries at reimbursement rates equivalent to traditional laparoscopy in Category A1.

AutoLap Asset Sale

On July 10, the Company announced the sale of certain AutoLap® image-based laparoscope positioning system (AutoLap) product and intellectual property assets to Great Belief International Limited (GBIL). The total proceeds to be paid to the Company for these assets is $17 million. In addition, GBIL is making an equity investment of $30.0 million in TransEnterix common stock at $2.00 per share. As a part of the sale agreement, the Company retains ownership of the broader intellectual property portfolio it acquired from M.S.T. - Medical Surgery Technologies in October 2018, and will enter into a cross-license agreement with GBIL under which it gains a license to use the AutoLap-related IP sold, and grants GBIL a non-exclusive license to use additional IP in connection with the AutoLap.

Second Quarter Financial Highlights

For the three months ended June 30, 2019, the Company reported revenue of $3.6 million as compared to revenue of $6.4 million in the three months ended June 30, 2018. Revenue in the second quarter of 2019 included $2.7 million in system sales, $560 thousand in instruments and accessories, and $342 thousand in services. The $2.7 million in system sales revenue includes the recognition of $1.3 million from a system sold in 2017 for which revenue was deferred until its first clinical use, which occurred in the second quarter.

For the three months ended June 30, 2019, total net operating expenses were $22.2 million, as compared to $18.5 million in the three months ended June 30, 2018.

For the three months ended June 30, 2019, net loss was $20.2 million, or $0.09 per basic share, as compared to a net loss of $34.2 million, or $0.17 per basic share, in the three months ended June 30, 2018.

For the three months ended June 30, 2019, adjusted net loss was $19.2 million, or $0.09 per basic share, as compared to an adjusted net loss of $11.7 million, or $0.06 per basic share in the three months ended June 30, 2018, after adjusting for the following charges: change in fair value of warrant liabilities, amortization of intangible assets, change in fair value of contingent consideration, loss on debt extinguishment, acquisition-related costs and the loss (gain) on the sale of the SurgiBot assets. Adjusted net loss is a non-GAAP measure. See the reconciliation to GAAP below.

The Company had cash and cash equivalents, restricted cash and short term investments of approximately $34.0 million as of June 30, 2019. The Company believes that existing cash and short term investments and the expected proceeds from the AutoLap transaction are sufficient to support the business into mid-2020.

Conference Call

TransEnterix, Inc. will host a conference call on Wednesday, August 7, 2019, at 4:30 p.m. ET to discuss its second quarter 2019 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 4293967 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.

Use of 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, amortization of intangible assets, change in fair value of contingent consideration, acquisition-related costs, loss on extinguishment of debt, and the loss (gain) on the sale of the SurgiBot assets. These financial measures are presented on a basis other than in accordance with the 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. 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 improved commercial execution will drive global system sales in the second half of the year, whether payments under the AutoLap sale agreement will be made on a timely basis, whether TransEnterix has sufficient cash, short term investments and the expected proceeds from the Autolap asset sale and equity raise to support the business into mid-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, 2018, filed with the SEC on February 27, 2019 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ 3,639	$ 6,389	$ 5,820	$ 11,156
Cost of revenue	3,936	3,732	6,403	6,287
Gross (loss) profit	(297)	2,657	(583)	4,869
Operating Expenses (Income)				
Research and development	6,295	5,281	11,950	10,546
Sales and marketing	7,868	6,046	15,542	12,016
General and administrative	4,489	3,627	9,049	6,303
Amortization of intangible assets	2,585	2,743	5,196	5,570
Change in fair value of contingent consideration	960	812	1,958	1,439
Acquisition related costs	—	—	45	—
Loss (gain) from sale of SurgiBot assets, net	—	37	97	(11,959)
Total Operating Expenses	22,197	18,546	43,837	23,915
Operating Loss	(22,494)	(15,889)	(44,420)	(19,046)
Other Income (Expense)				
Change in fair value of warrant liabilities	2,528	(17,507)	2,422	(15,678)
Interest income	178	320	496	590
Interest expense	(1,061)	(2,056)	(2,177)	(2,712)
Other (expense) income	(191)	1	(496)	(57)
Total Other Income (Expense), net	1,454	(19,242)	245	(17,857)
Loss before income taxes	$ (21,040)	$ (35,131)	$ (44,175)	$ (36,903)
Income tax benefit	869	883	1,479	1,773
Net loss	$ (20,171)	$ (34,248)	$ (42,696)	$ (35,130)
Comprehensive loss				
Foreign currency translation gain (loss)	1,240	(4,398)	(709)	(2,090)
Comprehensive loss	$ (18,931)	$ (38,646)	$ (43,405)	$ (37,220)
Net loss per common share:				
Basic	$ (0.09)	$ (0.17)	$ (0.20)	$ (0.17)
Diluted	$ (0.10)	$ (0.17)	$ (0.21)	$ (0.17)
Weighted average number of shares used in computing net loss per common share:				
Basic	217,471	204,504	217,135	202,214
Diluted	218,579	204,504	218,579	202,214

