UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

CURRENT REPORT

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

November 5, 2020

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 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
ollowing provisions (see General Instruction A.2. be	low):	
☐ Written communications pursuant to Rule 425 u	nder the Securities Act (17 CFR 230.425)	
Soliciting material pursuant to Rule 14a-12 under	er the Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to	o Rule 14d-2(b) under the Exchange Act (17	CFR 240.14d-2(b))
Pre-commencement communications pursuant to	` ,	3.77
•	· · ·	<i>、</i>
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	TRXC	NYSE American
\$0.001 par value per share		
ndicate by check mark whether the registrant is an er	nerging growth company as defined in Rule	405 of the Securities Act of 1933 (§230.405 of this
hapter) or Rule 12b-2 of the Securities Exchange Ac	t of 1934 (§240.12b-2 of this chapter).	
Emerging growth company \Box		

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. \Box

Item 2.02 Results of Operations and Financial Condition

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

Also on November 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 third quarter ended September 30, 2020. The Company had issued a press release on October 26, 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 November 5, 2020
- 99.2 November 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: November 9, 2020

TRANSENTERIX, INC.

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

Exhibit 99.1

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

November 5, 2020

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- November 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 third quarter of 2020.

Recent Highlights

- Year-to-date, eight clinical programs initiated with one additional system pending installation and over 1,200 procedures performed globally
- First procedures performed in the U.S. using the Intelligent Surgical UnitTM (ISUTM) enabling intra-operative, real-time augmented intelligence capabilities in surgery for the first time
- First robotically-assisted pediatric procedures performed utilizing fully reusable 3mm instruments in Europe
- Established Japanese training center for the Senhance® Surgical System to drive growth in Asia-Pacific region
- Filed FDA 510(k) submission for general surgery indication expansion to broaden addressable market
- Appointed Shameze Rampertab as Chief Financial Officer
- Raised \$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

"The third quarter was immensely productive for the Company despite the ongoing headwinds associated with COVID and the burden placed on hospitals globally. We achieved several key milestones, including the first surgical procedures using the Intelligent Surgical Unit in the U.S. and the first pediatric surgical cases with the Senhance in Europe," said Anthony Fernando, President, and CEO of TransEnterix. "Looking to the balance of 2020, we are focused on leveraging the continued momentum in system placement and procedures we have created in recent months to deliver on our strategy and bring Senhance's transformative technology to surgeons, hospitals, and patients globally."

Commercial and Clinical Update

During the quarter, three clinical Senhance programs were started and one new agreement was signed. Year to date in 2020, the Company has installed eight Senhance systems globally.

There is one additional system pending installation in Japan.

On August 4, 2020, the Company announced that it had filed its 510(k) submission with the FDA for a general surgery indication expansion. Upon clearance, this is expected to add approximately 800,000 general and bariatric procedures to the Company's addressable market.

On September 14, 2020, the Company announced that it established the first training center for the Senhance in the Asia-Pacific region in Japan at the Saitama Medical University International Medical Center in the Greater Tokyo Area. The Japanese Training Center is expected to drive increased utilization of our seven system installations in the Asia-Pacific region and encourage further adoption of our technology in additional hospitals.

On September 23, 2020, the Company announced it completed its first surgical procedures using the ISU at Hackensack Meridian Health Pascack Valley Medical Center in New Jersey. The ISU adds augmented intelligence to the Senhance. Currently, the ISU enables machine vision driven control of the camera which allows the System to recognize certain objects and locations in the surgical field, and provides seamless sharing of the surgeon console's view across all members of the operating room team in real-time, all the while allowing the surgeon to maintain full control. These initial capabilities are foundational to planned future augmented intelligence features such as scene cognition and surgical image analytics that are expected to further enhance the digital laparoscopic experience with Senhance.

On October 13, 2020, the Company announced the first pediatric patient procedures at Maastricht University Medical Center+ in the Netherlands. This is the first pediatric surgical program in the world to utilize the Senhance and integrate digital laparoscopy with instruments as small as 3 mm into their standard of surgical care. The Senhance is the only robotic-assisted surgical system in the world to provide fully reusable 3 mm instruments.

Underwritten Public Offering

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

Third Quarter Financial Results

For the three months ended September 30, 2020, the Company reported revenue of \$0.8 million as compared to revenue of \$2.0 million in the three months ended September 30, 2019. Revenue in the third quarter of 2020 included \$0.2 million in system leasing, \$0.2 million in instruments and accessories, and \$0.4 million in services.

For the three months ended September 30, 2020, total operating expenses were \$14.6 million, as compared to \$96.4 million in the three months ended September 30, 2019.

For the three months ended September 30, 2020, net loss attributable to common stockholders was \$15.1 million, or \$0.15 per share, as compared to a net loss of \$97.8 million, or \$5.55 per share, in the three months ended September 30, 2019.

For the three months ended September 30, 2020, the adjusted net loss attributable to common stockholders was \$11.9 million, or \$0.12 per share, as compared to an adjusted net loss of \$20.6 million, or \$1.17 per share in the three months ended September 30, 2019. Adjusted net loss is GAAP net loss adjusted in the third quarter of 2020 for the following items: goodwill impairment, change in fair value of contingent consideration, intangible asset impairment, amortization of intangible assets, change in fair value of warrant liabilities, loss from sale of SurgiBot assets, acquisition related costs, restructuring and other charges, deemed dividend related to beneficial conversion feature of the preferred stock, 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. A reconciliation from GAAP to Non-GAAP Measures can be found at the end of this earnings release.

