



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

February 26, 2019

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Feb. 26, 2019-- TransEnterix, Inc. (NYSE American: TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced its operating and financial results for the fourth quarter and full year 2018.

### **Recent Highlights**

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

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

### **Commercial and Clinical Update**

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

### ***Instrument Portfolio Expansion***

#### ***Ultrasonic Instrument System***

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

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

#### ***3mm Diameter Instrument Set***

On October 11, 2018, the Company received FDA 510(k) clearance for 3 millimeter diameter Senhance System instruments, as well as additional 5 millimeter Senhance System instruments. The clearance of the 3 millimeter diameter instruments will allow the Senhance System to be used for microlaparoscopic surgeries, enabling surgeons to operate through smaller incisions considered virtually scarless for patients, supporting the Company's mission of advancing minimally invasive surgical capabilities within digital laparoscopy.

#### ***Articulating Instruments***

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

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

### **Expansion of Geographic Regulatory Approvals**

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

### **Acquisition Agreement with MST**

On October 31, 2018, the Company announced the closing of the acquisition of substantially all of the assets of MST Medical Surgery Technologies Ltd. ("MST"), an Israel-based medical technology company. MST is a leader in the field of surgical technology, having developed a software-based image analytics platform powered by advanced visualization, scene recognition, artificial intelligence, machine learning and data analytics.

The addition of MST's technology, IP portfolio and R&D team will support and accelerate TransEnterix's vision to leverage its Senhance System to deliver digital laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability. The acquisition also provides immediate access to an established R&D center in Israel with a core team of experienced engineers.

#### **Fourth Quarter Financial Highlights**

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

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

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

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

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

#### **Conference Call**

TransEnterix, Inc. will host a conference call on Tuesday, February 26, 2019 at 8:00 AM ET to discuss its fourth quarter and fiscal year 2018 operating and financial results. To listen to the conference call on your telephone, please dial (844) 804-5261 for domestic callers or (612) 979-9885 for international callers and reference conference ID 6086178 approximately ten minutes prior to the start time. To access the live audio webcast or archived recording, use the following link <http://ir.transenterix.com/events.cfm>. The replay will be available on the Company's website.

#### **About TransEnterix**

TransEnterix is a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options in today's value-based healthcare environment. The Company is focused on the commercialization of the Senhance™ Surgical System, which digitizes laparoscopic minimally invasive surgery. The system allows for robotic precision, haptic feedback, surgeon camera control via eye sensing and improved ergonomics while offering responsible economics. The Senhance Surgical System is available for sale in the US, the EU and select other countries. For more information, visit [www.transenterix.com](http://www.transenterix.com).

#### **Non-GAAP Measures**

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

#### **Forward-Looking Statements**

This press release includes statements relating to the current regulatory and commercialization plans for the Senhance Surgical System, as well as 2018 fourth quarter and full year results and plans for 2019 and beyond. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether we will be able to leverage all of the progress we made in 2018 to grow the adoption and purchase of the Senhance System globally; whether the clearance of the 3 millimeter diameter instruments will allow the Senhance System to be used for microlaparoscopic surgeries; whether the addition of MST's technology, IP portfolio and R&D team will support and accelerate TransEnterix's vision to leverage its Senhance System to deliver laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability; and whether TransEnterix has sufficient cash and additional debt proceeds under the current agreement to fund the business into late 2020. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 8, 2018 and our other filings we make with the SEC, including the Form 10-K for the year ended December 31, 2018 expected to be filed prior to its filing deadline. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

**TransEnterix, Inc.**

**Consolidated Statements of Operations and Comprehensive Loss**

(in thousands except per share amounts)

(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenue	\$ 7,524	\$ 3,398	\$ 24,102	\$ 7,111
Cost of revenue	5,635	3,500	16,171	6,727
Gross profit (loss)	1,889	(102 )	7,931	384
Operating Expenses (Income)				
Research and development	6,439	5,175	21,823	21,989
Sales and marketing	7,901	5,536	25,736	17,536
General and administrative	3,865	3,587	13,854	12,275
Amortization of intangible assets	2,624	2,714	10,868	7,858
Change in fair value of contingent consideration	(1,092 )	800	(1,011 )	2,026
Issuance costs for warrants	—	—	—	627
Acquisition related costs	302	—	647	—
Gain from sale of SurgiBot assets, net	75	—	(11,840 )	—
Reversal of transfer fee accrual	—	—	(2,994 )	—
Total Operating Expenses (Income)	20,114	17,812	57,083	62,311
Operating Loss	(18,225 )	(17,914 )	(49,152 )	(61,927 )
Other Income (Expense)				
Change in fair value of warrant liabilities	10,118	(58,521 )	(14,320 )	(83,734 )
Interest income	418	184	1,400	308
Interest expense	(810 )	(862 )	(4,208 )	(2,443 )
Other income (expense)	1,235	(6 )	1,126	(300 )
Total Other Income (Expense), net	10,961	(59,205 )	(16,002 )	(86,169 )
Loss before income taxes	\$ (7,264 )	\$ (77,119 )	\$ (65,154 )	\$ (148,096 )
Income tax benefit	823	963	3,377	3,300
Net loss	\$ (6,441 )	\$ (76,156 )	\$ (61,777 )	\$ (144,796 )
Other comprehensive loss				
Foreign currency translation (loss) gain	(1,039 )	1,282	(3,690 )	10,797
Comprehensive loss	\$ (7,480 )	\$ (74,874 )	\$ (65,467 )	\$ (133,999 )
Net loss per share - basic and diluted	\$ (0.03 )	\$ (0.40 )	\$ (0.30 )	\$ (0.97 )
Weighted average common shares outstanding - basic and diluted	215,144	190,648	207,199	148,744

