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 5, 2020
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 27560
(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 5, 2020, TransEnterix, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the second quarter ended June 30, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 5, 2020, 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, 2020. The Company had issued a press release on July 22, 2020 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 5, 2020
99.2	August 5, 2020 conference call transcript
104	Cover Page Interactive Data File (formatted in inline XBRL)

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 7, 2020

TRANSENTERIX, INC.
/s/ Anthony Fernando
Anthony Fernando
Chief Executive Officer and President

Exhibit 99.1

TransEnterix, Inc. Reports Operating and Financial Results for the Second Quarter 2020

August 5, 2020

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- August 5, 2020 -- 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 2020.

Recent Highlights

- Submitted CE Mark application for the initial Intelligent Surgical Unit in the second quarter and expect approval by the end of 2020
- Filed FDA 510(k) submission for general surgery indication in the third quarter
- Reduced operating expenses sequentially over the first quarter of 2020 as a result of cost saving initiatives
- Raised approximately $15.0 million in gross proceeds in an underwritten public offering in July of 2020
- The Company now expects to have cash to support its operations into the second quarter of 2021
- Year-to-date, six clinical programs initiated with two additional systems pending installation

“Despite operating in a challenging environment throughout the second quarter, we made significant progress towards our goals for the year, which include increasing system installations, increasing procedure volumes globally, and continuing to gain regulatory approvals for new technologies and expanding indications for use for the Senhance,” said Anthony Fernando, President, and CEO of TransEnterix. “Leveraging the momentum we generated in the first quarter, we were able to sign two new system leases in the quarter while at the same time maintaining the quality of our pipeline. Additionally, we made progress against our portfolio expansion and clinical validation efforts. While procedure volumes were down in the quarter, we saw a strong rebound from April to June which has continued into July. We continue to believe we are well-positioned to deliver on our strategy and bring transformative technology to surgeons, hospitals, and patients globally.”

Commercial and Clinical Update

During the quarter, two Senhance systems were installed, one in the U.S. and one in Europe.

Subsequent to the end of the second quarter, one additional system has been installed in Europe.

Year to date in 2020, the Company has installed six Senhance systems globally and has two systems pending installation.

In late July, the Company filed its 510(k) submission with the FDA for a general surgery indication expansion, as announced on August 4, 2020.

Underwritten Public Offering

On July 6, 2020, the Company announced the closing of an underwritten public offering, raising gross proceeds of approximately $15.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares.

Second Quarter Financial Results

For the three months ended June 30, 2020, the Company reported revenue of $0.7 million as compared to revenue of $3.6 million in the three months ended June 30, 2019. Revenue in the second quarter of 2020 included no system sales, $0.3 million in system leasing and instruments and accessories, and $0.3 million in services.

For the three months ended June 30, 2020, total operating expenses were $13.6 million, as compared to $22.2 million in the three months ended June 30, 2019.

For the three months ended June 30, 2020, net loss attributable to common stockholders was $14.1 million, or $0.27 per share, as compared to a net loss of $20.2 million, or $1.21 per share, in the three months ended June 30, 2019.

For the three months ended June 30, 2020, the adjusted net loss attributable to common stockholders was $10.9 million, or $0.21 per share, as compared to an adjusted net loss of $19.2 million, or $1.15 per share in the three months ended June 30, 2019, after adjusting for the following items: change in fair value of warrant liabilities, amortization of intangible assets, change in fair value of contingent consideration, and deemed dividend related to the conversion of preferred stock into common stock. Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. See the reconciliation from GAAP to Non-GAAP Measures below.

The Company had cash and cash equivalents and restricted cash of approximately $16.2 million as of June 30, 2020.

As a result of restructuring, cost optimization efforts and recent equity financing, together with anticipated cash received from product and instrument sales and leases, we believe that current cash on hand will be sufficient to meet our anticipated cash needs into the second quarter of 2021.

Business Outlook

Given the continued uncertainty that exists within the global healthcare market, we cannot currently predict the specific extent or duration of the impact of the COVID-19 outbreak on our financial and operating results. As a result, we are not providing forward looking revenue guidance at this time.