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

	June 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	$ 23,302	$ 21,061
Short-term investments	9,973	51,790
Accounts receivable, net	5,669	8,560
Inventories	20,091	10,941
Interest receivable	30	26
Other current assets	10,240	9,205
Total Current Assets	69,305	101,583
Restricted cash	712	590
Property and equipment, net	5,782	6,337
Intellectual property, net	34,190	39,716
In-process research and development	10,667	10,747
Goodwill	79,904	80,131
Other long term assets	2,818	203
Total Assets	$ 203,378	$ 239,307
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 7,039	$ 4,433
Accrued expenses	8,182	9,619
Deferred revenue – current portion	897	1,733
Contingent consideration – current portion	74	72
Deferred consideration – MST Acquisition	6,310	5,962
Total Current Liabilities	22,502	21,819
Long Term Liabilities		
Deferred revenue – less current portion	68	109
Contingent consideration – less current portion	12,521	10,565
Notes payable - net of debt discount	29,528	28,937
Warrant liabilities	2,214	4,636
Net deferred tax liabilities	3,164	4,720
Other long term liabilities	1,894	—
Total Liabilities	71,891	70,786
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2019 and December 31, 2018; 217,625,492 and 216,345,984 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	217	216
Additional paid-in capital	682,736	676,373
Accumulated deficit	(552,095)	(509,406)
Accumulated other comprehensive income	629	1,338
Total Stockholders' Equity	131,487	168,521
Total Liabilities and Stockholders' Equity	$ 203,378	$ 239,307

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

	Six Months Ended June 30,	
	2019	**2018**
Operating Activities		
Net loss	$ (42,696)	$ (35,130)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Loss (gain) from sale of SurgiBot assets, net	97	(11,959)
Depreciation	1,126	1,277
Amortization of intangible assets	5,196	5,570
Amortization of debt discount and debt issuance costs	622	495
Amortization of short-term investment discount	(300)	—
Interest expense on deferred consideration – MST acquisition	387	—
Stock-based compensation	6,336	4,204
Deferred tax benefit	(1,479)	(1,799)
Write down of inventory	761	—
Change in fair value of warrant liabilities	(2,422)	15,678
Change in fair value of contingent consideration	1,958	1,439
Loss on extinguishment of debt	—	1,400
Changes in operating assets and liabilities:		
Accounts receivable	2,808	(762)
Interest receivable	(4)	(24)
Inventories	(10,301)	(1,560)
Other current and long term assets	(3,689)	1,905
Accounts payable	2,499	404
Accrued expenses	(1,454)	(359)
Deferred revenue	(862)	31
Other long term liabilities	1,879	—
Net cash and cash equivalents used in operating activities	(39,538)	(19,190)
Investing Activities		
Purchase of short-term investments	(12,883)	—
Proceeds from maturities of short-term investments	55,000	—
Proceeds related to sale of SurgiBot assets, net	—	4,496
Purchase of property and equipment	(189)	(358)
Proceeds from sale of property and equipment	—	32
Net cash and cash equivalents provided by investing activities	41,928	4,170
Financing Activities		
Payment of note payable	—	(15,305)
Proceeds from issuance of debt and warrants, net of issuance costs	(30)	18,870
Payment of contingent consideration	—	(395)
Proceeds from issuance of common stock and warrants, net of issuance costs	—	2
Taxes paid related to net share settlement of vesting of restricted stock units	(499)	—
Proceeds from issuance of common stock related to sale of SurgiBot assets	—	3,000
Proceeds from exercise of stock options and warrants	534	9,813
Net cash and cash equivalents provided by financing activities	5	15,985
Effect of exchange rate changes on cash and cash equivalents	(32)	(78)
Net increase in cash, cash equivalents and restricted cash	2,363	887
Cash, cash equivalents and restricted cash, beginning of period	21,651	97,606
Cash, cash equivalents and restricted cash, end of period	$ 24,014	$ 98,493
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 1,528	$ 599
Supplemental Schedule of Noncash Investing and Financing Activities		

Transfer of inventories to property and equipment	$ 415	$ 1,055
Reclass of warrant liability to common stock and additional paid-in capital	$ —	$ 7,060

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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Net loss (GAAP)	$ (20,171)	$ (34,248)	$ (42,696)	$ (35,130)
Adjustments				
Loss (gain) from sale of SurgiBot assets, net	—	37	97	(11,959)
Amortization of intangible assets	2,585	2,743	5,196	5,570
Change in fair value of contingent consideration	960	812	1,958	1,439
Acquisition related costs	—	—	45	—
Change in fair value of warrant liabilities	(2,528)	17,507	(2,422)	15,678
Loss on extinguishment of debt	—	1,400	—	1,400
Adjusted net loss (Non-GAAP)	$ (19,154)	$ (11,749)	$ (37,822)	$ (23,002)

(Unaudited, per basic share)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Net loss per share (GAAP)	$ (0.09)	$ (0.17)	$ (0.20)	$ (0.17)
Adjustments				
Loss (gain) from sale of SurgiBot assets, net	—	0.00	0.00	(0.06)
Amortization of intangible assets	0.01	0.01	0.03	0.03
Change in fair value of contingent consideration	0.00	0.00	0.01	0.01
Acquisition related costs	—	—	0.00	—
Change in fair value of warrant liabilities	(0.01)	0.09	(0.01)	0.08
Loss on extinguishment of debt	—	0.01	—	0.00
Adjusted net loss per share (Non-GAAP)	$ (0.09)	$ (0.06)	$ (0.17)	$ (0.11)

The non-GAAP financial measures for the three and six months ended June 30, 2019 and 2018 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. Loss from sale of SurgiBot assets relates to additional outside service costs to transfer the assets.

