
**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, 2018

Date of Report (date of earliest event reported)

TransEnterix, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

0-19437
(Commission
File Number)

11-2962080
(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 August 7, 2018, TransEnterix, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the second quarter ended June 30, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 7, 2018, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results for the second quarter ended June 30, 2018. The Company had issued a press release on July 24, 2018 to announce the scheduling of the conference call. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.2.

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

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release, dated August 7, 2018](#)

99.2 [August 7, 2018 conference call script](#)

SIGNATURES

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

Date: August 9, 2018

TransEnterix, Inc.

/s/ Joseph P. Slattery

Joseph P. Slattery
EVP and Chief Financial Officer

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

RESEARCH TRIANGLE PARK, N.C.—(BUSINESS WIRE)—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 2018.

Recent Highlights

- Total revenue of \$6.4 million, including the sale of four Senhance Systems
- Received FDA clearance for expanded indications for use for Senhance System
- Filed FDA 510(k) submission for additional Senhance System Instruments including 3mm diameter instruments
- Entered into financing agreement providing the company with up to \$40 million in term loans

“Our performance during the second quarter was solid as we continued to drive system sales both in the U.S. and abroad, while simultaneously making significant progress towards our 2018 goals, including the expansion of Senhance’s indications for use and broadening our portfolio of instruments,” said Todd M. Pope, President and CEO at TransEnterix. “We look forward to leveraging the significant progress we made during the first half of the year to drive increased global adoption of our Senhance System.”

Commercial and Clinical Update

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

On May 29, 2018, the Company received FDA 510(k) clearance for expanded indications of its Senhance System for laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery. There are approximately 760,000 inguinal hernia and 1.2 million laparoscopic cholecystectomy procedures performed annually in the U.S. With this clearance, Senhance System’s total addressable annual procedures in the U.S. has more than doubled to over three million.

On June 7, 2018, the Company announced that it had filed an FDA 510(k) submission for additional Senhance System instruments, including 3 millimeter diameter instruments.

Second Quarter Financial Highlights

For the three months ended June 30, 2018, the Company reported revenue of \$6.4 million as compared to revenue of \$1.6 million in the three months ended June 30, 2017. Revenue in the second quarter of 2018 included \$4.7 million in system sales, \$1.5 million in instruments and accessories, and \$200 thousand in services.

For the three months ended June 30, 2018, total net operating expenses were \$18.5 million, as compared to \$13.1 million in the three months ended June 30, 2017.

For the three months ended June 30, 2018, net loss was \$34.2 million, or \$0.17 per share, as compared to a net loss of \$14.7 million, or \$0.11 per share, in the three months ended June 30, 2017.

For the three months ended June 30, 2018, adjusted net loss was \$11.7 million, or \$0.06 per share, as compared to an adjusted net loss of \$11.2 million, or \$0.08 per share in the three months ended June 30, 2017, after adjusting for expenses related to the sale of SurgiBot assets, loss on extinguishment of debt, and non-cash charges for amortization of intangible assets, change in fair value of contingent consideration, and change in fair value of warrant liabilities.

On May 23, 2018, the Company entered into a loan and security agreement providing the company with up to \$40.0 million in term loans. The initial tranche of the term loan, \$20 million, was received at closing. The Company will be eligible to draw on the second tranche of \$10 million upon achievement of certain Senhance System revenue-related milestones for its 2018 fiscal year, and a third tranche of \$10 million upon achievement of designated trailing six months GAAP net revenue from Senhance sales. On the date of closing, the Company repaid all amounts owed under their previous loan provider.

The Company had cash and restricted cash of approximately \$98.5 million as of June 30, 2018. The Company now anticipates that it has sufficient cash to fund the business into 2020, exclusive of the \$20 million in potential future debt tranches.

Conference Call

TransEnterix, Inc. will host a conference call on Tuesday, August 7, 2018 at 8:30 AM ET to discuss its second quarter 2018 operating and financial results. To listen to the conference call on your telephone, please dial (844) 804-5261 for domestic callers or (612) 979-9885 for international callers and reference conference ID 4388237 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 gain from sale of SurgiBot assets, amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities, and loss on extinguishment of debt. These financial measures are presented on a basis other than in accordance with U.S. generally accepted accounting principles (“Non-GAAP Measures”). In the tables that follow under “Reconciliation of Non-GAAP Measures,” we present adjusted net loss and adjusted net loss per share, reconciled to their comparable GAAP measures. These items are adjusted because they are not operational or because these charges are non-cash or non-recurring and management believes these adjustments are meaningful to understanding the Company’s performance during the periods presented. These Non-GAAP Measures should be considered a supplement to, not a substitute for, or superior to, the corresponding financial measures calculated in accordance with GAAP.