The Company had cash and cash equivalents and restricted cash of approximately \$21.1 million as of September 30, 2020.

As a result of the restructuring completed in the first quarter of 2020, cost optimization efforts, and recent equity financing, together with anticipated cash received from operating activities, including cash from system sales and leases, instruments and accessories, and services, we believe that cash on hand will be sufficient to meet our anticipated cash needs into the second quarter of 2021.

COVID-19 Impact and 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 pandemic on our financial and operating results. We are not providing forward looking guidance at this time.

Conference Call

TransEnterix, Inc. will host a conference call on Thursday, November 5, 2020, at 4:30 PM ET to discuss its third quarter 2020 operating and financial results. To listen to the conference call on your telephone, please dial 1-800-931-4071 for domestic callers and 1-303-223-0117 for international callers, and reference conference ID 21971152 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 we call 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 our Intelligent Surgical UnitTM(ISUTM) 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 backing out goodwill impairment, change in fair value of contingent consideration, intangible asset impairment, amortization of intangible assets, change in fair value of warrant liabilities, loss from sale of SurgiBot assets, acquisition related costs, restructuring and other charges, deemed dividend related to beneficial conversion feature of the preferred stock, and deemed dividend related to the conversion of preferred stock into common stock. 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 Surgical System, as well as 2020 third quarter financial results and plans for the balance of 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 the Company will receive FDA clearance for its general surgery indication, whether we will be able to leverage our continued momentum in system placement and procedures to deliver on our strategy and bring Senhance's transformative technology to surgeons, hospitals and patients globally, and whether we have cash on hand sufficient, together with anticipated cash received from operating activities, including cash from system sales and leases, instruments and accessories, and services, to meet our anticipated cash needs into the second quarter of 2021. 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 inform

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

		Three Months Ended September 30,			Nine Months Ended September 30,			
		2020		2019		2020		2019
Revenue:								
Product	\$	436	\$	1,649	\$	992	\$	6,820
Service		378		375		1,076		1,024
Total revenue		814		2,024		2,068		7,844
Cost of revenue:								
Product		720		2,399		2,353		6,628
Service		703		1,047		2,220		3,221
Total cost of revenue		1,423		3,446		4,573		9,849
Gross loss		(609)		(1,422)		(2,505)		(2,005)
Operating Expenses:								
Research and development		4,673		5,884		12,867		17,834
Sales and marketing		3,136		6,883		10,291		22,425
General and administrative		3,462		5,908		10,426		14,959
Amortization of intangible assets		2,780		2,558		7,964		7,754
Change in fair value of contingent consideration		502		(11,647)		1,770		(9,689)
Restructuring and other charges		_		_		858		_
Goodwill impairment		_		78,969		_		78,969
Intangible assets impairment		_		7,912		_		7,912
Loss from sale of SurgiBot assets, net		_		_		_		97
Acquisition related costs		_		(40)		_		5
Total Operating Expenses		14,553		96,427		44,176		140,266
Operating Loss		(15,162)		(97,849)		(46,681)		(142,271)
Other Income (Expense):								
Change in fair value of warrant liabilities		63		614		(206)		3,036
Interest income		3		63		34		559
Interest expense		_		(1,230)		_		(3,407)
Other income (expense), net		16		(439)		(54)		(935)
Total Other Income (Expense), net		82		(992)		(226)		(747)
Loss before income taxes		(15,080)		(98,841)		(46,907)		(143,018)
Income tax (expense) benefit		(2)		1,070		1,386		2,549
Net loss		(15,082)		(97,771)		(45,521)		(140,469)
Deemed dividend related to beneficial conversion feature of preferred stock	-		_		-	(412)		
Deemed dividend related to conversion of preferred stock into common stock		_		_		(299)		_
Net loss attributable to common stockholders		(15,082)		(97,771)		(46,232)		(140,469)
Comprehensive loss:								,
Net loss		(15,082)		(97,771)		(45,521)		(140,469)
Foreign currency translation gain (loss)		2,101		(3,670)		2,191		(4,379)
Comprehensive loss	\$	(12,981)	\$	(101,441)	\$	(43,330)	\$	(144,848)
Comprehensive 1033	Ť	()==)	÷		÷	(-,,	÷	,,,,,,
Net loss per common share attributable to common stockholders – basic	\$	(0.15)	\$	(5.55)	\$	(0.77)	\$	(8.26)
Net loss per common share attributable to common stockholders – diluted	\$	(0.15)	\$	(5.55)	\$	(0.77)	\$	(8.34)
Weighted average number of shares used in computing net loss per common								
share – basic		97,538		17,629		59,737		17,015
Weighted average number of shares used in computing net loss per common		57,550	_	17,023		33,/3/		17,013
share – diluted		97,538		17,741		59,737		17,208
share unucu		57,550		17,771	_	55,757		17,200