Conference Call

TransEnterix, Inc. will host a conference call on Wednesday, August 5, 2020, at 4:30 PM ET to discuss its second quarter 2020 operating and financial results. To listen to the conference call on your telephone, please dial 1-855-327-6837 for domestic callers and 1-631-891-4304 for international callers, and reference conference ID 10010432 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

At TransEnterix, Inc., we are digitizing the interface between the surgeon and the patient to improve minimally invasive surgery (MIS) through a new category of care called Digital Laparoscopy. Digitizing the interface enables the use of advanced capabilities like augmented intelligence, connectivity and robotics in laparoscopy, and allows us to address the current clinical, cognitive and economic shortcomings in surgery. The system features the first machine vision system for use in robotic surgery which is powered by the new intelligent Surgical Unit (ISU) that enables augmented intelligence in surgery. The Senhance® Surgical System brings the benefits of Digital Laparoscopy to patients around the world while staying true to the principles of value-based healthcare. Learn more about Digital Laparoscopy with the Senhance Surgical System here: https://Senhance.com/. Now available for sale in the US, the EU, Japan, and select other countries. For a complete list of indications for use, please visit: https://www.transenterix.com/indications-for-use/.

Non-GAAP Measures

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

Forward-Looking Statements

This press release includes statements relating to the current market development and operational plans for the Senhance System, as well as 2020 second quarter financial results and plans for 2020. These statements and other statements regarding our future plans and goals constitute "forward-looking statements" within the meaning of 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 the extent of the impact of the COVID-19 pandemic on our current and future results of operations, whether we will be well-positioned to deliver on our strategy and bring transformative technology to surgeons, hospitals and patients globally, whether we have cash on hand sufficient, together with anticipated cash received from product and instrument sales and leases, to meet our anticipated cash needs into the second quarter of 2021 and whether we can meet the operational goals we have set forth for 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, 2019, which we filed on March 16, 2020 and our other SEC filings. 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,	
	2020	2019	2020	2019
Revenue:				
Product	$ 315	$ 3,342	$ 557	$ 5,171
Service	340	297	698	649
Total revenue	655	3,639	1,255	5,820
Cost of revenue:				
Product	720	2,956	1,633	4,229
Service	693	980	1,518	2,174
Total cost of revenue	1,413	3,936	3,151	6,403
Gross loss	(758)	(297)	(1,896)	(583)
Operating Expenses:				
Research and development	4,257	6,295	8,191	11,950
Sales and marketing	2,901	7,868	7,154	15,542
General and administrative	3,619	4,489	6,968	9,049
Amortization of intangible assets	2,619	2,585	5,183	5,196
Change in fair value of contingent consideration	212	960	1,268	1,958
Restructuring and other charges	—	—	858	—
Acquisition related costs	—	—	—	45
Loss from sale of SurgiBot assets, net	—	—	—	97
Total Operating Expenses	13,608	22,197	29,622	43,837
Operating Loss	(14,366)	(22,494)	(31,518)	(44,420)
Other Income (Expense):				
Change in fair value of warrant liabilities	(114)	2,528	(269)	2,422
Interest income	4	178	31	496
Interest expense	—	(1,061)	—	(2,177)
Other expense	(55)	(191)	(70)	(496)
Total Other Income (Expense), net	(165)	1,454	(308)	245
Loss before income taxes	(14,531)	(21,040)	(31,826)	(44,175)
Income tax benefit	691	869	1,388	1,479
Net loss	(13,840)	(20,171)	(30,438)	(42,696)
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	(412)	—
Deemed dividend related to conversion of preferred stock into common stock	(299)	—	(299)	—
Net loss attributable to common stockholders	(14,139)	(20,171)	(31,149)	(42,696)
Comprehensive loss:				
Net loss	(13,840)	(20,171)	(30,438)	(42,696)
Foreign currency translation gain (loss)	962	1,240	90	(709)
Comprehensive loss	$ (12,878)	$ (18,931)	$ (30,348)	$ (43,405)
Net loss per common share attributable to common stockholders – basic	$ (0.27)	$ (1.21)	$ (0.77)	$ (2.56)
Net loss per common share attributable to common stockholders – diluted	$ (0.27)	$ (1.35)	$ (0.77)	$ (2.68)
Weighted average number of shares used in computing net loss per common share – basic	52,351	16,729	40,628	16,703
Weighted average number of shares used in computing net loss per common share – diluted	52,351	16,814	40,628	16,814

