TRANSENTERIX INC.

FORM 8-K
(Current report filing)

Filed 10/17/17 for the Period Ending 10/13/17

Address	635 DAVIS DRIVE SUITE 300 MORRISVILLE, NC, 27560
Telephone	919-765-8400
CIK	0000876378
Symbol	TRXC
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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): October 13, 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 October 13, 2017, TransEnterix, Inc. (the "Company") announced that the Company has received clearance from the U.S. Food and Drug Administration ("FDA") for its Senhance™ Surgical Robotic System under Section 510(k) of the Food, Drug and Cosmetic Act. The Company issued a press release, which is attached as an exhibit to this Form 8-K and incorporated by reference herein, to disclose receipt of 510(k) clearance for the Senhance Surgical Robotic System.

The notice from the FDA triggers an acceleration of the expiration date of the Company's Series A Warrants to Purchase Common Stock ("Series A Warrants") to October 31, 2017. The notice of acceleration attached as an exhibit to this Form 8-K and incorporated by reference herein was provided to each registered holder of the Company's Series A Warrants.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

4.1 Notice, dated October 17, 2017, to Series A Warrant holders of acceleration of expiration date to October 31, 2017.

99.1 Press Release, dated October 13, 2017.

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Exhibit Index

Exhibit No.	Description
4.1	Notice, dated October 17, 2017, to Series A Warrant holders of acceleration of expiration date to October 31, 2017.
99.1	Press Release, dated October 13, 2017.

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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 hereunto duly authorized.

TransEnterix, Inc.

October 17, 2017

By: /s/ Joseph P. Slattery

Name: Joseph P. Slattery
Title: EVP and Chief Financial Officer

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Exhibit 4.1

TRANSENTERIX, INC.
NOTICE TO THE HOLDERS OF SERIES A WARRANTS TO PURCHASE COMMON STOCK

ACCELERATION OF EXPIRATION DATE

October 17, 2017

TransEnterix, Inc. (the "Company") hereby notifies you, as a registered holder of a Series A Warrant to Purchase Common Stock ("Series A Warrants") of the Company that the Company has received a Clearance Notice from the U.S. Food and Drug Administration providing clearance of the Company's 501(k) application with respect to its Senhance Surgical Robotic System.

In accordance with the terms of the Series A Warrants, the expiration date of the Series A Warrants has been accelerated to October 31, 2017, which is the date that is ten (10) trading days after the date of this Notice. **Unless exercised before such time, each Series A Warrant shall expire at 11:59 p.m. New York time on Tuesday, October 31, 2017.**

The exercise process is:

1. **Provide the exercise notice** for all or a portion of the Series A Warrant to the Company via email. The Company will acknowledge receipt of your exercise notice via email. Please refer to the notice dated September 15, 2017 from the Company for contact information.

2. **Pay the exercise price in cash** . The Company confirms that the Registration Statement is currently effective. The Company has previously provided you with its wire by notice dated September 15, 2017. Please send by wire or ACH. **Please insure** that no fees are deducted by your financial institution. **Please note** , ACH transactions are generally slower to process.

3. **Notify the Company** , in conformance with your internal procedures, when the wire or ACH has been sent.

4. **Issuance of Shares of Common Stock** . In accordance with the Series A Warrants, the Company's obligation is to deliver the shares on the trading day after the day the exercise price is actually received by the Company. **The Company will process all Series A Warrant exercises that it receives at or before 11:59 p.m. New York time on Tuesday, October 31, 2017.**

5. **Delivery of Series A Warrant** . If you exercise the entire Series A Warrant, or upon exercise of the last portion of a Series A Warrant, you **must** deliver the original Series A Warrant to the Company in accordance with the terms of the Series A Warrant.

Exhibit 99.1

October 13, 2017

TransEnterix Announces US 510(k) FDA Clearance for Senhance Surgical Robotic System

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 received FDA 510(k) clearance for the Senhance™ Surgical Robotic System.

"The clearance of the Senhance System in the US is a milestone in the progress of robotics and is expected to deliver improvement in the efficacy, value and choices offered to patients, surgeons and hospitals," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "Millions of surgical procedures in the US are performed each year laparoscopically with basic manual tools that limit surgeons' capability, comfort and control. New choices are needed that enhance the senses, control and comfort of the surgeon, minimize the invasiveness of surgery for the patient, and maximize value for the hospital. Senhance is this new choice."

With this clearance, the Senhance becomes the first new market entrant into the field of abdominal surgical robotics since 2000. Using the system, a surgeon directs small surgical instruments and a camera with precise movements and comfort. The system builds on the foundation of laparoscopy and features the security of haptic feedback and eye-sensing camera control for the first time in a robotic surgery platform. Additionally, the Senhance utilizes an open architecture, which allows hospitals and surgeons to leverage existing technology investments within the operating room ecosystem. The system is specifically engineered to manage operative costs effectively, making robotic surgery cost-effective on a per-procedure basis through the use of fully reusable instruments.

"Surgeons are approaching the boundaries of minimally invasive care performed with handheld manual instruments and cameras, and are seeking new technologies that will allow us to advance beyond these boundaries," said Dr. Steve Eubanks a general surgeon and Executive Director of Academic Surgery at Florida Hospital. "The future will be driven by the appropriate use of robotics and information tools in the operating room. The Senhance platform grants laparoscopic surgeons robotic precision, control of our vision, and haptic feedback while minimizing procedural costs, and is a welcome revolution in our field."

TransEnterix will host a conference call on Tuesday, October 17, 2017 at 8:00 AM ET to discuss the FDA clearance of the Senhance. To listen to the conference call on your telephone, please dial (844) 804-5261 for domestic callers or (612) 979-9885 for international callers, reference conference code 1546349. 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 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 received FDA 510(k) clearance and has been granted a CE Mark. For more information, visit the TransEnterix website at www.transenterix.com .

Forward-Looking Statements

This press release includes statements relating to 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 and include whether the Senhance Surgical Robot will deliver improvement in the efficacy, value and choices offered to patients, surgeons and hospitals, whether the Senhance System will maximize value for hospitals and whether the Senhance platform grants laparoscopic surgeons robotic precision, control of surgeon's vision and haptic feedback while minimizing procedural costs. 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 7, 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.

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