Forward-Looking Statements

This press release includes statements relating to the 2018 second quarter results and plans for 2018 and beyond. These statements and other statements regarding our future plans and goals constitute “forward looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether we have made significant progress towards our 2018 goals, including the expansion of Senhance’s indications for use and broadening our portfolio of instruments; whether we can leverage the significant progress from the first half of the year to drive increased global adoption of our Senhance System and whether the Company has sufficient cash to fund the business into 2020, exclusive of the \$20 million in potential future debt tranches. For a discussion of the risks and uncertainties associated with TransEnterix’s business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 8, 2018 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Revenue	\$ 6,389	\$ 1,584	\$ 11,156	\$ 3,530
Cost of revenue	3,732	972	6,287	2,306
Gross profit	2,657	612	4,869	1,224
Operating Expenses (Income)				
Research and development	5,281	5,070	10,546	11,925
Sales and marketing	6,046	3,749	12,016	7,472
General and administrative	3,627	2,719	6,303	5,768
Amortization of intangible assets	2,743	1,687	5,570	3,323
Change in fair value of contingent consideration	812	(774)	1,439	453
Issuance costs for warrants	—	627	—	627
Gain from sale of SurgiBot assets, net	37	—	(11,959)	—
Total Operating Expenses (Income)	18,546	13,078	23,915	29,568
Operating Loss	(15,889)	(12,466)	(19,046)	(28,344)
Other Income (Expense)				
Change in fair value of warrant liabilities	(17,507)	(2,326)	(15,678)	(2,326)
Interest expense, net	(1,736)	(622)	(2,122)	(956)
Other income (expense)	1	(40)	(57)	(100)
Total Other Income (Expense), net	(19,242)	(2,988)	(17,857)	(3,382)
Loss before income taxes	\$ (35,131)	\$ (15,454)	\$ (36,903)	\$ (31,726)
Income tax benefit	883	741	1,773	1,599
Net loss	\$ (34,248)	\$ (14,713)	\$ (35,130)	\$ (30,127)
Other comprehensive loss				
Foreign currency translation (loss) gain	(4,398)	5,430	(2,090)	6,563
Comprehensive loss	\$ (38,646)	\$ (9,283)	\$ (37,220)	\$ (23,564)
Net loss per share – basic and diluted	\$ (0.17)	\$ (0.11)	\$ (0.17)	\$ (0.24)
Weighted average common shares outstanding – basic and diluted	204,504	132,386	202,214	127,052

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

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	\$ 97,743	\$ 91,217
Accounts receivable, net	2,210	1,536
Inventories	11,040	10,817
Interest receivable	104	80
Other current assets	7,243	9,344
Total Current Assets	<u>118,340</u>	<u>112,994</u>
Restricted cash	750	6,389
Property and equipment, net	6,676	6,670
Intellectual property, net	45,909	52,638
Goodwill	70,813	71,368
Other long term assets	259	192
Total Assets	<u>\$ 242,747</u>	<u>\$ 250,251</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 4,108	\$ 3,771
Accrued expenses	10,270	10,974
Deferred revenue	1,083	1,088
Deferred gain from sale of SurgiBot assets	—	7,500
Contingent consideration – current portion	547	719
Notes payable – current portion, net of debt discount	—	4,788
Total Current Liabilities	<u>16,008</u>	<u>28,840</u>
Long Term Liabilities		
Contingent consideration – less current portion	12,915	11,699
Notes payable – less current portion, net of debt discount	18,952	8,385
Warrant liabilities	22,708	14,090
Net deferred tax liabilities	6,446	8,389
Total Liabilities	<u>77,029</u>	<u>71,403</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at June 30, 2018 and December 31, 2017; 207,712,291 and 199,282,003 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	207	199
Additional paid-in capital	645,332	621,261
Accumulated deficit	(482,759)	(447,640)
Accumulated other comprehensive income	2,938	5,028
Total Stockholders' Equity	<u>165,718</u>	<u>178,848</u>
Total Liabilities and Stockholders' Equity	<u>\$ 242,747</u>	<u>\$ 250,251</u>

