
**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**

**October 1, 2018
Date of Report (date of earliest event reported)**

TransEnterix, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

0-19437
(Commission
File Number)

11-2962080
(I.R.S. Employer
Identification Number)

**635 Davis Drive, Suite 300
Morrisville, North Carolina**
(Address of principal executive offices)

919-765-8400
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On October 1, 2018, TransEnterix, Inc., a Delaware corporation (the “Company”), issued a press release announcing an update with preliminary financial results for the third quarter ended September 30, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.

The information included herein and in Exhibit 99.1 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 October 1, 2018](#)

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: October 2, 2018

TransEnterix, Inc.

/s/ Joseph P. Slattery
Joseph P. Slattery
EVP and Chief Financial Officer

October 1, 2018 4:05 PM

TransEnterix Provides Corporate Update

- *Announces four Senhance system sales in third quarter of 2018*
- *Preliminary unaudited revenue of approximately \$5.4 million for the third quarter of 2018*
- *Preliminary unaudited cash and cash equivalents of approximately \$82 million as of September 30, 2018*
- *Announced entry into acquisition agreement for technology assets and IP of MST Medical Surgery Technologies*
- *Received CE Mark for Senhance Ultrasonic Instrument System*

RESEARCH TRIANGLE PARK, N.C.—(BUSINESS WIRE)— TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between surgeons and patients to improve minimally invasive surgery, today provided a corporate update, including preliminary unaudited revenue for the third quarter ended September 30, 2018.

“We made significant progress during the third quarter, including the continued adoption of Senhance, driven by the advancement of our sales and marketing strategy, the announcement of the MST acquisition agreement and the expansion of our instrument portfolio,” said Todd M. Pope, President and CEO at TransEnterix. “As we look towards the remainder of 2018 and into 2019, we are focused on increasing the applicability of Senhance to more patients, surgeons, and hospitals and growing on a global basis.”

Third Quarter 2018 Revenue Outlook

For the third quarter ended September 30, 2018, the Company expects to report revenue of approximately \$5.4 million. This revenue is primarily driven by the sale of four Senhance systems, as follows:

- In the US, UPMC purchased a Senhance Surgical System to be utilized at its Magee-Womens Hospital in Pittsburgh. Magee combines a wealth of specialty services with a focus on gynecologic and obstetric services. UPMC is a \$19 billion world-renowned health care provider and insurer, which is focused on new models of accountable, cost-effective, and patient-centered care.
- In EMEA (Europe, Middle East, Africa), three systems were sold:
 - A system was sold to Maxima Medical Center, in Veldhoven, the Netherlands, which is a member of a cooperative association of the 20 largest Dutch teaching hospitals that work together in areas of education and quality control, to guarantee the best level of healthcare.

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- Two systems were sold to distributors, one of which was a demonstration system purchased to support territory marketing and regulatory initiatives.

Balance Sheet

Preliminary unaudited cash and cash equivalents as of September 30, 2018 totaled approximately \$82 million. The Company anticipates that it has sufficient cash to fund the business through 2020, assuming the funding of the \$20 million in potential future debt tranches available under the Company's existing debt financing agreements.

Acquisition Agreement with MST

On September 23, 2018, the Company announced that it had entered into an agreement to acquire substantially all of the assets of MST Medical Surgery Technologies Ltd. ("MST"), an Israel 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 Surgical System to deliver digital laparoscopy, thereby increasing control in the surgical environment and reducing surgical variability. In addition, the acquisition will provide immediate access to an established R&D center in Israel with a core team of experienced engineers. The acquisition is expected to close in the fourth quarter of 2018, and is subject to customary closing conditions.

Instrument Portfolio Expansion

Ultrasonic Instrument System

- On September 6, 2018, the Company announced that it had filed its application for FDA 510(k) clearance for its Senhance Ultrasonic Instrument System, ahead of expectations. The Company expects to achieve an FDA 510(k) clearance in the first quarter of 2019.
- As announced on October 1, 2018, the Company received a CE Mark for its Senhance Ultrasonic Instrument System. The Company continues to expect to commercially launch the Ultrasonic Instrument System in CE Mark countries in the fourth quarter of 2018.

3mm Diameter Instrument Set

- The Company continues to anticipate receiving FDA 510(k) clearance for its expanded instrument set, including 3mm diameter instruments, by the end of 2018.

Articulating Instruments

- The Company continues to expect to submit its application for FDA 510(k) clearance for its 5mm diameter articulating instruments during the fourth quarter of 2018.
- The Company continues to expect to receive CE Mark for its 5mm diameter articulating instruments during the fourth quarter of 2018.

Expansion of Geographic Regulatory Approvals

The Company continues to expect to receive Taiwanese FDA approval for the Senhance Surgical System instruments by the end of 2018. In the second quarter of 2018, the Company received approval in Taiwan for the Senhance Surgical System.

Appointment of Chief Commercial Officer

On September 4, 2018, the Company announced that Eric Smith has been named Chief Commercial Officer, effective August 31, 2018. In this newly created role, which reports directly to the Chief Executive Officer, Mr. Smith leads the company's global commercialization efforts, with a focus on both strategic and tactical execution efforts in sales, upstream and downstream marketing, field clinical support and training with a focus on adoption and clinical excellence.

About TransEnterix, Inc.

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.

Forward-Looking Statements

This press release includes statements relating to the anticipated third quarter 2018 financial results, the acquisition agreement with MST, the Senhance Surgical System, the Senhance Ultrasonic Instrument System and our current regulatory and commercialization plans for these and our other products. 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 the preliminary unaudited 2018 third quarter revenue will be approximately \$5.4 million, whether preliminary cash and cash equivalents will be \$82 million as of September 30, 2018, whether, for the remainder of 2018 and into 2019, we will be able to increase the applicability of Senhance to more patients, surgeons and hospitals and growing on a global basis, whether the MST transaction will be able to close in the 2018 fourth quarter, whether we will achieve an FDA clearance of the Senhance Ultrasonic Instrument System in the 2019 first quarter, whether we will commercially launch the Ultrasonic Instrument System in CE Mark countries in the 2018 fourth quarter, whether we will receive FDA 510(k) clearance for our expanded instrument set, including 3mm diameter instruments, by the end of 2018, whether we will submit our FDA 510(k) clearance for our 5mm diameter articulating instruments during the 2018 fourth quarter, whether we will receive CE Mark for our 5mm diameter articulating instruments during the 2018 fourth quarter, whether we will receive Taiwanese FDA approval for the Senhance Surgical System instruments by the end of 2018 and whether we will have sufficient cash to fund the business through 2020, assuming the funding of the \$20 million in potential future debt tranches available under our existing debt financing agreements. 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 filed on March 8, 2018 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For TransEnterix, Inc.

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