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

	September 30, 2020		December 31, 2019		
	(1	unaudited)			
Assets					
Current Assets:					
Cash and cash equivalents	\$	19,964	\$	9,598	
Accounts receivable, net		903		620	
Inventories		10,856		10,653	
Other current assets		5,780		7,084	
Total Current Assets		37,503		27,955	
Restricted cash		1,154		969	
Inventories, net of current portion		6,769		7,594	
Property and equipment, net		8,702		4,706	
Intellectual property, net		24,139		28,596	
In-process research and development		_		2,470	
Net deferred tax assets		41		_	
Other long term assets		1,836		2,489	
Total Assets	\$	80,144	\$	74,779	
Liabilities and Stockholders' Equity					
Current Liabilities:					
Accounts payable	\$	2,973		3,579	
Accrued expenses	Ψ	7,492		8,553	
Deferred revenue – current portion		818		818	
Notes payable – current portion, net of debt discount		279		_	
Contingent consideration – current portion		_		73	
Total Current Liabilities		11,562		13,023	
Long Term Liabilities:		11,502		15,025	
Deferred revenue – less current portion		_		27	
Contingent consideration – less current portion		2,780		1,011	
Notes payable - net of issuance costs		2,536			
Warrant liabilities		124		2,388	
Net deferred tax liabilities				1,392	
Other long term liabilities		973		1,403	
Total Liabilities		17,975		19,244	
Commitments and Contingencies		17,575		15,244	
Stockholders' Equity					
Common stock \$0.001 par value, 750,000,000 shares authorized at September 30, 2020 and December 31,					
2019; 99,879,029 and 20,691,301 shares issued and outstanding at September 30, 2020 and December 31,					
2019, respectively		100		21	
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at		100		21	
September 30, 2020 and December 31, 2019		_		_	
Additional paid-in capital		770,368		720,484	
Accumulated deficit		(709,120)		(663,600)	
Accumulated other comprehensive income (loss)		821		(1,370)	
Total Stockholders' Equity		62,169		55,535	
• •	\$	80.144		74,779	
Total Liabilities and Stockholders' Equity	Ψ	00,144		/4,//9	

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

Nine Months Ended September 30,

		Septem	DCI DU	
Out of the Anti-View		2020		2019
Operating Activities:	ф	(45 521)	ď	(1.40, 400)
Net loss	\$	(45,521)	\$	(140,469)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:				07
Loss from sale of SurgiBot assets, net		_		97
Goodwill and intangible assets impairment				86,881
Depreciation		2,015		1,651
Amortization of intangible assets		7,964		7,754
Amortization of debt discount and debt issuance costs				1,437
Amortization of short-term investment discount				(328
Stock-based compensation		5,800		9,727
Interest expense on deferred consideration – MST acquisition		- (4.222)		762
Deferred tax benefit		(1,386)		(2,549
Bad debt expense		_		1,630
Write down of inventory		_		761
Change in fair value of warrant liabilities		206		(3,036
Change in fair value of contingent consideration		1,770		(9,689
Changes in operating assets and liabilities:				
Accounts receivable		(252)		4,313
Interest receivable		_		3
Inventories		(4,410)		(14,141)
Other current and long term assets		2,233		(2.313
Accounts payable		(706)		(914
Accrued expenses		(1,191)		(1,439
Deferred revenue		(56)		(867
Other long term liabilities		(376)		1,613
Net cash and cash equivalents used in operating activities		(33,910)		(59,116
Investing Activities:	_	(55,515)		(55,110
Purchase of short-term investments		_		(12,883
Proceeds from maturities of short-term investments		_		65,000
Purchase of property and equipment		(3)		(392
		(3)		51,725
Net cash and cash equivalents (used in) provided by investing activities		(3)		31,723
Financing Activities:				
Proceeds from issuance of common stock, preferred stock and warrants under 2020 financing, net of		40 505		
issuance costs		13,525		
Proceeds from issuance of common stock, net of issuance costs		24,861		23,725
Proceeds from notes payable, net of issuance costs		2,815		(30
Payment of note payable		_		(15,000
Taxes paid related to net share settlement of vesting of restricted stock units		(33)		(499
Payment of contingent consideration		(74)		_
Proceeds from exercise of stock options and warrants		3,340		539
Net cash and cash equivalents provided by financing activities		44,434		8,735
Effect of exchange rate changes on cash and cash equivalents		30		(191
Net increase in cash, cash equivalents and restricted cash		10,551		1,153
Cash, cash equivalents and restricted cash, beginning of period		10,567		21,651
Cash, cash equivalents and restricted cash, end of period	\$	21,118	\$	22,804
Supplemental Disclosure for Cash Flow Information				
••	¢		ď	2.072
Interest paid	\$		\$	2,073
Supplemental Schedule of Non-cash Investing and Financing Activities	ф	F 000	ф	450
Transfer of inventories to property and equipment	\$	5,839	\$	478
Exchange of common stock for Series B Warrants	\$	2,470	\$	_
Transfer of in-process research and development to intellectual property	\$	2,425	\$	_
Issuance of common stock – MST acquisition	\$	_	\$	6,600
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)