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 Medical Surgery Technologies Ltd. purchase agreement and consist of legal, accounting, and other costs.

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 statements of operations and comprehensive loss for the three and six months ended June 30, 2018.

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Exhibit 99.2
Company: TRANSENTERIX, INC.
Conference Title: Q2 2019 TransEnterix Inc. Earnings Call
Moderator: Mark Klausner
Date: August 7, 2019

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the TransEnterix Second Quarter 2019 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*

Good afternoon, and thank you for joining us for the TransEnterix second-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 any guidance provided, 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 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, filed on February 27, 2019, and the Form 10-Q for the quarter ended June 30, 2019, expected to be filed prior to the filing deadline and the other filings we make with the SEC.

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 operating 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 second quarter 2019 conference call. On today's call, I will discuss our recently announced AutoLap transaction and provide an update on our second-quarter operating performance. I'll then turn the call over to Joe to provide a financial overview, after which we'll open up the line for questions.

Starting with our second-quarter performance, we reported revenue of $3.6 million comprised of one system sale as well as instruments, accessories and service, and the recognition of revenue from prior system sales in Taiwan that was deferred until surgery at those sites began. The system sale was made to an end-user hospital in the EMEA region.

We're disappointed with our commercial results during the quarter having come in below our guidance. As we've stated before, capital sales are inherently difficult to predict, particularly, when working with a developing pipeline. We continue to feel that we're putting in place a solid foundation to drive improved performance in the back half of the year. However, we understand that we need to provide stronger and more consistent commercial results to regain investor confidence. In just a moment, I will review a number of key areas of our business and how we've adjusted our strategy to drive that improved performance.

I'd like to provide an overview of the AutoLap divestiture that we announced on July 10th. In October 2018, we acquired MST with the intent to leverage their surgical image analytics technology and IP to bolster the technological capability of Senhance. In addition to a very strong IP portfolio, MST had commercially launched a product called AutoLap, which is an image-based scope positioning system used in traditional laparoscopic procedures. When we announced the acquisition, we stated that we would not be investing in the AutoLap as a stand-alone product so that we could remain focused on commercializing the Senhance. In the July 2019 sale transaction, we were selling the inventory, tooling and other physical assets of the AutoLap product to GBIL, the same company that acquired the SurgiBot assets. We retained all relevant legacy MST IP, the entire team, talent and know-how, so this asset sale has no impact on our plans to incorporate the IP and software acquired from MST into the Senhance. We continue to make good progress on this front, which I'll expand on later in the call. The total proceeds to be paid to the company are $17 million in cash. In addition, GBIL is making an additional equity investment of $30 million into the company, which Joe will provide more details on shortly.

I would now like to spend some time discussing our global commercial progress, starting with our efforts to drive adoption of digital laparoscopy with Senhance in the U.S. I would like to begin by sharing some of the key learnings from our initial commercialization in the U.S. and the changes we are making in our approach to this market as we move forward.

First, our initial approach was focused more heavily on sales resources and activities in targeted geographies, with less of a focus on broader market development activities. While we did make some initial sales, these early sites did not quickly ramp case volumes or routinely performed surgery across a broad spectrum of specialties. As a result, we did not establish a foundation to allow surgeon advocacy to bolster our sales efforts and grow our base of surgeon speakers and proctors.

We have now added resources to drive clinical utilization within our existing installed base, and we have sites that are consistently performing surgery across a variety of procedures. We also have a number of surgeons who are actively using the system. And we have begun to convert this into a network of proctors and public speakers. We added marketing resources to help us craft a stronger clinical and economic story and worked with hospitals to help them envision programs to successfully market their Senhance purchase to potential patients. We are now routinely engaging the hospital C-Suite with thoughtful healthcare economic arguments, value-based analysis and marketing plans.

Secondly, the U.S. robotics market is mature with the well-established competitor, so potential customers have high expectations. Early Senhance system experience did not consistently delight prospects and customers, which impacted early system evaluations and clinical use. While we worked quickly to resolve them, these experiences negatively impacted our pipeline activities and early customer satisfaction feedback. In addition, the initial launch configuration also lacked an advanced energy device, which is a commonly used instrument in laparoscopy.

We have leveraged our early experience and customer feedback to make improvements to the system, such as a significantly better visual experience with the introduction of a best-in-class 3D-4K monitor and the most advanced eye tracking hardware and software available. We have also continued to pay off the promise of delivering open architecture as we now have video compatibility with leading imaging products from Stryker, Novadaq, Storz and Conmed. These changes have resulted in a higher quality, more consistent surgeon experience, which has led us to a growing clinical use of the system within our installed base. We've also launched our ultrasonic energy system, which substantially increased the attractiveness of Senhance to laparoscopic surgeons.

Lastly, our early commercial approach was to hire salespeople that had experience selling in the robotics market. As a result, their strongest relationships were primarily with urologists and surgeons performing open procedures. Given that our focus is on digital laparoscopy, we pivoted and began hiring U.S. salespeople with strong surgeon relationships in laparoscopy, as opposed to a focus on robotic capital sales. This initially allowed us to build a large funnel of clinical opportunities with enthusiastic surgeon support. However, our team had limited experience navigating the capital selling process, making it even more challenging to convert surgeon interest into system sales.