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

	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,603	$ 9,598
Accounts receivable, net	971	620
Inventories	10,857	10,653
Other current assets	6,881	7,084
Total Current Assets	34,312	27,955
Restricted cash	627	969
Inventories, net of current portion	6,334	7,594
Property and equipment, net	6,963	4,706
Intellectual property, net	25,802	28,596
In-process research and development	—	2,470
Net deferred tax assets	40	—
Other long term assets	1,896	2,489
Total Assets	$ 75,974	$ 74,779
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,347	$ 3,579
Accrued expenses	6,840	8,553
Deferred revenue – current portion	868	818
Contingent consideration – current portion	—	73
Total Current Liabilities	10,055	13,023
Long Term Liabilities:		
Deferred revenue – less current portion	—	27
Contingent consideration – less current portion	2,278	1,011
Notes payable - net of issuance costs	2,815	—
Warrant liabilities	187	2,388
Net deferred tax liabilities	—	1,392
Other long term liabilities	1,082	1,403
Total Liabilities	16,417	19,244
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2020 and December 31, 2019; 56,902,140 and 20,691,301 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	57	21
Preferred stock, $0.01 par value, 25,000,000 shares authorized, including 7,937,057 and 0 shares of Series A Convertible Preferred Stock at June 30, 2020 and December 31, 2019, and 0 shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	754,818	720,484
Accumulated deficit	(694,038)	(663,600)
Accumulated other comprehensive loss	(1,280)	(1,370)
Total Stockholders' Equity	59,557	55,535
Total Liabilities and Stockholders' Equity	$ 75,974	$ 74,779

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

	Six Months Ended June 30,	
	2020	**2019**
Operating Activities:		
Net loss	$ (30,438)	$ (42,696)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Loss from sale of SurgiBot assets, net	—	97
Depreciation	1,162	1,126
Amortization of intangible assets	5,183	5,196
Amortization of debt discount and debt issuance costs	—	622
Amortization of short-term investment discount	—	(300)
Stock-based compensation	3,856	6,336
Interest expense on deferred consideration – MST acquisition	—	387
Deferred tax benefit	(1,388)	(1,479)
Write down of inventory	—	761
Change in fair value of warrant liabilities	269	(2,422)
Change in fair value of contingent consideration	1,268	1,958
Changes in operating assets and liabilities:		
Accounts receivable	(350)	2,808
Interest receivable	—	(4)
Inventories	(2,332)	(10,301)
Other current and long term assets	827	(3,689)
Accounts payable	(1,221)	2,499
Accrued expenses	(1,736)	(1,454)
Deferred revenue	22	(862)
Other long term liabilities	(258)	1,879
Net cash and cash equivalents used in operating activities	(25,136)	(39,538)
Investing Activities:		
Purchase of short-term investments	—	(12,883)
Proceeds from maturities of short-term investments	—	55,000
Purchase of property and equipment	(3)	(189)
Net cash and cash equivalents (used in) provided by investing activities	(3)	41,928
Financing Activities:		
Proceeds from issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs	13,525	—
Proceeds from issuance of common stock, net of issuance costs	11,212	—
Proceeds from notes payable, net of issuance costs	2,815	(30)
Taxes paid related to net share settlement of vesting of restricted stock units	(33)	(499)
Payment of contingent consideration	(74)	—
Proceeds from exercise of warrants	3,340	534
Net cash and cash equivalents provided by (used in) financing activities	30,785	5
Effect of exchange rate changes on cash and cash equivalents	17	(32)
Net increase in cash, cash equivalents and restricted cash	5,663	2,363
Cash, cash equivalents and restricted cash, beginning of period	10,567	21,651
Cash, cash equivalents and restricted cash, end of period	$ 16,230	$ 24,014
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ —	$ 1,528
Supplemental Schedule of Non-cash Investing and Financing Activities		
Transfer of inventories to property and equipment	$ 3,403	$ 415
Exchange of common stock for Series B Warrants	$ 2,470	$ —
Transfer of in-process research and development to intellectual property	$ 2,425	$ —
Conversion of preferred stock to common stock	$ 79	$ —

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, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net loss attributable to common stockholders (GAAP)	$ (14,139)	$ (20,171)	$ (31,149)	$ (42,696)
Adjustments				
Loss from sale of SurgiBot assets, net	—	—	—	97
Amortization of intangible assets	2,619	2,585	5,183	5,196
Change in fair value of contingent consideration	212	960	1,268	1,958
Acquisition related costs	—	—	—	45
Change in fair value of warrant liabilities	114	(2,528)	269	(2,422)
Restructuring and other charges	—	—	858	—
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	412	—
Deemed dividend related to conversion of preferred stock into common stock	299	—	299	—
Adjusted net loss attributable to common stockholders (Non-GAAP)	$ (10,895)	$ (19,154)	$ (22,860)	$ (37,822)