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

	Six Months Ended June 30,	
	2018	2017
Operating Activities		
Net loss	\$(35,130)	\$(30,127)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Gain from sale of SurgiBot assets, net	(11,959)	—
Depreciation	1,277	1,142
Amortization of intangible assets	5,570	3,323
Amortization of debt discount and debt issuance costs	495	43
Stock-based compensation	4,204	3,679
Deferred tax benefit	(1,799)	(1,580)
Loss on extinguishment of debt	1,400	308
Change in fair value of warrant liabilities	15,678	2,326
Change in fair value of contingent consideration	1,439	453
Changes in operating assets and liabilities:		
Accounts receivable	(762)	(487)
Interest receivable	(24)	39
Inventories	(1,560)	(862)
Other current and long term assets	1,905	(1,473)
Accounts payable	404	(1,909)
Accrued expenses	(359)	(390)
Deferred revenue	31	—
Net cash and cash equivalents used in operating activities	<u>(19,190)</u>	<u>(25,515)</u>
Investing Activities		
Proceeds related to sale of SurgiBot assets, net	4,496	—
Purchase of property and equipment	(358)	(1,397)
Purchase of intellectual property	—	(398)
Proceeds from sale of property and equipment	32	—
Net cash and cash equivalents provided by (used in) investing activities	<u>4,170</u>	<u>(1,795)</u>
Financing Activities		
Payment of notes payable	(15,305)	(13,343)
Proceeds from issuance of debt and warrants, net of issuance costs	18,870	13,196
Payment of contingent consideration	(395)	—
Proceeds from issuance of common stock and warrants, net of issuance costs	2	29,193
Taxes paid related to net share settlement of vesting of restricted stock units	—	(168)
Proceeds from issuance of common stock related to sale of SurgiBot assets	3,000	—
Proceeds from exercise of stock options and warrants	9,813	—
Net cash and cash equivalents provided by financing activities	<u>15,985</u>	<u>28,878</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(78)</u>	<u>2</u>
Net increase in cash, cash equivalents and restricted cash	887	1,570
Cash, cash equivalents and restricted cash, beginning of period	<u>97,606</u>	<u>34,590</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 98,493</u>	<u>\$ 36,160</u>
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 599	\$ 368
Supplemental Schedule of Noncash Investing and Financing Activities		
Transfer of inventories to property and equipment	\$ 1,055	\$ —
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	\$ 7,060	\$ —

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
(Unaudited, U.S. Dollars, in thousands)				
Net loss	\$(34,248)	\$(14,713)	\$(35,130)	\$(30,127)
Adjustments				
Gain from sale of SurgiBot assets, net	37	—	(11,959)	—
Amortization of intangible assets	2,743	1,687	5,570	3,323
Change in fair value of contingent consideration	812	(774)	1,439	453
Change in fair value of warrant liabilities	17,507	2,326	15,678	2,326
Loss on extinguishment of debt	1,400	308	1,400	308
Adjusted net loss	<u>\$(11,749)</u>	<u>\$(11,166)</u>	<u>\$(23,002)</u>	<u>\$(23,717)</u>
(Unaudited, per diluted share)				
Net loss per share	\$ (0.17)	\$ (0.11)	\$ (0.17)	\$ (0.24)
Adjustments				
Gain from sale of SurgiBot assets	0.00	—	(0.06)	—
Amortization of intangible assets	0.01	0.02	0.03	0.03
Change in fair value of contingent consideration	0.00	(0.01)	0.00	0.00
Change in fair value of warrant liabilities	0.09	0.02	0.08	0.02
Loss on extinguishment of debt	0.01	0.00	0.01	0.00
Adjusted net loss per share	<u>\$ (0.06)</u>	<u>\$ (0.08)</u>	<u>\$ (0.11)</u>	<u>\$ (0.19)</u>

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

- a) Gain from sale of SurgiBot assets relates to amounts received from Great Belief International Limited in excess of the carrying amount of the assets sold.
- b) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.
- c) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
- d) The Company's Series A and Series B Warrants are measured at fair value using a simulation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected volatility, holding cost and the risk-free interest rate for the term of the warrant. The warrant liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
- e) 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. In May 2017 in connection with its entrance into the Innovatus Loan Agreement, the Company repaid its then-existing credit facility with Silicon Valley Bank and Oxford Finance LLC. The Company recognized a loss of \$308,000 on the extinguishment of notes payable which is included in interest expense on the consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017.

Exhibit 99.2
Company: TRANSENERIX, INC.
Conference Title: Q2 2018 TransEnterix Inc. Earnings Call
Moderator: Mark Klausner
Date: August 7, 2018

PRESENTATION

Operator

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

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

Good morning, and thank you for joining us for TransEnterix's second quarter conference call. Joining us on today's call are TransEnterix's President and Chief Executive Officer, Todd Pope; and its Executive Vice President and Chief Financial Officer, Joe Slattery.

I would like to remind you that this call is being webcast live and recorded. A replay of the event will be available following the call on our website. To access the webcast, please visit the Events link in the IR section of our website, transenterix.com.

Before we begin, I would like to caution listeners that certain information discussed by management during this conference call 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, 2017, and the Form 10-Q for the quarter ended June 30, 2018, expected to be filed shortly.