**TransEnterix, Inc.**

**Consolidated Balance Sheets**

(in thousands, except share amounts)

(Unaudited)

	December 31, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	\$ 21,061	\$ 91,217
Short-term investments	51,790	—
Accounts receivable, net	8,560	1,536
Inventories	10,941	10,817
Interest receivable	26	80

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

## TransEnterix, Inc.

### Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

#### Twelve Months Ended December 31, 2018      2017

Operating Activities		
Net loss	\$ (61,777 )	\$ (144,796 )

Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:

Gain from sale of SurgiBot assets, net	(11,840 )	—
Depreciation	2,420	2,486
Amortization of intangible assets	10,868	7,858
Amortization of debt discount and debt issuance costs	725	510
Amortization of short-term investment discount	(351 )	—
Stock-based compensation	9,039	7,078
Non-employee warrant awards	—	838



**Adjustments**

Gain from sale of SurgiBot assets, net	75	—	(11,840 )	—
Amortization of intangible assets	2,624	2,714	10,868	7,858
Change in fair value of contingent consideration	(1,092 )	800	(1,011 )	2,026
Acquisition related costs	302	—	647	—
Reversal of transfer fee accrual	—	—	(2,994 )	—
Change in fair value of warrant liabilities	(10,118 )	58,521	14,320	83,734
Loss on extinguishment of debt	—	—	1,400	308
<b>Adjusted net loss (Non-GAAP Measure)</b>	<b>\$(14,650 )</b>	<b>\$(14,121 )</b>	<b>\$(50,387 )</b>	<b>\$(50,870 )</b>

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
(Unaudited, per diluted share)	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>Net loss per share (GAAP Measure)</b>	<b>\$(0.03 )</b>	<b>\$(0.40 )</b>	<b>\$(0.30 )</b>	<b>\$(0.97 )</b>

**Adjustments**

Gain from sale of SurgiBot assets	0.00	—	(0.06 )	—
Amortization of intangible assets	0.01	0.01	0.05	0.05
Change in fair value of contingent consideration	(0.01 )	0.00	0.00	0.01
Acquisition related costs	0.00	—	0.00	—
Reversal of transfer fee accrual	—	—	(0.01 )	—
Change in fair value of warrant liabilities	(0.04 )	0.32	0.07	0.57
Loss on extinguishment of debt	—	—	0.01	0.00
<b>Adjusted net loss per share (non-GAAP Measure)</b>	<b>\$(0.07 )</b>	<b>\$(0.07 )</b>	<b>\$(0.24 )</b>	<b>\$(0.34 )</b>

The non-GAAP financial measures for the three and twelve months ended December 31, 2018 and 2017 provide management with additional insight into the Company's results of operations from period to period without non-recurring and non-cash charges, and are calculated using the following adjustments:

- Gain from sale of SurgiBot assets relates to amounts received from Great Belief International Limited in excess of the carrying amount of the assets sold.
- Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.
- 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.
- Acquisition related costs were incurred in connection with the MST purchase agreement and consist of legal, accounting, and other costs.
- In connection with the Senhance acquisition, the Company recorded an accrual in 2015 third quarter for potential assessment of additional transfer fees. In September 2018, the Company determined that the accrual was no longer required and reversed the accrual.
- 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.
- In May 2018, in connection with its entrance into the Hercules Loan Agreement, the Company repaid its existing loan and security agreement with Innovatus Life Sciences Lending Fund I, LP. The Company recognized a loss of \$1.4 million on the extinguishment of notes payable which is included in interest expense on the consolidated statement of operations and comprehensive loss for the twelve months ended December 31, 2018. In May 2017, in connection with its entrance into the Innovatus Loan Agreement, the Company repaid its then-existing credit facility with Silicon Valley Bank and Oxford Finance LLC. The Company recognized a loss of \$308,000 on the extinguishment of notes payable which is included in interest expense on the consolidated statement of operations and comprehensive loss for the twelve months ended December 31, 2017.

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