(Unaudited, per basic share)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net loss per share attributable to common stockholders (GAAP)	$ (0.27)	$ (1.21)	$ (0.77)	$ (2.56)
Adjustments				
Loss from sale of SurgiBot assets, net	—	—	—	0.01
Amortization of intangible assets	0.05	0.15	0.13	0.31
Change in fair value of contingent consideration	0.00	0.07	0.03	0.13
Acquisition related costs	—	—	—	0.00
Change in fair value of warrant liabilities	0.00	(0.15)	0.01	(0.15)
Restructuring and other charges	—	—	0.02	—
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	0.01	—
Deemed dividend related to conversion of preferred stock into common stock	0.01	—	0.01	—
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	$ (0.21)	$ (1.14)	$ (0.56)	$ (2.26)

The non-GAAP financial measures for the three and six months ended June 30, 2020 and 2019 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) Loss from sale of SurgiBot assets relates to additional outside service costs to transfer the assets in connection with the sale of SurgiBot assets to Great Belief International Limited.

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

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

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

e) 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.

f) During the fourth quarter of 2019, we announced the implementation of a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. During March 2020, the Company continued the restructuring efforts with additional headcount reductions which resulted in $0.9 million related to severance costs in the six months ended June 30, 2020.

g) During the first quarter of 2020, the Company closed an underwritten public offering under which it issued, as part of units and the exercise of an over-allotment option, 25,367,646 Series C Warrants, each to acquire one share of Common Stock at an exercise price of $0.68 per share, and 25,367,646 Series D Warrants, each to acquire one share of Common Stock at an exercise price of $0.68 per share. The Company concluded that the Series C Warrants and Series D Warrants are considered equity instruments. The fair value of the Series C and Series D Warrants on the issuance date was determined using a Black-Scholes Merton model. The unit proceeds were then allocated to the Series A preferred stock, Series C Warrants, and Series D Warrants, respectively, based on their relative fair values. As a result, the Company determined that a beneficial conversion feature was created by the difference between the effective conversion price of the preferred stock of $0.37 and the fair value of the Company's common stock as of the issuance date of $0.42. The Company therefore recorded a beneficial conversion charge of $0.4 million as an immediate charge to earnings available to common stockholders for the six months ended June 30, 2020. Upon conversion of the preferred stock to common stock during the three months ended June 30, 2020, an additional deemed dividend of $0.3 million was recorded as an immediate charge to earnings available to common stockholders for the three and six months ended June 30, 2020.

Investors:
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Exhibit 99.2

Company: TRANSENTERIX, INC.
Conference Title: Q2 2020 TransEnterix, Inc. Earnings Call
Moderator: Mark Klausner
Date: August 5, 2020

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the TransEnterix Second Quarter Business Update Conference Call.

At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will follow at that time.

I would now like to turn the call over to Mr. Mark Klausner of Westwicke. Please go ahead.

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

Thanks, Operator. Good afternoon, everyone, and thank you for joining us on today's call. On the call with me today are Anthony Fernando, President and Chief Executive Officer, and Brett Farabaugh, Interim Chief Financial Officer.

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, including any impact from the COVID-19 pandemic. 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 filed on March 16, 2020 and 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.

It is now my pleasure to turn the call over to TransEnterix President and Chief Executive Officer, Anthony Fernando.

Anthony Fernando – *TransEnterix, Inc. – President, CEO and Director*

Thanks, Mark, and thank you, all, for joining us today. On today's call, I will provide a quick update on the impact of COVID-19 during the quarter. Brett will then provide an update on our second quarter performance, after which I will provide an update on recent trends in the business and the progress made towards our 2020 strategic initiatives. Lastly, I will be taking your questions.

Starting with a quick COVID update. Throughout the second quarter, we were focused on operating while ensuring the health and safety of all our employees and their families. One of our key focus areas during the initial onset of the pandemic has been ensuring the continuity of our manufacturing operation in Milan, Italy. We are pleased to say that the facility is back up and running and operational at normal levels.