We believe that our sales team is best positioned for success if it includes a diversity of experience that includes laparoscopic, emerging robotic and more mature robotics companies. We have bolstered our sales talent by recently hiring a Vice President of Sales, who has a wealth of experience with emerging robotics technologies, and that supplemented our team with additional capital sales leadership and talent. These new hires bring substantial capital robotics experience, including at Intuitive Surgical in the early years of their commercial launch, Mako Surgical, Blue Belt Robotics and Medrobotics.

One example of a recent success with our new approach is Hackensack Meridian Health at Pascack Valley, which began performing Senhance surgery in March, and is now routinely performing over 15 procedures per month and frequently exceeds that number. Pascack Valley has launched a regional print and radio campaign to drive adoption and to feature the use of Senhance as part of its strategy to grow volume in their local market. Dr. Amit Trivedi has become a proctor for our system and has participated in multiple public-speaking opportunities to share his positive experience with the Senhance. He was also featured in a recent cover story in the periodical *OutPatient Surgery* that described his experience and optimism about Senhance's role in his hospital setting.

We feel that we now have momentum in the U.S. pipeline to close deals. As mentioned before, we've always had a deep pipeline, but we now feel it is more probable to yield revenue. It is still early in the process, and it'll take some time before we can describe the U.S.

market as sufficiently developed to drive substantial growth. When these building blocks are established, we will increase our sales footprint meaningfully to maximize our ability to capitalize on this opportunity.

Transitioning to EMEA, the system sale in the second quarter was a direct sale to a German hospital. The system was sold to the Evangelical Hospital of Wesel in North Rhine-Westphalia. This is a 305 bed, comprehensive hospital with extensive inpatient and outpatient facilities, and they have already begun successfully using Senhance in surgery. This sale is a direct result of elevated efforts to expand our customer base in western Europe. The EMEA region is further advanced in the U.S. in terms of Senhance market development. Senhance is becoming a familiar brand, and the geographic breadth of the installed base has netted us considerable surgeon advocacy and name recognition in both the lay press and the medical community. We believe the first half performance of the EMEA region has more to do with the ebbs and flows of the capital sales process. This region has multiple accounts where the system is routinely used in surgery, week in and week out. For example, Maxima Medical Center in the Netherlands has performed over 100 surgeries in a multi-specialty environment since beginning to use the system in late 2018. Our EMEA region spans many countries where we are supported by a small direct sales team in western Europe, as well as distributors in other countries. Each country is developing at its own pace, but there are now several that have the benefit of one or more customers that have integrated Senhance into frequent use. Many of these hospitals are able to help us advance our advocacy efforts.

Turning to Asia, we continue to make significant progress in Taiwan with three active sites having surgeon advocates that are quickly ramping up their utilization of the system. Our first two installations, Fu Jen Catholic University Hospital and Veterans General Hospital Taipei, have completed over 65 surgeries in the first three months using the system. The third account started their clinical program in late July and is making good progress. In the third quarter, we have received a purchase order from another Taiwanese hospital, representing the fourth system sale in the region, and we plan to install this in the third quarter.

Turning to Japan, as we have previously announced, we have made tremendous progress in the short amount of time that we have focused on this market. In less than 18 months, we've established a focused team, received regulatory approval and obtained very broad reimbursement for the use of Senhance. We're very proud of this accomplishment as ushering a medical device through the regulatory and reimbursement process in Japan typically takes far longer than what we were able to achieve. We are thrilled by the recent reimbursement decision, which applies to 98 benign and malignant laparoscopic procedures across general, colorectal, gynecologic, bariatric and urologic surgeries and reimbursement rates equivalent to that of traditional laparoscopy. This is a fantastic result for Senhance and for patients in Japan as it covers a wide range of high-volume procedures across a variety of specialties. As a reminder, the Japanese market sets up extremely well for Senhance for several reasons. First, it's the second largest surgical robotics market in the world, which demonstrates the level of interest in new technologies. Second, it is a world leader in laparoscopic adoption with laparoscopy representing approximately 70% of all surgeries. And third, it is among the highest in the world in terms of government funding for healthcare costs, leading to an extremely cost-sensitive environment. For these reasons, our reusable instrument strategy and digital laparoscopic focus position us well for success with the best-in-class per procedure cost in the robotics space.

In our last call, we had announced that we were planning to appoint a distributor in Japan in the near future. Considering the robust reimbursement coverage, we are deferring the decision to appoint a distributor while we reassess the total addressable market and re-evaluate our overall go-to-market strategy, given the strong, long-term opportunity in Japan.

Now let me shift gears to our instrumentation and product development efforts.

On that front, we achieved a significant milestone in the first quarter with the FDA approval of the Senhance Ultrasonic energy system. These products perform extremely well and are now in use in virtually all of our installations in the U.S. and EMEA. Of note, this product replaces a standard laparoscopic instrument, so this allows us to increase our revenue per procedure without adding costs to the hospital. We estimate that, over time, this product will be used in at least 30% of Senhance surgeries.

