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): March 24, 2016

# 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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**Item 8.01 Other Events.**

On March 24, 2016, TransEnterix, Inc., a Delaware corporation (the "Company") announced that it has been in discussions with the U.S. Food and Drug Administration ("FDA") with respect to the Company's pending 510(k) application for its SurgiBot™ System Robotic Platform System. The Company has updated its timing expectations and now expects to obtain a final determination from the FDA by mid-April 2016.

The Company's press release is attached as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

Exhibit No. Description

99.1 Press release, dated March 24, 2016

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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.

*March 24, 2016*

*By: /s/ Joseph P. Slattery*

*Name: Joseph P. Slattery*
*Title: EVP and CFO*

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Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release, dated March 24, 2016 |

**Exhibit 99.1**
**March 24, 2016**

# TransEnterix, Inc. Provides Update on SurgiBot FDA 510(k) Submission Process

RESEARCH TRIANGLE PARK, N.C., — (BUSINESS WIRE) — TransEnterix, Inc. (NYSE MKT: TRXC), a medical device company that is pioneering the use of robotics to improve minimally invasive surgery, today announced that the Company has received an update from the FDA on the status of the 510(k) submission for the SurgiBot™ System.

The FDA advised the Company that it has not yet concluded the review of the Company's 510(k) submission and provided an update on the status of the filing. The Company has updated its timing expectations and now expects to receive a decision from the FDA by mid-April, 2016. The Company previously expected a decision from the FDA in the first quarter of 2016.

"We have been engaged in constructive dialogue with the FDA throughout the entire submission process," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We appreciate the proactive exchange with the FDA and look forward to their decision, and continue to expect clearance for the SurgiBot."

**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 development and commercialization of the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform, and the commercialization of ALF-X®, 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 tracking camera control. The SurgiBot System is not yet available for sale in any market. The ALF-X has been granted a CE Mark but is not available for sale in the US. For more information, visit the TransEnterix website at www.transenterix.com.

**Forward Looking Statements**
This press release includes statements relating to the ALF-X® System, the SurgiBot™ System and our current regulatory and commercialization plans for these 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, including whether we will obtain SurgiBot clearance, if at all, from the FDA by mid-April 2016; and whether we will be able to successfully commercialize the SurgiBot System and the ALF-X System 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 3, 2016 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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