

TRANSENERIX INC.

FORM 8-K (Current report filing)

Filed 09/18/17 for the Period Ending 09/18/17

Address	635 DAVIS DRIVE SUITE 300 MORRISVILLE, NC, 27560
Telephone	919-765-8400
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Symbol	TRXC
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of Earliest Event Reported):

September 18, 2017

TransEnterix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

0-19437

11-2962080

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

635 Davis Drive, Suite 300, Morrisville, North
Carolina

27560

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

919-765-8400

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:

- 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))

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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. []

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Item 8.01 Other Events.

On September 18, 2017, TransEnterix, Inc. (the "Company") issued a press release to disclose that it had filed its response to the U.S. Food and Drug Administration's Additional Information request related to the Company's Senhance Surgical Robotic System 510(k) submission. The press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated September 18, 2017.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 18, 2017.

September 18, 2017

TransEnterix, Inc. Reports Progress on Senhance FDA Submission

*- Files additional information response with FDA -
- Continues to expect 510(k) clearance in 2017 -*

RESEARCH TRIANGLE PARK, N.C.—(BUSINESS WIRE) — TransEnterix, Inc. (NYSE American: TRXC), a medical device company that is pioneering the use of robotics to improve minimally invasive surgery, today announced the Company has filed its response to the Food and Drug Administration’s (“FDA”) Additional Information (“AI”) request related to the Company’s Senhance Surgical Robotic System 510(k) submission.

“We are very pleased to have submitted our AI response ahead of schedule, demonstrating our team’s effectiveness and our ongoing collaboration with the FDA,” said Todd M. Pope, President and Chief Executive Officer of TransEnterix. “The submission of our response is a key step towards achieving 510(k) clearance for the Senhance, which we continue to expect in 2017.”

About TransEnterix

TransEnterix is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options. The Company is focused on the commercialization of the Senhance™ Surgical Robotic System, a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology such as haptic feedback and eye sensing camera control. The Company also developed the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform. The Senhance Surgical Robotic System has been granted a CE Mark but is not currently available for sale in the United States. For more information, visit the TransEnterix website at www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to our second quarter 2017 results, the Senhance™ Surgical Robotic System and our current regulatory and commercialization plans for this product. 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, including, whether the Senhance 510(k) will achieve clearance in 2017, if at all. 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, 2016, which was filed on March 6, 2017, 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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