We've also been working on bringing 5-millimeter articulating instruments to the Senhance in the U.S. As a reminder, we have had 10-millimeter articulated instruments based on a completely different design available with the Senhance in countries that accept the CE mark for some time, and this product has contributed to our commercial success in EMEA. We received CE mark for the 5-millimeter instruments in the fourth quarter of last year and undertook surgeon evaluations in Europe to gain feedback on the best clinical application of these devices. We also filed for FDA clearance of these products in December 2018 with the expectation of a clearance later this year. When we received feedback from the FDA, one of their requests was for us to perform a usability study. These studies are time consuming to plan and execute, and can routinely cost over $2 million to conduct. While we were implementing the plans to conduct this testing, our limited launch in EMEA highlighted some opportunities to further increase the utility of these instruments. We have determined that we cannot incorporate these changes within the timeframe required by the FDA to maintain the current application. As such, we will withdraw our current application from the FDA, focus on the EMEA limited launch of these products, better define the best use cases for these new tools and resubmit with the FDA when those activities are completed. We will also work to align our other projects that may require a usability study, so that we can leverage one usability study for multiple initiatives. The addition of more products to a single usability study does not dramatically increase the study costs, allowing us to spread the investment across multiple initiatives.

Also on our last call, we briefly shared our approach to exploring a pediatric indication for the Senhance. As a reminder, pediatric surgeons typically are forced to utilize larger instruments and devices designed for the adult population. Because instrument and visualization control is so important when working on smaller anatomy, robotics would seem to be a natural solution. But the larger instruments of existing technologies have limited the adoption in this population.

Based on the Senhance's robotic instrument control, haptic feedback in first-ever three millimeter robotic instruments, we believe we may be in a unique position to address this market. Since our last update, we have continued to make progress on this front. We anticipate submitting for CE mark approval in the fourth quarter of this year, followed by obtaining CE mark next year. We will then leverage the CE mark to gain clinical experience to best determine how to position the Senhance across this opportunity in other markets around the world. Ultimately, we expect these learnings to inform us as to timing and approach to expand over Senhance FDA indications.

And regarding the integration of MST's surgical image analytics technology, we continue to make made solid progress with the ongoing product development and testing followed by submission of an FDA 510(k) application. We continue to expect to complete the filing around the end of 2019, and the future of these new capabilities has energized our installed base, as well as the interest shared in our pipeline accounts.

I would now like to 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 June 30, 2019, the company reported revenue of $3.6 million as compared to revenue of $6.4 million in the three months ended June 30, 2018. The company sold one system in the second quarter of 2019 as compared to four systems in the prior year period. Revenue for the quarter included the recognition of $1.3 million of deferred revenue related to a system delivered to Taiwan in 2018, which became recognizable as a result of completing the first surgeries during the quarter.

Revenue related to system sales was $2.7 million in the second quarter as compared to $4.7 million in the prior year period. Instruments and accessories revenue in the second quarter was $560,000 as compared to $1.5 million in the prior year period. Service revenue increased to $342,000 in the second quarter as compared to $222,000 for the comparable prior year period.

Gross margin for the second quarter was negative 8% due to fixed and variable costs in excess of revenues as well as an $800,000 charge for inventory obsolescence that related to certain system components.

R&D expenses in the quarter increased to approximately $6.3 million as compared to the prior year period at $5.3 million, due primarily to increased personnel and supplies costs. Sales and marketing expenses in the quarter increased to $7.9 million from $6 million in the prior year period, due primarily to increased personnel and travel-related costs. General and administrative expenses in the quarter increased to approximately $4.5 million from approximately $3.6 million in the prior year period, due primarily 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 $0.09 per share compared to a GAAP net loss of $34.2 million or $0.17 per share in the prior year period. For the three months ended June 30, 2019, adjusted net loss was $19.2 million or $0.09 per share as compared to an adjusted net loss of $11.7 million or $0.06 per share in the three months ended June 30, 2018 after adjusting for acquisition-related costs and the gain/loss on the sale of the SurgiBot assets, as well as non-cash charges for the change in fair value of warrant liabilities, amortization of intangible assets, change in fair value of contingent consideration and loss on debt extinguishment. Adjusted net loss is a non-GAAP financial measure that we believe allows a clearer picture of period-over-period comparisons. A reconciliation of GAAP to non-GAAP financial measures is posted on our website.

Cash and short-term investments as of June 30 was $33.3 million. We have not raised any capital through the ATM that we announced last December. We estimate that our existing cash, together with the proceeds from the AutoLap product and equity sale transaction, will support the business into mid-2020.

Now, I'll turn the call back over to Todd. Todd?

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

Thank you, Joe.

Certainly, the first half of 2019 did not meet our expectations in terms of commercial sales. We learned a number of lessons in the U.S. that we are now implementing into our commercial strategy going forward. We continue to build our pipeline in EMEA, and we made significant progress entering Asia.

Due to the difficulty of accurately predicting the timing of sales at this stage of our commercial ramp, we've decided not to provide the

formal quarterly system sales guidance at this time.

Overall, we continue to believe that we'll drive adoption of Senhance in the U.S., EMEA and Asia. We remain confident in the quality of our pipeline and expect to show meaningful commercial progress in the back half of the year as we seek to drive improved performance.

And with that, I'd like to open up the line for any questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Ladies and gentlemen, if you have a question at this time, please press the star, then the number one key on your touchtone telephone. If your question has been answered, or if you wish to remove yourself from the queue, please press the back key. Our first question comes from Rick Wise from Stifel.

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

Hi, Todd. Hi, Joe. I mean, obviously, very frustrating for you, frustrating for us. Let me kind of come at it in a couple of ways. Just trying to understand what's going on. I appreciate that going to market and, you know, with new technology from a young company can be a challenge. But help us understand what changed from your comments in mid-May when you indicated that you hoped for two-to-four systems this quarter still and you feel good. Again, I appreciate that timing these things is always tough, but maybe just help us understand what changed or what didn't happen and, you know, why maybe we could be hopeful that some of this volume that you'd hoped for might be more visible in the second half.

