

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

January 6, 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 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 January 6, 2020, TransEnterix, Inc., a Delaware corporation (the “Company”), issued a press release announcing an update with preliminary financial results for the fourth quarter and full year ended December 31, 2019. A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	<u>No.</u>	<u>Description</u>
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	<u>99.1</u>	Press Release, dated January 6, 2020
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SIGNATURES

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

TransEnterix, Inc.

Date: January 6, 2020

/s/ Anthony Fernando

Anthony Fernando

President and Chief Executive Officer

Exhibit 99.1

TransEnterix Provides 2019 Year End Corporate Update

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--January 6, 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 provided a year-end corporate update.

“The challenges we faced in 2019 shouldn’t overshadow the significant progress we made in putting the pieces in place to make 2020 a transformative year for TransEnterix,” said Anthony Fernando, President and CEO of TransEnterix. “We have recently signed agreements with two hospitals that will be initiating their digital laparoscopy programs utilizing the Senhance[®] System beginning in the first quarter of 2020. In addition, our current Senhance clinical sites are performing more volume and more complex surgery than ever before. We believe we are on the cusp of introducing transformative technological capabilities in augmented intelligence and instrumentation.”

Fourth Quarter Senhance System Placements

As part of the Company’s market development efforts, during the quarter ended December 31, 2019, the Company entered into two customer agreements: one in the United States and one in Germany to lease Senhance Systems to allow such hospitals to perform Senhance surgeries. These Senhance Systems are expected to be installed in January 2020 and clinical cases are expected to begin in the first quarter.

Clinical Cases

In 2019, surgeons performed over 1,600 procedures utilizing the Senhance System, representing a 194% increase over the previous year. During 2019, there were 16 peer-reviewed clinical papers published featuring results of the Senhance System across gynecology, general surgery, urology and colorectal procedures demonstrating the breadth of usage and the complexity of procedures being performed.

Product Portfolio Initiatives

During 2019, the Company completed the following product portfolio initiatives:

- Obtained Senhance System FDA 510(k) clearance for the Senhance Ultrasonic Instruments
- Obtained Japanese regulatory approval for the Senhance System and reimbursement for 98 procedures
- Initiated a European limited market release of 5mm articulating instruments
- Developed and launched the Senhance System Simulator
- Completed CE submission for expanded indications for pediatric patients
- Expanded list of visualization systems compatible with the Senhance System to include systems from KARL STORZ and Olympus

AutoLap Sale

The Company sold the AutoLap laparoscope positioning system and related assets for \$17.0 million and has received all payments related to this transaction.

Fourth Quarter and Full Year 2019 Revenue

During the quarter ending December 31, 2019, the Company expects to report preliminary unaudited revenue of approximately \$0.6 million. For the full year, preliminary unaudited 2019 revenue is expected to be approximately \$8.3 - \$8.5 million, representing revenues from the sale of a total of three Senhance Systems and related revenues from consumables and service contracts.

Balance Sheet

As of December 31, 2019, the Company had no debt and had preliminary unaudited cash, cash equivalents and restricted cash of approximately \$10.6 million. As previously announced, the Company is evaluating strategic alternatives to raise additional capital to support the growth of the business.

As of December 31, 2019, there were approximately 20.7 million shares of common stock outstanding.

2020 Corporate Objectives

The Company expects to make significant progress in 2020 as it continues to build out its leadership position in Digital Laparoscopy by focusing on the following key corporate objectives:

- Expand the number of sites using the Senhance System in the United States, Europe, and Japan and convert more existing sites into “foundational” sites that are on a rate to perform 100+ cases annually with multiple surgeons or specialties;
- Double the number of clinical cases performed on the Senhance System over the prior year;
- Generate meaningful clinical and economic evidence that supports utilization of the Senhance System and increase the number of surgeon advocates to reinforce key messages; and,
- Complete the following product portfolio initiatives:
 - launch the scene cognition and augmented intelligence module in the United States by mid-2020;
 - expand the European launch of 5mm Articulating Instruments and submit for US clearance in the fourth quarter; and,
 - obtain general surgery and bariatric indications in the US, and obtain a pediatric indication in Europe.

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 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 System is available for sale in the US, the EU, Japan and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and our current commercialization plans for this product and related products in 2020. 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 2020 will be a transformative year for TransEnterix, whether we are on the cusp of introducing transformative technological capabilities in augmented intelligence and instrumentation; whether one Senhance System will be installed in each of the United States and Germany, respectively, in January 2020, with the resulting clinical cases beginning in the 2020 first quarter; whether 2019 fourth quarter revenue will be approximately \$0.6 million; whether 2019 revenue for the full year will be approximately \$8.3 - \$8.5 million; whether cash, cash equivalents and restricted cash will be \$10.6 million as of December 31, 2019; and whether the Company will achieve any of its 2020 corporate objectives. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 27, 2019 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Source: TransEnterix, Inc.

For TransEnterix, Inc.

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