During the call, we will also present certain non-GAAP financial information relating 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 forecasts and strategic plans, to benchmark our performance externally against competitors, and for certain compensation decisions. Reconciliations between U.S. GAAP and non-GAAP results are presented in the tables accompanying our earnings release, which can be found in the Investor Relations section of our website. With that, it's my pleasure to turn the call over to TransEnterix President and Chief Executive Officer, Todd Pope.

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

Thank you, Mark, and welcome to our second quarter 2018 conference call. On today's call, I'll start by discussing our recent accomplishments, then turn the call over to Joe for a second quarter financial update. We will then open the line up for your questions.

Second quarter was strong commercially, as the continued development of our global pipeline drove four system sales, one in the U.S. and three in the EMEA region. In addition, we continued to make meaningful progress toward our key goals for 2018.

As a reminder, those goals are:

- maximizing the effectiveness of our global commercial sales infrastructure,
- expanding the portfolio of instruments available for use with Senhance,
- expanding Senhance's indications for use, and
- continuing to obtain regulatory clearances in key geographies.

I would now like update you on our progress and will begin with an update on our commercial and clinical activities in each of our geographic regions.

Starting in the U.S., in the second quarter, we sold a system to LSU Health, with the system being installed at UMC New Orleans. UMC New Orleans is home to a well-respected academic research hospital and has partnerships with a number of colleges and universities in the New Orleans area, including LSU Health New Orleans and the Tulane School of Medicine. UMC New Orleans plans to utilize the Senhance in gynecologic, colorectal and general surgery, and multiple surgeons have already been trained. And I am pleased to announce that UMC New Orleans recently began using Senhance clinically, performing the first GYN case in the United States just last week.

On our last call, we announced that Florida Hospital performed the first-ever Senhance cases in the U.S. in the second quarter. Since that time, their utilization has expanded beyond colorectal to include both unilateral and bilateral inguinal hernia repair as well as cholecystectomy. We are encouraged with their expansion into new procedures and will continue to work alongside their surgical team to train additional surgeons on Senhance.

The feedback we've received thus far in the U.S. is very positive and consistent with our experience in Europe. Surgeons view the safety of haptic feedback and the ability to control three robotic arms at the same time with eye-tracking camera control as key differentiating features of the Senhance. Surgeons also continue to comment on the ergonomic benefits relative to laparoscopy, noting a reduction in fatigue as well as a reduction in discomfort and pain. Surgeons have also commented that they see the potential for Senhance to extend careers by reducing the physical stresses imposed upon laparoscopic surgeons on a daily basis.

We remain focused on building out our presence in the U.S. As we increase the number of systems installed and in use, our ability to convert pipeline hospitals into sales also increases. Those active sites generate clinical data, increase the number of opportunities for pipeline surgeons to view live cases, and increase our ability to provide surgeon proctoring and training before and after a system has been installed.

In the second quarter, we continued to generate increasing interest for Senhance in the U.S. We attended two conferences during the quarter. Of note was SAGES, the 16th World Congress of Endoscopic Surgery held in Seattle, Washington in April. During the conference, several thousand attendees had an opportunity to view or interact with the Senhance. A surgical program was delivered by Dr. Dietmar Stephan, reviewing results of his first 173 general surgery cases with Senhance across a wide range of procedures, including hernia repairs, gallbladder, foregut and colorectal surgeries. This presentation was well attended by U.S. surgeons and a contingent of surgeons from around the world.

In an effort to introduce a greater number of interested surgeons and hospitals to the Senhance, we continue to host a variety of mobile events throughout the United States. These multiday events allow us to provide surgeons, clinical staff and executives quality hands-on time with Senhance by bringing the Senhance to them. In the second quarter, over 75 physicians were able to test drive and evaluate the system at these events.

To highlight one such event that speaks to both the benefit of these programs as well as the significant interest Senhance is receiving in the market, we recently hosted a week-long mobile event at an academic medical center. This gave us exposure to over 20 surgeons from six different hospitals and hospital networks at one location and included extended hands-on experience with the Senhance. We continue to be very pleased with the steady flow of surgeons, administrators and surgical staff actively looking to educate themselves on Senhance in the United States.

Moving to EMEA. We sold three systems within the region during the second quarter. Each of these systems were sold by one of our distribution partners to an end-user hospital. We continue to be pleased with the ability of our distribution partners to drive system sales, and their understanding of the local landscape is incredibly valuable when working with a complex sale in the hospitals. Based on the success of our distribution partners in EMEA, we are continuing to focus our internal spend towards distributors and distribution support, which includes training, regulatory, language continuity, service and sales support.