From a proactive initiative perspective, we took this time to pilot a novel remote support technology. One of the biggest hurdles in the time from when we sign an agreement with a hospital is the time to get a new site up and running. This requires sufficient training and support. As we are a global organization and have installations in a variety of geographies, it can be challenging to quickly have a team of surgeons get up to speed if clinical staff cannot be in person – particularly in a travel restricted environment. Our novel technology allows us to support our customers by offering training and case support remotely at both new and existing installations.

I will now turn the call over to Brett to provide the second quarter financial review.

Brett Farabaugh – *TransEnterix, Inc. – Interim CFO*

Thanks, Anthony.

In the quarter ended June 30, 2020, the company reported revenue of $0.7 million as compared to revenue of $3.6 million in the prior year quarter. Revenue in the second quarter included $153,000 in instruments and accessories, $162,000 in system leases, and $340,000 in services.

In the quarter, total operating expenses were $13.6 million as compared to $22.2 million in the prior year quarter. I would note that on a sequential basis our operating expenses decreased significantly from the first quarter of 2020, including $1.4 million in savings realized as the impact of our restructuring actions continue to be recognized and due to a reduction in travel and other costs due to the COVID-19 pandemic.

In the quarter, net loss attributable to common stockholders was $14.1 million as compared to a net loss of $20.2 million in the prior year quarter. In the quarter, the adjusted net loss attributable to common stockholders was $10.9 million as compared to an adjusted net loss of $19.2 million in the prior year quarter, after adjusting for the following charges: change in fair value of warrant liabilities, amortization of intangible assets, change in fair value of contingent consideration, and deemed dividend related to conversion of preferred stock into common stock.

Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. See the reconciliation from GAAP to non-GAAP measures included in our press release. The company had cash and cash equivalents and restricted cash of approximately $16.2 million as of June 30, 2020.

I will now turn the call back to Anthony.

Anthony Fernando

Thanks, Brett.

I would now like to provide an update on recent performance as well as the progress we have made on the four key areas that we are focused on in 2020. Despite the challenging environment due to COVID-19, we have made significant progress in market development, clinical validation, portfolio expansion, and capital funding.

Beginning with new system installations. Our goal for 2020 was to have 12 to 15 new systems installed. Given the challenges faced by hospitals around the world as they deal with the ongoing COVID-19 pandemic, beginning in March 2020, there was uncertainty about our ability to get new systems installed in the near term. However, we have continued to make solid progress in line with our expectations up to this point in the year.

In the first quarter, we installed three systems, one in the U.S., one in Germany, and one in Japan. In the second quarter, we installed two systems, one in the U.S. at Sinai Health Chicago, and one in Germany at Sana Klinikum Esslingen. Subsequent to the end of the second quarter, we installed an additional system in Austria at LKH Feldkirch and signed a new agreement in the Netherlands at Maastricht UMC. In addition, we have one other signed agreement with a hospital where installation has not yet taken place as a result of COVID-19 at St. Marianna University School of Medicine Toyoko Hospital, a hospital in the greater Tokyo metropolitan area. This agreement was signed in the second quarter, and we are targeting the installation of Senhance at their facility in the third quarter.

To summarize, year-to-date, we have installed and started six clinical programs and have one pending installation in Japan and one other in the Netherlands, both planned for installation in the third quarter, totaling eight systems year-to-date, and keeping us on track towards our goal of installing 12 to 15 systems in 2020.

Shifting to our pipeline. We continue to have a strong global pipeline of potential hospital customers despite the current COVID-19 environment. A perfect example of this strength is in Europe where our pipeline has continued to expand. We attribute this to the execution of our strategic market development efforts – specifically our continued publication of clinical data across Europe, as well as the introduction of new instrumentation and indications for use, particularly the availability of a pediatric indication.

In Asia, momentum has tapered slightly as COVID-19 has taken priority with hospitals and administrators in key geographies, such as Japan. While we haven't seen pipeline accounts fall out of the funnel, we have seen increased uncertainty around timing of installation. Lastly, in the U.S., we continue to make progress in line with our expectations and feel good about our efforts as we have been able to place an additional system in the U.S. since the end of the first quarter of this year.

As part of our efforts to convert new customers, as well as quickly enable surgeons to begin doing cases using Senhance, we have put a significant emphasis on training. To optimize training in Asia and Europe, we expect to add dedicated training facilities, one in each geography, later this year. Once complete, we will provide incremental color on both of these new facilities.