Todd M. Pope

Yes. Thanks, Rick. Certainly appreciate your sentiments. You know, specifically, on our comments we had on our second quarter call, you know, we disclosed that we had one PO in hand, and we had another one that we expected to close shortly. The one, we did close. The second PO was received from a distributor in EMEA, and we just hadn't shipped that one yet. We were just negotiating terms with the distributor. So that one didn't happen and was delayed. We felt like we were, you know, having to call it pretty good visibility to one, certainly two, and we felt like we would close a few others. Those that we didn't close that we expected to have continued to slip, not necessarily go away.

And as we talked about a little bit earlier in the comments, we do feel like our pipeline, you know, continues to progress that we felt like we needed better utilization of the system. You know, its volume and consistency. So when some of these pipeline accounts wanted good referenceable accounts, they could talk to folks that were not only using the system, but had kind of graduated to be proctors and speakers.

We feel like, also, we haven't had a Head of Sales in place, and that's always tough on the sales force. We've added a VP of Sales in the last, you know, seven weeks. As we talked about, it's a person that we feel like has got a good, quality background in robotic sales early in their life, you know, cycle, not necessarily after the companies mature. We mentioned four companies that he and some of the other people we've recently brought in can really, we think, can help us round out the sales force with the right kind of diversity of experience. So, from that standpoint, that was primarily the U.S.

You know, Europe, we think it's a little bit just more, you know, really timing related. Not a lot of deals that we felt like we lost. They just continue to get caught up in processes.

And for us, in Asia, you know, it's early. Well, I think we certainly feel encouraged by what's going on in Taiwan. We feel like we set the table well in Japan. But I think, primarily, those early comments that I made are reflective of the U.S., which is probably most of your questions.

Frederick Allen Wise

Right. And, again, I'm appreciating and totally understanding that you might not want to be very precise about the second half for -- or give us specific guidance. I get that. But I'm not sure how to square, Todd, the comments about your adjusting your sales and go-to-market strategy. Again, it all makes sense what you're saying, but how does that square with the potential to, just to quote you, that you'll show meaningful second half progress? I can't quite, you know, articulate to myself whether these changes that you're talking about all sound logical and sensible. But why is that going to help translate into meaningful second half progress, just in terms of putting the numbers on the board?

Todd M. Pope

Certainly. Well, you know, when we talked about, you know, our kind of strategy development as we approach sales, that's not anything we've done necessarily in the last week, two or three. You know, over the last quarter. So, we kind of realized that we did not

focus enough on market development. So we've gone out over the last three or four months and added resources. We've hired folks that have got pretty deep experience in driving clinical utilization and building out networks of proctors and public speakers. They've done it with other emerging technologies. We think that's really important to kind of feed into a podium and publication strategy, which is very important for early emerging technologies. We've also gone out and added marketing resources because these hospitals want to help -- you know, they want to help crafting, you know, their own clinical and economic story. They want to be able to continue to recruit surgeons. They want to be able to say, "Hey, we've got some of the most cutting-edge technology available, including the newest robot approved, Senhance." They want help crafting that message, and they want help crafting messages for patient recruitment. And we've gone out and hired people that have expertise in that, and we've hired them kind of early in the summer.

So we've kind of launched a much more focused effort with new folks on the team over the last three or four months around that market development, around clinical utilization, around hospitals being able to tell their message on how they're using the technology, and that we're starting to see that show up. If you look at our website, we've got some good testimonial videos there. We've got some of our busiest users going out, advocating for the product. And that means a lot to the pipeline that's in waiting. You know, we haven't, you know, had that as much in the past. And I know you've asked me famously about my comments of four to six quarters, you know, to have an inflection, and we're coming into our sixth quarter of approval here in the U.S. And some of those, you know, market development activities with busy committed surgeons are now starting to yield tools and advocacy that we think can, you know, impact the pipeline here in the back half.

So that's not a changing go-to-market now. This is something that we've evolved into, added the resources, and we think it's starting to pay off, for sure.

Joseph P. Slattery

And Rick, Joe, I would just add that, you know, the other thing that we look at to understand where we stand with the pipeline is, you know, deals that are at the contract review stage tend to become more predictable in terms of, you know, probability. Timing can still be a wide range, but they certainly escalate on our radar. And, you know, our, you know, I would say, confidence about, you know, making the second half come out a lot better than the first half, really comes from the number of contracts that we have out right now under review really in all of our territories.

Frederick Allen Wise

Oh, that's really helpful, Joe. And as long as you're speaking, Joe, turning to cash, I just want to make sure that we're all clear. So, with the cash you have on hand, without -- you know, with the sale of AutoLap but with not assuming any use of the ATM and not assuming the equity investment from GBL, so just the cash on hand and AutoLap gets you to the middle of the year, and then you have that incremental potential to extend beyond that with those other potential sources of funds. Is that the right way to say it?

Joseph P. Slattery

Not really. But I think you're trying to kind of -- I'll help you with the math that you're trying to square up there.

Frederick Allen Wise

Please.

Joseph P. Slattery

Because we announced that we had 47 million coming in, and we also pulled back our cash runway a little bit. That's the question, right?