In the United Kingdom, the NHS tender discussed in our prior call has been a positive for us and we're beginning to see solid leads materialize, and we look at 2019 for this tender process to deliver revenue. We also continue to be encouraged with our clinical progress in EMEA. More surgeons are being trained on the Senhance, which is increasing utilization as well as the breadth of procedures being performed.

In the Asia Pacific region, we made meaningful progress in Japan. Japan has the second largest robotics market in the world, behind only the United States, and we continue to see significant in-bound interest in that region. As a result, we've already set up a Japanese subsidiary and built

a small team to manage the regulatory process and plan our future commercial efforts. Much like in Europe and the United States, successfully entering the market is impacted by our ability to provide interested parties with access to Senhance, be it through surgeons viewing in-person surgeries, proctoring or training.

As we mentioned on our last call, we've begun performing clinical cases at Saitama Medical University. We believe that having an established customer base within Japan will be extremely beneficial as we look to drive increased sales, initially through sales via physician's import license, and once approved by the regulatory body, a traditional sales infrastructure. We've begun the regulatory process in Japan, but would remind you that registration of medical devices in this market is complicated and can take up to 3 years.

In Taiwan, we continue to progress through the regulatory approval pathway. Earlier this year, we received approval from the Taiwanese FDA for the Senhance system, and we are now working through the regulatory process for our instruments, and remain on track for a fourth quarter 2018 clearance. With this clearance, we would expect to see commercial momentum build in 2019 and beyond.

Before we move on from our commercial discussion, I would like to provide you with an update on our progress thus far in the third quarter. We currently anticipate three Senhance sales in the third quarter, one in the U.S. and two in EMEA. Given that the third quarter is traditionally slow, we're encouraged by this performance. MMC Veldhoven, a major hospital in the Netherlands, has made a public announcement of their intention to purchase the Senhance, and this potential sale is included in our expectations.

Earlier this year, we announced several new product initiatives for 2018, and I'm pleased to report that we remain on track with the timeline we communicated on all of these programs. These programs are: obtaining FDA clearance in launching 3-millimeter instruments in the U.S., launching the ultrasonic energy device and launching 5-millimeter articulating instruments. We filed a 510(k) submission for the 3-millimeter instruments in June, which was ahead of our expectations, and continue to expect clearance by the end of 2018. We continue to anticipate achieving a CE Mark for the ultrasonic energy device and articulating instruments by the end of 2018. And in addition, we intend to submit for 510(k) clearance of 5-millimeter articulating instruments by the end of 2018. We believe that the launch of these products will not only drive additional revenue per procedure over time, but also accelerate our Senhance sales pipeline.

Shifting gears to our efforts to expand the Senhance's indications for use. In the second quarter, we received FDA 510(k) clearance for expanded indications for Senhance to include both laparoscopic inguinal hernia repair and laparoscopic gallbladder surgery. These are both high volume procedures traditionally performed laparoscopically, and approximately double our addressable procedure market to over three million procedures per year.

In the U.S., Senhance is now cleared for laparoscopic, colorectal, gynecologic, inguinal hernia and cholecystectomy surgery. This enables Senhance to be used for some of the most common abdominal surgeries, including procedures in general surgery and gynecology. We believe this indication expansion significantly increases the applicability of Senhance to more institutions, particularly those with a busy general surgery practice.

I'll now turn the call over to Joe to review our financial results.

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

Thanks, Todd, and good morning, everyone.

For the three months ended June 30, 2018, we reported revenue of \$6.4 million comprised of \$4.7 million in Systems, \$1.5 million in Instruments and accessories, and \$200,000 in Services. Gross margin for the quarter was 41.6%, up from 38.6% in the prior year quarter. The increase in gross margin was due primarily to improved manufacturing efficiency as a result of higher sales.

R&D expenses in the quarter increased to approximately \$5.3 million as compared to the prior year period at \$5.1 million, primarily due to increased personnel and project expenses.

Sales and marketing expenses in the quarter increased to \$6 million from \$3.7 million in the prior year period as we 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 \$3.6 million from approximately \$2.7 million in the prior year period, primarily due to employee-related expenses to support the business growth.

GAAP net loss for the quarter was \$34.2 million or \$0.17 per share compared to a GAAP net loss of \$14.7 million or \$0.11 per share in the prior year period.

Adjusted net loss for the quarter, which excludes loss on extinguishment of debt, non-cash amortization of intangibles, non-cash change in fair value of warrant liabilities and contingent consideration and the gain from the sale of the SurgiBot assets, was \$11.7 million or \$0.06 per share compared to adjusted net loss of \$11.2 million or \$0.08 per share in the prior year period.