Shifting to procedure volume. As with most other medical devices used in primarily elective procedures, we saw significant headwinds in the quarter. However, year-to-date, we have made great progress in driving procedural volumes. Prior to COVID, we had developed tremendous momentum, with February growing 116% over February of last year, and even with the material impact in March, first quarter procedure volumes grew approximately 43% over the first quarter of 2019. While we were negatively impacted in the second quarter, the momentum we generated in the first quarter helped drive the rebound in procedures in May and June. In the second quarter, total procedure volumes were down approximately 55% year-over-year. April was hit the hardest, after which we saw a rebound in May, and the rebound continued into June. The rebound is largely a function of our European installations in key geographies getting back to perform procedures after reopening during the quarter. Looking at the first six months of the year in total, our procedure volume was down 15% compared to the previous year.

Shifting to an update on our foundational sites. As a reminder, foundational sites are those that are performing procedures at an annualized rate of greater than 100 procedures per year. We currently have nine foundational sites, up from seven at the start of 2020, and expect to continue to add foundational sites during the second half of the year. The slowdown in elective procedures has slowed the expansion of these foundational sites in recent months.

Turning to clinical validation. In 2020, we continue to focus on the development of health, economic, and clinical performance data, with an emphasis on the cost impact of Senhance relative to traditional laparoscopy as well as other surgical robotic systems. The early trends are very positive, and we remain on track for some initial data to publish later this year. In addition, we expect that a handful of current Senhance users will continue to publish studies outlining their experiences and outcomes.

Moving on to our portfolio expansion efforts. Following the FDA clearance for the first machine vision system in robotic surgery with the Intelligent Surgical Unit, or ISU, we continued to progress towards additional indications with the technology. We are very excited to announce that we are planning to install the first set of ISUs at multiple clinical sites in the U.S. shortly, and the first cases are expected to be performed during the third quarter.

In the second quarter, we made our CE Mark submission for the ISU and expect to receive clearance by year-end. In addition, we continue to look to add incremental ISU features, namely the next generation of machine vision and augmented intelligence capabilities. Given some of the delays caused as a result of the COVID-19 shutdown, we now plan to file our next ISU feature set with the FDA in the first quarter of 2021. This next iteration of the ISU represents the next step in delivering on our digital strategy. We will continue to invest in the ongoing development of Senhance by bringing innovative technology and capabilities onto the platform.

We also remain focused on the expansion of indications in the U.S. for use with the Senhance System, with the initial efforts devoted to a broader general surgery indication, which we submitted to the FDA earlier this week. As it relates to our instrument expansion efforts, we are planning to file our FDA 510(k) submission for articulating instruments in the first quarter of 2021.

Finally, an update on capital funding. On July 6, we announced the closing of an underwritten public offering, including the full exercise of the over-allotment option, bringing in net proceeds of approximately $13.7 million. With current cash on hand, together with anticipated cash received from product and instrument sales and leases, we now believe that we have sufficient cash to support our operations into the second quarter of 2021.

From a cash conservation perspective, we continue to find ways to preserve cash, in the near term that includes reduced marketing, trade show, and T&E expenses. As part of an effort to be more efficient with our cash resources, we will soon be transitioning to a new corporate headquarters facility near our current facility in Research Triangle Park, North Carolina. This new facility will provide better utilization and functionality while at the same time reducing our expenses and streamlining operations.

Turning to guidance. Given the continued uncertainty that exists within the global healthcare market, we cannot currently predict the specific extent or duration of the impact of the COVID-19 outbreak on our financials and operating results. As a result, we are not providing forward-looking revenue guidance at this time.

To recap, even with the headwinds associated with COVID-19, we continue to make proactive steps to drive towards our goal for 2020 and set ourselves up for success in 2021 and beyond, and I'm very proud of our team and their response during this uncertain and unprecedented time. We are aggressively executing on the components of our long-term strategy while being mindful of our cash usage.

Year-to-date, we have made significant progress across the board: we have installed six systems globally and have two more under contract. Procedure volumes are showing signs of recovery. We have made tremendous progress towards the publication of compelling clinical evidence. We have expanded our indications for use with the clearance of the ISU in the U.S., the pediatric indication in Europe, and are making progress towards a general surgery indication in the U.S. And last but not least, we have bolstered our balance sheet. We remain very excited about the opportunity that exists for Senhance.