	Three Months Ended September 30, 2020 2019			Nine Montl Septemb 2020				
(Unaudited, U.S. Dollars, in thousands)	 		_					
Net loss attributable to common stockholders (GAAP)	\$ (15,082)	\$	(97,771)	\$	(46,232)	\$	(140,469)	
Adjustments								
Loss from sale of SurgiBot assets, net	_		_		_		97	
Amortization of intangible assets	2,780		2,558		7,964		7,754	
Change in fair value of contingent consideration	502		(11,647)		1,770		(9,689)	
Acquisition related costs	_		(40)		_		5	
Change in fair value of warrant liabilities	(63)		(614)		206		(3,036)	
Restructuring and other charges	_				858			
Goodwill impairment	_		78,969		_		78,969	
Intangible assets impairment	_		7,912		_		7,912	
Deemed dividend related to beneficial conversion feature of preferred stock	_		_		412		_	
Deemed dividend related to conversion of preferred stock into common stock	_		_		299		_	
Adjusted net loss attributable to common stockholders (Non-GAAP)	\$ (11,863)	\$	(20,633)	\$	(34,723)	\$	(58,457)	
	Three Months Ended				Nine Months Ended			
	Septem		30,		Septem		30,	
(Unaudited, per basic share)	Septem 2020	ber	30, 2019		Septem 2020	ber	30, 2019	
(Unaudited, per basic share) Net loss per share attributable to common stockholders (GAAP)	\$ Septem 2020	ber	30,	\$	Septem	ber	30,	
	\$ Septem 2020	ber	30, 2019	\$	Septem 2020	ber	30, 2019	
Net loss per share attributable to common stockholders (GAAP)	\$ Septem 2020	ber	30, 2019	\$	Septem 2020	ber	30, 2019	
Net loss per share attributable to common stockholders (GAAP) Adjustments	\$ Septem 2020	ber	30, 2019	\$	Septem 2020	ber	30, 2019 (8.26)	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net	\$ Septem 2020 (0.15)	ber	30, 2019 (5.55)	\$	Septem 2020 (0.77)	ber	30, 2019 (8.26)	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets	\$ Septem 2020 (0.15) — — 0.03	ber	30, 2019 (5.55) — 0.14	\$	Septem 2020 (0.77) — — 0.13	ber	30, 2019 (8.26) 0.01 0.46	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration	\$ Septem 2020 (0.15) — — 0.03	ber	30, 2019 (5.55) — 0.14 (0.66)	\$	Septem 2020 (0.77) (0.77) — 0.13 0.03	ber	30, 2019 (8.26) 0.01 0.46 (0.57)	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) 0.14 (0.66) (0.00)	\$	Septem 2020 (0.77) (0.77) — — 0.13 (0.03) —	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs Change in fair value of warrant liabilities	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) 0.14 (0.66) (0.00)	\$	Septem 2020 (0.77) (0.7	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs Change in fair value of warrant liabilities Restructuring and other charges	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) 0.14 (0.66) (0.00) (0.03)	\$	Septem 2020 (0.77) (0.7	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00 (0.18)	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs Change in fair value of warrant liabilities Restructuring and other charges Goodwill impairment	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) — 0.14 (0.66) (0.00) (0.03) — 4.48	\$	Septem 2020 (0.77)	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00 (0.18) — 4.64	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs Change in fair value of warrant liabilities Restructuring and other charges Goodwill impairment Intangible assets impairment	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) — 0.14 (0.66) (0.00) (0.03) — 4.48	\$	Septem 2020 (0.77) (0.7	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00 (0.18) — 4.64	
Net loss per share attributable to common stockholders (GAAP) Adjustments Loss from sale of SurgiBot assets, net Amortization of intangible assets Change in fair value of contingent consideration Acquisition related costs Change in fair value of warrant liabilities Restructuring and other charges Goodwill impairment Intangible assets impairment Deemed dividend related to beneficial conversion feature of preferred stock	\$ Septem 2020 (0.15) (0.15) (0.03) (0.00) (0.00)	ber	30, 2019 (5.55) — 0.14 (0.66) (0.00) (0.03) — 4.48	\$	Septem 2020 (0.77) (0.7	ber	30, 2019 (8.26) 0.01 0.46 (0.57) 0.00 (0.18) — 4.64	

The non-GAAP financial measures for the three and nine months ended September 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 nine months ended September 30, 2020.
- g) As of September 30, 2019, goodwill was deemed to be fully impaired, and the Company recorded an impairment charge of \$79.0 million. As of September 30, 2019, IPR&D was deemed to be significantly impaired, and the Company recorded an impairment charge of \$7.9 million. No impairment charges were recorded during the three or nine months ended September 30, 2020.

h) 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 overallotment 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 nine months ended September 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 nine months ended September 30, 2020.

Investors:

Mark Klausner, 443-213-0501 invest@transenterix.com or **Media:** Terri Clevenger, 203-856-8297

terri.clevenger@icrinc.com

Exhibit 99.2

Company: TRANSENTERIX, INC.

Conference Title: Q3 2020 TransEnterix, Inc. Earnings Call

Moderator: Mark Klausner Date: November 5, 2020

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the TransEnterix Third 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 Shameze Rampertab, 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 attributable to common shareholders, and adjusted net loss per common share attributable to common stockholders. 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

Good afternoon, everyone, and thank you for joining us. With me on today's call is TransEnterix's newly appointed Chief Financial Officer, Shameze Rampertab. After we review our third quarter results, I will shift to a high-level overview of our third quarter activity and recent trends in the business. We will then open the line for questions.