On May 23, the Company entered into a loan and security agreement with Hercules Capital, providing the company with up to \$40 million in term loans. The initial tranche of the term loan, \$20 million, was received at closing. The Company will be eligible to draw on the second tranche of \$10 million upon achievement of revenue-related milestones for its 2018 fiscal year, and a third tranche of \$10 million upon achievement of a trailing six months revenue milestone. On the date of closing, the Company repaid all amounts owed under the previous loan.

We finished the second quarter with cash of approximately \$98.5 million, of which \$750,000 was restricted cash. We anticipate that this amount is sufficient to fund the business into 2020, exclusive of the \$20 million in future debt tranches.

Todd?

Todd M. Pope

Thank you, Joe. I'm extremely proud of what our team has accomplished in the first half of 2018. We've executed against our commercial goals and making progress toward our other operational goals.

We are pleased to have sold six systems in the first half of the year and our commercial momentum has continued into the third quarter.

We've made significant progress on our portfolio expansion initiatives and the expansion of our indications for use, both of which we expect to broaden the applicability of Senhance, helping to drive adoption in the future.

Overall, we continue to be very enthusiastic about the strong growth trends in surgical robotics and Senhance's unique attributes and positioning in the market. We look forward to building on our recent momentum as we drive to continue the adoption of Senhance.

And with that, we'd like to open up the line for your questions.

QUESTIONS AND ANSWERS**Operator**

(Operator Instructions) Our first question comes Glenn Novarro with RBC Capital Markets.

Glenn John Novarro - *RBC Capital Markets, LLC, Research Division - Analyst*

Hi, good morning. Todd, a couple questions for you on the U.S. market. So you sold one to Orlando in the fourth quarter of last year, we've now sold one to LSU. Can you talk about the lead funnel that the sales force is creating? And the reason I'm asking is because on past calls, you've talked about, it takes 4 to 6 quarters to really start actively selling robots. And I'm just wondering, when we finally hit that inflection point where we start to see more robot sales? So that's my first question.

Todd M. Pope

Sure, Glenn. And thanks for the question. Yes, we're - with our U.S. pipeline, we're pleased it's developing right in line with what we would say is our expectations. We continue to believe, as you said, that the pipeline in capital equipment like this takes 4 to 6 quarters. We got approval in the U.S. in the fourth quarter of last year. So we're out in the market 2 quarters, so far, in 2018. So we're, kind of, in the early, I think, ramp of that pipeline development. So we feel great about that. And going into the Q4 and into 2019, the pipeline is progressing just as we would hope.

Glenn John Novarro

Okay. So from our point of view, is the inflection really going to be the first half of next year verses at any point this year?

Todd M. Pope

I think it's just going to be a steady increase. I don't think we're going to see one moment in time where that's going to have an inflection. We've got a group of sales folks out there, as we talked about. We're continuing to be at shows, continuing to be at the big conferences, continuing to publish more, we're having more success in Europe, which plays well here when people can hear surgeons speak about their experiences. We're having more videos that surgeons can watch on how the Senhance is being used around the world, which really helps. So that just continues to build. And we talked about in the call, a moment ago, we're doing mobile events. We had 75 surgeons be able to spend extended time in the second quarter with the system by taking it to their hospital, or their geography, they don't have to travel. This all just continues to build momentum. So we feel really good about where we are. And we think we're going to see continued conversion of that pipeline to sales.

Glenn John Novarro

And then, one follow-up for the U.S. So LSU, you've already placed a robot, they've done their first case. Did LSU already have a robot? Or this is the first robot for them? And then, just broadly speaking, as you talk to hospitals in the U.S., what kind of traction are you getting? Is it easier to get traction with hospitals that already have a robot? Or is it easy get traction for hospitals that don't have a robot and are looking at Senhance as their first move into robotics?

Todd M. Pope

Sure, as far as the first part of your question, most hospitals are not stand alone, they're part of some type of system. And most of those systems have exposure to a robot at one or all of their locations. So the majority of the folks we're talking to have been using a robot for some time. But what we find is, their usage is really clustered down to a handful of procedures. So what people are excited about, they already are known in their community for maybe a destination for patients for robotic surgery, but it's been a fairly narrow procedure range. With Senhance, we're bringing features to the market that they've not seen up to this point in robotics, they're able to have 5-millimeter instruments going down to three, which is a real benefit for patients. The surgeons really love the safety of haptic feedback. We have individual arms, so their set up can be very similar to laparoscopic surgery, which they love. The ability to have eye-tracking control is not only a nice feature, but this allows them to simultaneously control three robotic arms at once, they've just not been able to do that up to this point. They worked hard to get contracts for certain trocars. They're able to use those trocars with our system. They're able to use certain video systems that they already have in place in the hospital and they like that because it's an efficient use of their capital that they've already invested in. But videos, also a physician preference item, the physicians love to be able to use both in laparoscopic surgery and with the Senhance. And you cap all that off with the ability to take their cost per procedure down very similar to what they're experiencing with laparoscopic surgery today, which is a vast departure from the cost per procedure of robotics currently. All that rolls into current hospitals that have