Frederick Allen Wise

Yes.

Joseph P. Slattery

Yes. Okay. So, you know, finishing the last quarter roughly with 30 million. As part of the $47 million AutoLap transaction, we agreed to release the assets for the sale. We agreed to pay down our debt by 15, which also took 20 million of debt potential capacity out of our debt availability that was in the old cash runway. Okay? So, basically, 47 million coming in for AutoLap minus 35 million of net debt capacity doesn't change things much. And the, you know, the sales results over the last quarter has had us moderate our internal expectations somewhat, and that pulled forward the date a little bit as well.

Frederick Allen Wise

I figured. Yes. Just last for me, for now. I'm going to take your comments about Japan. Obviously, the regulatory approval and reimbursement were hugely positive. And I'm going to take your comment, Todd, that you're reevaluating how you go-to-market in

your strategy there. I'm going to take that as a positive as well and reflecting what I'm guessing is your optimism about having an impact there. But a couple of things, just --you know, so when might we imagine that you're going to be through this re-evaluation process? When should we dream of revenues from Japan? Is it -- I assume it's not this year. Or revenues post the approval and reimbursement, when -- is that next year? Is it '21? Maybe just help us at a high level think through that as well.

Todd M. Pope

Sure.

Frederick Allen Wise

Thank you very much.

Todd M. Pope

Well, you're right to characterize our re-evaluation of Japan go-to-market as a positive. We were hoping for the best, for sure. And I think we even exceeded our own expectations with nearly 100 procedures reimbursed at traditional laparoscopic levels. That's a big deal for us. It allowed us to really think differently of how we model out the next few years.

I would say, to answer your question, specifically, I don't think we have to wait until next year to gain some traction. We believe we're going to get some initial traction in the market this year. And then that will become more meaningful next year in 2020. But that is a market that has been very focused on robotic acquisition, but they've been challenged a little bit on utilization due to cost per procedure and some of the things we've mentioned in the past.

So, the fact that we have this many procedures across so many specialties, I think you're starting to see some traction this year.

Frederick Allen Wise

Thanks so much.

Todd M. Pope

Alright. Thanks, Rick.

Operator

Your next question comes from Jeffrey Cohen from the Ladenburg Thalmann. Your line is open.

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

Hi, Todd and Joe, how are you?

Todd M. Pope

Hi, Jeff

Joseph P. Slattery

Hi, Jeff.

Jeffrey Scott Cohen

So I'm just trying to make sense of some of the commentary and follow up with a few that you just mentioned as well. So is this a change to the commercial strategy? And could you talk about the current commercial team, number of folks out in the field, at least domestically as far as capital and clinical? And then talk about, maybe, the size of the team expanding. It sounds like I've heard expansion a few times as far as market development, marketing, patient recruitment, et cetera. Thank you.

Todd M. Pope

Well, yeah. I would say it's not necessarily a change to go-to-market. We're really evolving. You know, we're adding some things. We went out there. We had a lot of early interest. We put some systems out there. And you get to be focused on capital sales and moving to the next capital sale. And what we realized, as we've talked about, is we really need to augment our focus on sales and revenue with market development. We're bringing a new robot to market. There's only been one in the market the last 20 years. We've got some education to do on what we do differently, the different, you know, features that we bring to the market, and that requires some market development, which requires advocacy from users. They don't want to just hear it from us. And you have to get advocacy from multiple users and multiple specialties that's using the product, week in and week out. And it has just taken a little bit of time to get there, and that's impacted our pipeline. Now that we do have those folks, we've added some resources internally to really bolster some

of the things they want to do as they think about posters, publications, podiums, where they want to speak, how they want to talk about the device, proctoring new users, hosting pipeline accounts. So, I would characterize it, Jeff, as more of an evolution.

And then, to your question more specifically about current headcount, we still have around 15 sales professionals in the U.S. I would think, as you think about most emerging med-tech companies, that's a very small number. So you've heard a little bit about expansion. All we're saying is, when we feel like we've got the market development resources in, when our clinical utilization is, you know, clipping at a rate that we feel good about on our current installations, we certainly realize that to take advantage of a more national opportunity, you can't do that with 15 reps. You've got to expand that. And I think when the time is right, as we look to next year, I think we have plans to expand that sales footprint so we can take, you know, advantage of the opportunities all across the nation, not in just a handful of geographies.

Jeffrey Scott Cohen

Okay. Got it. And one more, if I may. Could you talk a little bit about any trends in utilization that you've seen? It looks like utilization was essentially flat from Q1. Do you expect any pick up there? Or is that going to come hand-in-hand with new placements? What are you seeing as far as existing placements and number of procedures and types of procedures?

Joseph P. Slattery

Jeff, this is Joe. We don't disclose any of those details. But I can tell you, I'm not sure where you picked up utilization was flat. Actually, you know, what we're seeing is this -- you know, a lot of the themes that Todd discussed were -- we started putting in place late last year. So, we've seen some really strong improvement in our utilization on our systems. Now, we still have a small base, and we've got several installations that -- you know, we have some accounts that bought a robot that really never intended to use it a lot, but we also -- we're seeing more and more accounts, you know, exceeding the 10-procedure-a-month rate and growing. So, I think the -- a good way to look at it is to think about the installations that we've made in the last year perform at a substantially higher level than those that did before. And that really owes to all the lessons that we've learned and how we have gone to the market and done a better job of getting additional surgeons across multiple specialties engaged with the program, either in advance of the install or shortly thereafter.