First, I would like to introduce and welcome our new CFO, Shameze Rampertab. He brings over 20 years of financial leadership experience in the healthcare sector to the Company. In addition to significant experience in corporate leadership roles, his background also includes time spent as an investment banker and sell-side equity research analyst. He has a proven track record of successfully implementing financial strategies and sourcing capital at publicly traded healthcare companies. We are excited to have him on board as we pursue our next phase of growth as an organization.

With that, I will hand the call over to Shameze to provide a financial update for the third quarter. Shameze?

Shameze Rampertab – *TransEnterix*, *Inc.* – *Executive Vice President and CFO*

Thanks, Anthony. I am excited to be here and look forward to being a part of the organization as we seek to drive the adoption of Senhance globally.

Turning to the third quarter, for the three months ended September 30, 2020, the Company reported revenue of \$800,000 as compared to revenue of \$2.0 million in the three months ended September 30, 2019. Revenue in the third quarter of 2020 included \$200,000 in systems leasing, \$200,000 in instruments and accessories, and \$400,000 in services.

For the three months ended September 30, 2020, total operating expenses were \$14.6 million, as compared to \$96.4 million in the three months ended September 30, 2019.

For the three months ended September 30, 2020, net loss attributable to common stockholders was \$15.1 million, or \$0.15 per share, as compared to a net loss of \$97.8 million, or \$5.55 per share, in the three months ended September 30, 2019. During the three months ended September 30, 2019, the Company recorded a goodwill impairment charge of \$79.0 million and an in-process research and development impairment charge of \$7.9 million. No impairment charges were recorded during the three months ended September 30, 2020.

For the three months ended September 30, 2020, the adjusted net loss attributable to common stockholders was \$11.9 million, or \$0.12 per share, as compared to an adjusted net loss of \$20.6 million, or \$1.17 per share in the three months ended September 30, 2019. Adjusted net loss is GAAP net loss adjusted for the following items: goodwill impairment, change in fair value of contingent consideration, intangible asset impairment, amortization of intangible assets, change in fair value of warrant liabilities, and loss from the sale of Surgibot assets, all of which are non-cash charges. Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. A reconciliation from GAAP to non-GAAP measures can be found in our earnings release.

Turning to the balance sheet, the Company had cash and cash equivalents and restricted cash of approximately \$21.1 million and working capital of \$25.9 million as of September 30, 2020.

On July 6, 2020, we announced the closing of an underwritten public offering, including the full exercise of the over-allotment option, bringing in gross proceeds of \$15 million.

We continue to optimize our operations subsequent to our completed restructuring efforts. In the first quarter of 2021, we will be moving to a new leased premises in Research Triangle Park, North Carolina, benefiting financially from a smaller footprint in a modern facility.

As a result of the completed restructuring and cost optimization efforts, we believe that existing cash and cash equivalents, together with cash we will receive from operating activities and realization of other current assets, will be sufficient to meet our anticipated cash needs into the second quarter of 2021.

I will turn the call back over to Anthony.

Anthony Fernando

Thank you, Shameze.

I will now provide an update on recent performance as well as the progress we have made on the key areas that we are focused on in 2020.

As a reminder, these areas of focus are: first, market development, which involves building awareness of the Senhance System, and effectively demonstrating the clinical and economic value in the marketplace by increasing the visibility of the success that our customers are having with the Senhance. Second, clinical validation, which emphasizes the development of clinical evidence supporting the value propositions of the Senhance. And third, portfolio expansion, which focuses on broadening the applicability of Senhance by adding new indications, features and new instruments

Starting with our first focus area, market development. Specific to new system installs, as of the end of the third quarter, we have entered into nine leasing agreements and started eight clinical programs. We continue to believe we are on track to meet our goal of 12 to 15 installations for the year.

In the third quarter, we initiated clinical programs at three new sites, two in Europe and one in Japan. The European clinical programs were initiated at LKH Feldkirch in Austria and Maastricht University Medical Center in the Netherlands. The third clinical program was started at St. Marianna University School of Medicine Toyoko Hospital, a hospital in the greater Tokyo metropolitan area.

Near the end of the third quarter, we signed an additional system lease agreement with Toshima Hospital, a hospital in Tokyo, Japan, and plan to initiate this clinical program in the fourth quarter.

As it relates to our pipeline, the demand for Senhance remains strong, particularly in Asia. To help support that demand, we have added a dedicated training facility in Japan. As announced in September, we inaugurated a training facility at the Saitama Medical University International Medical Center in the Greater Tokyo area. The Asia-Pacific region has seen a significant increase in new system placements and Senhance utilization, a trend that we expect to continue.

We expect the Japanese Training Center will help drive increased utilization of our seven, soon to be eight, system installations in the Asia-Pacific region and encourage further adoption of our technology in additional hospitals. Similarly, we continue to see strong demand for Senhance in Europe, and expect to launch an additional training center in Europe before the end of 2020.

After a strong start to the year, procedure volumes were materially impacted by COVID-19 beginning late in the first quarter. However, the back half of the second quarter, and throughout the third quarter, we have seen a rebound. Year to date, procedures were down just 12% over 2019. The trends during the year have varied across our three primary geographies.