robotics placed are excited about all the things we've just talked about, expanding their use of robotics. Now they can market robotics to a larger patient base, many more procedures, and surgeons within their hospital are finally seeing a system with Senhance that is really custom built for them and they're excited about taking many more procedures that haven't been ideal for robotics up to this point and using them with Senhance. So I would say, all that really adds up to the fact of people usually are understanding how to market robotics within their institution, but that's been fairly limited, and Senhance really broadens the aperture of the different procedures we can go after. So I think all that adds up to, most of the systems that we are talking to, have a current robot but they're excited about proliferating their use.

Glenn John Novarro

Okay, great. Thanks, Todd. I'll get back into queue.

Todd M. Pope

Thanks, Glenn.

Operator

Thank you. Our next question comes from Rick Wise with Stifel. Your line is now open.

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

Good morning, Todd. Let me start with the third quarter guidance. If I heard you correctly, three systems, one in the U.S., two in EMEA, that's already one more than we were modeling. And just because I want to understand a couple things about it, I want to know what you're thinking. When you share a number like that with us, does that mean, there's very likely virtually no possibility of more in the quarter? Or this is your best sales right now? Or just how do we think about it? And maybe just as you answer that, Todd, maybe talk just a little bit more about the sales force, both U.S. and international, where are you now? Are you where you need to be? Is the sales force stable? Just a little more color about the team and how you're thinking about it evolving from here, based on this early success?

Todd M. Pope

Certainly, and thanks for calling in. I appreciate your question, Rick. As far as the first question, as we go quarter-to-quarter, we're understanding a little bit more about the sales process and how Senhance is being positively received in the market. So we're going to try to be a little more forward looking with what we think our results will be. So this quarter, we do- we are guiding to three systems, as you said, one in the U.S., two in EMEA. And that's a little different than last quarter, when we already had several systems sold and delivered by the time we had our call. We don't have all three of those sold and delivered yet, but it's guidance. As you know, Q3 is typically a slow quarter for capital anyway, particularly in the EMEA region where more of our sales have come to- come from up to this point. So we feel actually good that we're able to guide

toward three. We think that's a good number. We think we'll be able to get that. We're not insinuating any more or less than that. We think we'll get to three. We don't have those today, but we are trying to provide a little more color as we go from quarter-to-quarter. As far as your question, where we are with sales. We feel good. Relatively speaking, we still have a small unit sales force in the U.S., kind of in the mid-teens as we've talked about in the past. So where we're focusing, we're having good momentum. Now that we're understanding kind of the way that Senhance is being received, we probably will continue to, as our pipeline progresses, look at different geographies and add people as it makes sense when we get a sales person that has multiple leads and they really can't follow up with the timeliness that we want, we'll cut in another territory there. And then over time, we'll move out a little further west, and we haven't really put a footprint out in the western part of the United States. And then, in Europe, as we've talked about, we have a handful of direct folks that are out there working with the customers with Senhance, but as our product has more and more success, and now that more product is being used in EMEA with Senhance, more distributors are coming to us saying they think that the Senhance would be an incredible addition to their portfolios. So as we talked about in the call, probably lean more toward resources being invested in distribution partners in Europe and other parts of the world. And we think that'll be a little more effective for us going forward into 2019.

Frederick Allen Wise

That's great. And I apologize for doing this, but just, Todd, you - in response to Glenn's question, you were talking about seasonality and your basic feeling is that maybe because of, such a, if I can put words in your mouth, you're at such an early stage that seasonality is going to be probably a little less than a factor given all the momentum from launch, and training and education and instrument approvals, et cetera. But I think there's still some fourth quarter seasonality and that whatever your third quarter number is, it's reasonable to imagine that fourth quarter will not be slightly better, but a little more than that, given all these trends, and given the normal fourth quarter, some capital budget, let's get it done, this year kind of mentality. Is that the right way to think about it?