With that, I would like to open the line for questions.

Operator

Thank you. We will now begin the question-and-answer session. To join the question queue, you may press star, then one, on your telephone keypad. You will hear a tone acknowledging your request. If you are using a speakerphone, please pick up your handset before pressing any key. To withdraw your question, please press star, then two. We will pause for a moment as callers join the queue.

Our first question comes from Jeffrey Cohen with Ladenburg Thalmann. Please go ahead.

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

Hi, Anthony and Brett. How are you?

Anthony Fernando

Doing good, Jeff.

Jeffrey Cohen

Thanks again so much for the couple of surgeons that we were able to have some discussions with, and congrats on the general surgery filings. Does that sound like something that will take quarters to turn around, or is that something that you think could happen more swiftly?

Anthony Fernando

Jeff, I think that, difficult timeline prior to COVID, but something in the four- to six-month range. So, given COVID, I know they had some delays in intake as well, so we are not sure exactly of the timeline, but pre-COVID, it's been a four- to six-month kind of timeframe. So we are hopeful it'll be sometime in that timeframe, not knowing exactly what the current timelines and delays on the FDA front, but it should be – I think that should be the average number we should be expecting to hear back from them.

Jeffrey Cohen

Okay. Could you talk a little bit about the AI ISU platform? You mentioned that it's in some sites now in the U.S. Can you talk about those sites and some of the experiences they had, and then remind us with your filing to the EU, what might that turnaround time be like?

Anthony Fernando

Sure, Jeff. So just to clarify, we have not installed these systems at U.S. hospitals yet. We are planning to do so, hopefully towards the end of this month or early September will be the installations, and then soon after the install, we'll be performing clinical cases in the U.S.

And with respect to Europe, again, the same product – the same product that we got approved in the U.S. is what we've submitted in Europe now, and the timeline, again, approximately towards the end of this year is when we are expecting to hear back from the notified bodies in Europe so that we can get the ISU integrated into the system in Europe as well.

Jeffrey Cohen

Okay. Got it. And then as far as utilization of the platform out there, you talked about Q1 being up 43% and Q2 down 55%. I imagine, could you talk about July over June and if that was better, and then talk about back half of the year, if you could? Does it sound like or seem like to you that the trajectory from Q2 to Q3 may be there in the positive sense, and will we see some carry through into the fourth quarter as well?

Anthony Fernando

I think so. I think April was the real low point, and since April – May was better than April, and June was better than May, and July is better than June. So, we've been on the uptick primarily because of the re-openings in Europe. They've kind of been leading the way in terms of procedures. So we are definitely hoping to have a much better third quarter in terms of cases compared to the second quarter. So definitely, I think cases are going in the right direction. It's trending the right way, but I think we've continued to see modest growth from quarter to quarter in Q3 and then on to Q4.

Jeffrey Cohen

Okay, got it. Lastly, for me, any experience from the field as far as some commentary, as far as your articulation, the ensuing articulation in the five millimeter size from users out there? Are there – can you give us a sense of the number of users or the percentage of systems out there that are utilizing the articulation now?

Anthony Fernando

Yes. So I think, Jeff, like we said, we've been on somewhat of a limited launch in Europe, and the articulated instruments are being used. Obviously, more surgeons are using it, and we're getting some really good feedback and very positive feedback from the surgeons. So that's currently in Europe, and we've continued to expand utilization of it with the surgeons in Europe. The rest of this year – that's kind of the plan we laid out and we'll continue to do that in Europe through the third and fourth quarter.

Jeffrey Cohen

Okay. Got it. That does it for me. Thanks for taking the questions.

Anthony Fernando

Thank you, Jeff.

Operator

Our next question comes from James Meyer with RBC Wealth Management. Please, go ahead.

James Meyer – *RBC Wealth Management*

I would just like to thank you for saving the company and the hard work you do. That's all. Carry on.

Anthony Fernando

Thank you, James.

Operator

That concludes our question-and-answer session for today. I would now like to turn the call back to Anthony Fernando for closing remarks.

Anthony Fernando

Thank you, all, for joining us on today's call. We appreciate your interest in TransEnterix and look forward to updating you on our progress next quarter. Thank you very much.

Operator

This concludes today's conference call. You may disconnect your lines. Thank you for participating and have a pleasant day.