In Asia, we have continued to grow our active installed base, and procedure volumes have followed suit, with volumes growing 37% year over year during the quarter. In the U.S., despite the negative impact due to COVID, procedure volumes in the third quarter were down only 11% over the prior year. Lastly, in the EMEA region, where we continue to see COVID-driven disruption, volumes declined approximately 28% over the prior year quarter. Despite the year over year decline in the EMEA region, we did see a significant rebound in volumes in the third quarter, growing nearly 200% sequentially as compared to the second quarter of 2020. We continue to monitor the COVID pandemic developments on our business as much of the world enters a new phase.

We are very excited about the work in one of our specialty areas—pediatrics. Earlier this year, we received a CE Mark approval that enabled us to use digital laparoscopy with Senhance and our unique 3-millimeter instruments on pediatric patients.

Pediatric surgeons are skilled minimally invasive surgeons who treat a wide range of patients from infants to adolescents. Working with small anatomy presents unique obstacles for the surgeon. Utilizing small instruments in small cavities can heighten challenges with visualization, instrument control and surgical access.

These are key areas where Senhance can help. In addition to stable-visualization, Senhance can minimize traumatic forces exerted by instruments on the abdominal wall through tremor filtration capabilities and the use of a digital fulcrum point. The combination of these two features create an optimal microlaparoscopic working environment for the surgeon. Furthermore, the Senhance system is the only robotic-assisted surgical system in the world to provide fully-reusable 3-millimeter instruments. Pediatric surgeons strongly prefer the use of 3-millimeter instruments to reduce invasiveness, but don't use them regularly because they are difficult to manipulate and control manually. These advantages in digital laparoscopy with the Senhance Surgical System has the potential to reduce invasiveness in surgery, reduce surgical variability, especially in complex surgeries, and meaningfully improve outcomes for pediatric patients.

On October 12, the Company announced that surgeons at Maastricht University Medical Center, or MUMC, in the Netherlands, successfully operated on multiple pediatric patients. This is the first pediatric surgical program in the world to utilize our Senhance system and integrate robotic instruments as small as 3 millimeters into their standard of surgical care.

We view pediatrics as a highly underserved market that will benefit significantly from the capabilities Senhance provides. We are leveraging the momentum we are seeing in Europe to increase the number of pediatric Senhance programs.

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 11 foundational sites, up from seven at the start of 2020. The slowdown in elective procedures has slowed the expansion of these foundational sites since the beginning of the year, but we are optimistic that we will continue to add foundational sites during the rest of the year.

Turning to our second focus area, 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. We have made good progress during the quarter on several studies, including: two cost comparative studies, one in the U.S. and one in Europe, comparing the average cost per procedure between Senhance, laparoscopy and robotics; one on the ergonomic benefits of using Senhance; one on the clinical performance when using 3-millimeter instruments; and one on OR efficiency, ease of use and integration of Senhance in a hospital's existing clinical program or OR team.

The early trends, as reported by the investigators, are very positive and we remain on track for some initial data to publish later this year.

Turning to our third focus area, portfolio expansion. Following the FDA clearance of the first machine vision system in robotic surgery with the Intelligent Surgical Unit, or ISU, in March of this year, we continue to progress towards offering additional features with the technology. The ISU adds a new cooperative component to robotic-assisted surgery by enabling 'intra-operative', real-time augmented intelligence capabilities in surgery for the very first time. It has the potential to change the role of robotic-assisted technology in the OR from being transactional with the surgical team, to being cooperative with them. This signals a significant and meaningful shift in how robotic-assisted technologies add value in surgery. The ISU will provide true competitive advantages to laparoscopic surgeons globally and even the playing field, giving surgeons a shorter learning curve and confidence to use digital laparoscopy when performing surgery.

The innovative machine vision based camera control features that were recently introduced enable the system to recognize certain objects and locations in the surgical field. Based on current clinical usage, we have seen that the seamless tracking of instruments by the system during surgery has improved ease of use and efficiency in intraoperative camera control, potentially reducing the risk of surgical errors driven by poor camera control during surgery.

On September 23, we announced the completion of the first surgeries utilizing the ISU's machine vision capabilities. The surgeries were completed at Hackensack Meridian Health Pascack Valley Medical Center, a hospital in New Jersey. The patients were treated by Dr. Amit Trivedi, Chair of Surgery at Hackensack Meridian Health Pascack Valley Medical Center, and his team, in multiple general surgery procedures. We are excited about the early successes we have seen with procedures where the ISU has been utilized as it validates the benefits of the technology.

It's a platform that will continue to evolve. We are working to add incremental ISU features, namely the next generation of machine vision and augmented intelligence capability, such as scene recognition and surgical image analytics. This next software update for the ISU that we will seek FDA clearance on represents the next step in delivering on our digital surgery strategy.

Shifting to general surgery. In August, we announced that we filed a 510(k) for indication expansion with the FDA. Based on currently approved indications for use with the Senhance, approximately 1.4 million procedures are addressable in the U.S. Assuming we receive clearance for the general surgery indication expansion, we will add approximately 800,000 additional general and bariatric procedures to our total addressable market in the U.S.