Todd M. Pope

Yes, I think as you said, we still are to a point where we're providing guidance that we did give commentary in Q3 that it's typically seasonally slow. And I think in fairness, Q4 is typically a little stronger quarter for capital equipment for multiple reasons, and a lot of patients have reached deductible limits, so they're scheduling surgeries by year-end. So we think that, although Q3 is typically slow, we think Q4 is typically stronger for capital equipment, and we think we'll fit right into that trend. We feel really good the way we're coming out of the summer and heading into the back part of the year with our pipeline, both in the U.S. and abroad. Remember, we talk a lot about how we're building things in the U.S. and we're excited about that, but we've got a very strong footprint now in the EMEA region. And as we talked about, we're excited about the Asia Pacific also. We're certainly attacking the globe here in these early days of commercialization.

Frederick Allen Wise

And one last one from me about - as you said Asia Pacific. You highlighted and reiterated your expectation that we'll see that fourth quarter '18 Taiwanese approval, setting you up nicely for '19. How do we think about that market and that opportunity? And do you think it's possible if, assuming the approval comes, will we see (inaudible) in '19 or no, this is more like 2020 and beyond? Thanks.

Todd M. Pope

Yes, Asia Pacific is, obviously, country by country, your specific question is on Taiwan. As you said, we received the approval for the system earlier this year, we're now trying to get instruments approved by the end of the year. And if we get that approved by the fourth quarter 2018, we think we're going to have pretty good commercial momentum heading into 2019. So I think when we think about our four- to six- quarter sales cycle that also is true in Asia Pacific, but we have been out there working with some of those markets to really market develop, talk to them about Senhance. And you have to understand, we go to these big shows, like the American College of Surgery and SAGES and AAGL and ASCRS, a lot of surgeons from Europe and Asia Pacific are there. So they're getting to see surgeons stand up and present the Senhance, show the video of their cases, how they're doing different procedures, and it's really being received positively. So we're not starting from a standing start in some of these Asia Pacific regions, specifically Taiwan. We feel like we can have some success in 2019 for those reasons.

Frederick Allen Wise

Thanks Todd.

Todd M. Pope

Thank you, Rick.

Operator

Thank you. Our next question is a follow-up from Glenn Novarro with RBC Capital Markets. Your line is now open.

Glenn John Novarro

Just some follow-up clarification questions. One, Todd, the three that you expect to sell, the three systems, are these at the point where there are contracts sitting on a CFO's desk and we're just waiting on signatures? Just want to get a sense of why you're so confident that you'll sell three. And then, as a follow-up, can you give us a sense of, in 2Q what the average selling price for the systems were? The reason I'm asking is, because you sold three, we plugged into the model and it seems like pricing is jumping around a bit, so maybe help us with the pricing. Thanks.

Todd M. Pope

Sure, well, I will just say in the Q3, that we're guiding the three systems. It's a long process. And I think we - fair to say, we're at the very end of those processes. So we feel confident enough that we have enough going on to guide toward three systems. So we feel pretty comfortable in that respect.

Glenn John Novarro

And then on pricing?

Joseph P. Slattery

Yes, Glenn, this is Joe. So the way we manage the expectations in terms of the ASP is, typically worldwide we sell a system anywhere from \$1.2 million to \$1.8 million, the majority of the sales have fallen in that range. Obviously, they're very varied because of the configuration of the system may have three arms or four arms, it may come with a vision system or without a vision system. And then, there's geographic diversity and currency as well. So the way we guided it for you to think about this is, in Europe the typical initial purchase order is at the high end of that range, with about 80% of that PO in the system, about 15% of it being instruments and accessories and about 5% of it being reserved for service. And in the U.S., those ratios are about the same and- but it's more at the lower end of that range.

Glenn John Novarro

Okay. And let me ask you one other question, Todd, this is just on the pipeline. So you're able to double your TAM in the second quarter with new indications. Can you talk to us about anymore surgical indications in the pipeline? Thanks.

Todd M. Pope

Yes, thank you, Glenn. And it's a good question on our indications for use. We talk about that as a headline, but sometimes don't dive into it. Being able to double the total available market that's covered under Senhance in the U.S. is a big deal. That is another thing that's really, kind of, widening our pipeline approach. So when we go to a hospital, we not only can talk about colorectal and GYN, but now really get into a lot of the general surgery discussions, which really helps. And we think, as we stand today, that's a good, broad indication of for Senhance, it gives us plenty of opportunity to go out and talk to most anyone in the hospital. So right now, we're going to focus on selling into that indications for use. And as we get more and more clinical experience in Europe, since they had a little bit of a head start and now in the U.S., we'll kind of see what other procedures drive interest and we get clinical data on. But right now, we feel great about where we are, not only in the U.S., but outside the U.S.

Glenn John Novarro

Okay, great. Thank you.

Todd M. Pope

Thank you.

Operator

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

Todd M. Pope

Yes, thanks, everyone, for joining us on the call today. And we certainly look forward to updating you on our progress on our next quarterly call. Good day.