Jeffrey Scott Cohen

Perfect. Okay, that does it for me. Thanks, guys.

Todd M. Pope

Thanks, Jeff.

Operator

Your next question comes from Larry Keusch from Raymond James. Your line is open.

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

Thank you. Hey, Todd, I was -- I know that there's probably a bunch of moving pieces around the FDA process with the 5-millimeter articulating instruments. But can you sort of help us understand, you know, kind of next steps for you and maybe help us think about when you might be in a position to file that, because if I'm hearing you correctly, it sounds like that's not going to happen this year?

Todd M. Pope

Hey, Larry. Thanks for the question. Yes. And I know you've always been particularly interested in those products, so I'm glad you asked the question.

Yes. I mean, look, our -- I think we've described it pretty well in the call. You know, as we think about some of the feedback we're getting from Europe, people like the device. But as always, post-approval, you get feedback. And you have to kind of make a decision, is that kind of a next generation? Do you want to incorporate it now? As we were going through, you know, beginning of our usability study, we got some of that feedback. We really just stepped back and said, "Should we go through, you know, with a multi-million dollar cost of the full usability study? Or should we incorporate some of this feedback?" And then we also have some other products that would be coming down the regulatory pipe. You're never quite sure exactly what's going to demand a usability study or not. That's depending on a larger matrix as the regulatory authorities here in the U.S. think about it. But we felt like we do have some other pretty significant product offerings that we want to put through the agency in the coming quarters that very well may require a usability study. So we just stepped back and said, "Look, let's don’t go through with the whole thing. Let's couple some of those things together." And, you know, one of those devices also may be our 10-millimeter articulating. You know, we've been out in Europe long enough now. The current market norm is eight millimeter. Ten millimeter's not that big of a difference. We were excited about five millimeter and still continue to be, but we're also getting some good traction with our 10 millimeter. So we may add that in addition to the

usability study of the five millimeter.

Haven't made an exact calculation of when we'll restart that. I would not necessarily rule out this year. We haven't said that. What we're going to do is take a look at the other products we may want to include in a usability study, try to get some early read from the agency on what will and will not be required for a usability study and then roll that all into one. And, you know, as soon as we, you know, make that determination and get that kicked off, we could provide a little bit better, you know, feedback on timing.

But, you know, one thing, Larry, I'll just continue to say, and this has already been an age-old debate, you know, for us, is, we go out and focus on laparoscopic surgeons. Certainly, people across many procedures value articulation, but that inherently adds to the cost of procedure. And one kind of bedrock foundation for Senhance is to try to provide cost per procedure that's similar to laparoscopy. And that is hard to do when you have articulating instruments because you can't reuse those over time like you can other instruments because of the difficultly in cleaning them time and again.

So we continue to have very good uptake across a lot of procedures, that people love the capabilities of our system, and they're doing them very well. And it's also, I think, reflected some of the regulatory approvals we get. We feel like we've got a very, you know, broad mandate of what we can do with the system today.

We always felt like advanced energy was the number one thing we needed to add, and we're glad we added it. So we'll continue to consider bringing, you know, articulation to as many geographies as it makes sense, because I think it will have its place. But for us to be able to stay focused on cost per procedure similar to lap, which has really propelled us into some of these, you know, reimbursement-favorable decisions we had, it's just not always the front and center, you know, product we feel like we've got to bring next.

So, a long answer to your question, but I wanted to try to cover it from a couple of different aspects.

Lawrence Soren Keusch

Yes. Thank you. That was very helpful. And then -- look, I know that you're not, at this point, ready to provide any quarterly system guidance. But I guess the one question that I was hoping that you might be able to shed a little light on, if you had to think about the second half of the year and you talked about at least one U.S. -- excuse me, an OUS installation that should occur during the third quarter. As we think about the second half of the year, do you think that you can actually place U.S. systems? Or should we really be thinking about it, again, a -- an OUS-dominated second half for system installations?

Todd M. Pope

Yeah, good question. As we said, as we kind of wrapped up our prepared comments, you know, we feel like we expect to show meaningful commercial progress in the back half. So, that's, obviously, kind of related to our first half. We believe that all of our geographies should contribute to that, frankly -- EMEA, Asia and the U.S., for sure. We believe that all three should contribute to the -- a meaningful back half commercial progress.

Lawrence Soren Keusch

Okay. And then, last one, and maybe for Joe. Just -- again, just trying to understand here from a -- sort of a revenue outlook. Is there anything that you can sort of help us think about, you know, how we should be thinking about revenues for the year now that you've sort of had the first half and you got some visibility into your pipeline?

Joseph P. Slattery

Hi, Larry, it is Joe. I'm sorry that, you know, we're not giving out guidance. So I'm not sure there's any way I can answer that question.

Lawrence Soren Keusch

Okay, appreciate it. Thanks, guys.

Todd M. Pope

Alright. Thanks, Larry.

Operator

That concludes our question-and-answer session for today. I will turn the call back over to Todd Pope for closing remarks.

Todd M. Pope

Well, thank you, again, for joining us on the call today. And we certainly look forward to updating you on our next quarterly call. Thank you.

Operator

That does conclude our conference for today. Thank you for participation in today's conference. You may now disconnect at this time.