As it relates to our upcoming regulatory milestones: we continue to expect to receive a CE Mark for the ISU in Europe by the end of 2020; we expect to receive FDA 510(k) clearance for our General Surgery indication expansion during the first quarter of 2021; we continue to expect to file for FDA 510(k) clearance for the next generation ISU features during the first quarter of 2021; and lastly, we expect to file for FDA 510(k) clearance for articulating instruments in the first quarter of 2021.

In summary, we are very proud of everything we have been able to accomplish during the third quarter and into the fourth quarter, particularly given the challenging global environment brought on by COVID-19. We made progress across each of our key areas of focus: we continue to initiate Senhance programs across the globe; we are facilitating the ongoing increase in system utilization through the addition of training centers in key geographies; we had several "first procedures" for high-impact indications and new technology introductions; we continue to develop critical clinical data; we have added talent in key areas within the organization; and we continue to make tremendous strides with our regulatory initiatives. We look forward to leveraging this momentum into the balance of 2020 and into 2021 to bring the benefits of Senhance for more surgeons, hospitals, and patients across the globe. I would like to thank our global team for their efforts during these uncertain times. COVID-19 has presented a variety of challenges, and the team has shown tremendous adaptability, creativity, and resolve to continue to deliver through the pandemic.

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

Operator

Thank you. To ask a question please press the one followed by the four on your telephone keypad. You will hear a three-tone prompt to acknowledge your request. If the question has already been asked and you would like to withdraw your registration please press one, three. Once again to queue up for a question you may press the one followed by the four on your telephone keypad. One moment please for the first question.

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

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

Hi, Anthony and Shameze. How are you?

Anthony Fernando

Very good, Jeff. How are you doing?

Jeffrey Cohen

Just fine. Great. So a couple of questions for you. Firstly, Anthony, you were talking about one specific publication that you expect out by the end of the year. Is that correct? Can you review with us where the publication is coming from, and in what format we'll see it, and what's your main focus?

Anthony Fernando

Yes. I think, Jeff, the first publication is going to be a U.S. publication. It's a cost comparison publication comparing laparoscopy, Senhance and other robotics platform. But with respect to where it's going to come from, it's in the review process so I'm unable to disclose where it's submitted with the investigators. But we believe we'll be able to see it come out before the end of this year. Amongst other things, right, all the—even on the other topics, we are very active in trying to get the data, and work with the investigators to get the data to be published. So we'll at least get the process started with the first one here in short order.

Jeffrey Cohen

Okay. So there's some other publications you're aware of as well?

Anthony Fernando

Yes. Yes. So I think we are working on multiple fronts, right? One is on the cost front in the U.S. and Europe, one on ergonomics, another one on the clinical outcomes or benefits of using 3-millimeter instruments. So we're trying to hit on multiple different vectors to make sure that there's clinical evidence and data that gets published in a kind of a high-impact manner.

Jeffrey Cohen

Got it. Okay. Can you give us any flavor for the ISU capabilities now? Any idea as far as number of cases Dr. Trivedi has done? And any insight into the ISU capabilities for the other systems existing in the U.S., at least for this year?

Anthony Fernando

I think just to clarify if—once the ISU is installed, every case that the surgeon performs uses the ISU, whether the surgeon chooses to use those features are not—it kind of becomes native to the system. So the initial features that the surgeons are using are primarily on camera control. So that—and tracking of instruments just so that it helps them maneuver and navigate surgical field by moving the instrument. So that's one of the features they're using.

And the other one kind of really focuses more on collaboration within the OR, enabling the rest of the OR team to be able to see exactly what the surgeon is seeing; not just the surgical site, but also the inputs, output coming out of the robot. So it kind of creates more of a collaborative nature within the OR.

Those are kind of the primary features. Collaboration is one angle and the second one is around visualization.

The next part to your question about what's to come, I think we're kind of going to build on this platform by continuing to add additional features to the current platform by means of software upgrades to the system. And that you'll start to see us making those—FDA—they'll have to go through the FDA, but you'll see those FDA submissions, the second wave of features, which will be more around analytics and more information on the surgical field that the surgeon can query. So that, you'll see sometime in the first quarter that we'll go into, go into the FDA.

Jeffrey Cohen

And would you expect some additional centers to come online in the U.S.?

Anthony Fernando

Yes. So we piloted—we initially plan to pilot that at two U.S. sites. We have one up and running and very soon, we'll have the second site up and running. And then once we have these two sites up, then we'll expand to all the sites.

And I think—so I think you also asked about how many. I think I'd say that it's north of 15 cases so far. So pretty much like every case, these surgeons do use the ISU right now.

Jeffrey Cohen

Okay. And what's the pathway for Europe? You spoke about anticipating a CE Mark by the end of the year? Has that been filed? Or is there a dialogue ongoing now?

Anthony Fernando

Yes. I first submitted, I believe it was in July of this year, that we submitted it to the notified body in Europe, and we are expecting to get the CE Mark approved towards the end of this year.

Jeffrey Cohen

Okay. And then can you touch upon the articulating instrumentation that you spoke about coming to market perhaps in 2021? Where will that be? Is that U.S. or CE as far as filings? And specific to instruments that you're offering now, which ones do you expect initially will go through articulation?

Anthony Fernando

So with respect to articulation, we already have a CE Mark, and the articulating instruments are in use in Europe already. It's had a few sites. We've been collecting data, and primarily performance data, and that's already ongoing in Europe. And with respect to the U.S., we believe that we plan to file the 510(k) sometime in the first quarter of 2021, and then however long it takes for approval. And once we get the approval, we'll roll it out in the U.S. But in Europe, it's already approved and on the market.

Jeffrey Cohen

Okay. And finally, for me, could you—you spoke about some numbers on procedure volume. So what I heard was for Q3: Asia, plus 37%; U.S., minus 11%; and EMEA, minus 28%. But then you were talking about a 200% swing to the upside. Was that for EMEA from the previous quarter?

Anthony Fernando

Yes. If you were to look at Q2 versus Q3 for EMEA, they were up 200%. We're showing the rebound of cases coming back in Europe. So that 200% was specific to EMEA.

Jeffrey Cohen

Okay. EMEA sequential from Q2 to Q3 was up 200%, but Q3 was down 28% year-over-year.

Anthony Fernando

Correct.

Jeffrey Cohen

I got it. Okay, that does it for me Anthony, Shameze. Thanks a lot for taking my questions.

Anthony Fernando

Thank you, Jeff.

Shameze Rampertab

Thank you.

Operator

Our next question comes from the line of Frank Harris, Raymond James. Please, go ahead.

Frank Harris – Raymond James & Associates – Equity Research Analyst

Hey, good afternoon, this is Frank on for Larry. I just have a couple of questions. So first, on the general surgery filing, was there any clinical data submitted for the general surgery indication? And if so, what were the general surgery procedures that formed the basis for the filing?

Anthony Fernando

Okay. Frank, I think—so I'll say that, yes, clinical data was included because as you know, we have—we perform all the general surgery cases in Europe and some general surgery cases in U.S. already. So I mean the hernias, gall bladders and the colorectal procedures that have been approved in the U.S. already, so we are leveraging some of that and also some additional procedures in order to create—make the submission.

What we are about to get probably, trying to get it—just to broaden it even further and also into bariatric procedures that we currently don't have on label. So that—it's really a broadening of the general surgery kind of umbrella that will include bariatric. So I'll kind of keep it shy of that because we have this in review right now, and I think the specifics, we will only kind of be able to finalize once we get that approval.

Frank Harris

Okay. That's helpful. And then if you could maybe expand a little bit on the 800,000 of additional general surgery procedures. Could you—is it possible you can break out the various procedures and the annual opportunity for each? Or is it too early for that?

Anthony Fernando

I think it's a little bit too early for that. I mean, if you look at the overall procedures, general surgery procedures and what we have on our label and what we don't have on our label, that's kind of how we distinguish the 800,000. Eight-hundred thousand is not procedures that we currently have on label, which we would have access to once we get this approved. But I think it's a bit too early to dive into the next layers in detail and then kind of talk about it.

Frank Harris

Okay. That's all right. And then could you remind us how many Senhance systems you currently have in inventory? And what is your thoughts on timing for manufacturing additional systems?

Anthony Fernando

Okay. So I think, I mean, we have a pretty good pipeline going in terms of production. I mean we continue to produce systems based on needs. And I think even on an inventory point, there's no shortage of inventory, and we are able to fulfill all the new systems that come online through these leasing programs pretty much in two to three weeks, we are able to install systems and get them up and running.

I wouldn't want to get into details about exactly how much systems we have in inventory. But I think we are pretty well positioned to be able to meet our pipeline demand that we are projecting over the—for the next one, two, three quarters. I think we're pretty good in terms of inventory to be able to support all of that.

Frank Harris

Okay. That's helpful. And then just last for me. As we think about competition as new surgical robots start to come on the market, we're just hearing a lot more from some of the competitors like Medtronic. How should we just think about the basis for competition moving forward from here?

Anthony Fernando

Yes. I think, Frank, it's a very good question. I think we still continue to believe that digital laparoscopy with the Senhance is very uniquely positioned, and no one is really trying to mimic what we are doing. Everything from the surgeon training, the surgical technique and the cost per procedure, we are extremely uniquely positioned. So that's one key differentiator; even with all the competitive systems that we are aware of, we can very comfortably say that we are truly differentiated there.

And second, I think if you really look at the overall market penetration on a global ecosystem, I think global robotic penetration is, what, like less than 5% globally, I think. So that also talks about—this goes to show there's plenty of opportunity for other players to enter the market.

And I think personally also, I believe that competition drives innovation. So I think it's a good thing to have multiple platforms. I think that will drive for better surgery, better robotics platforms and also drive better outcomes at the end. And while there is, I think good—there's talk about other players entering the market, I think it's going to be a while, right? I think some of these U.S. players don't have regulatory approvals. They're planning to do IDE studies, but on the flip side, we are way beyond the regulatory stage, and we're doing good surgery in all different parts of the world every day.

So, I think we're looking—I think we welcome the competition and all the other players coming into the market. And we're going to keep moving on the clinical front and advancing the platform as we go along.

Frank Harris

Great, thanks so much.

Anthony Fernando

Thank you, Frank.

Operator

I am now turning the call over back to you, Mr. Fernando. Please go ahead.

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

That concludes today's call. We thank you for your participation and ask you to please disconnect your lines.