
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):

April 20, 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 April 20, 2016, TransEnterix, Inc., a Delaware corporation (the "Company") announced that the United States Food and Drug Administration ("FDA") notified the Company on April 19, 2016 that the FDA has determined that the SurgiBot™ System does not meet the criteria for substantial equivalence based upon the data and information submitted by TransEnterix in its 510(k) submission.

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 April 20, 2016

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.

April 20, 2016

By: */s/ Joseph P. Slattery*

Name: Joseph P. Slattery

Title: Executive Vice President and CFO

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 20, 2016

April 20, 2016

TransEnterix Receives Response from the FDA on SurgiBot 510(k) Submission

RESEARCH TRIANGLE PARK, N.C. — (BUSINESS WIRE) —TransEnterix, Inc. (NYSE MKT: TRXC) today announced that the United States Food and Drug Administration (“FDA”) notified the Company on April 19, 2016 that the FDA has determined that the SurgiBot™ System does not meet the criteria for substantial equivalence based upon the data and information submitted by TransEnterix in its 510(k) submission.

“The FDA’s decision is extremely disappointing. We are in the process of reviewing all aspects of the FDA’s communication,” said Todd M. Pope, President and CEO of TransEnterix. “We will work to complete this review, and will provide an update on the regulatory strategy for the SurgiBot System together with our first quarter 2016 financial and operating results during our quarterly conference call on May 10, 2016.”

First Quarter Financial and Operating Results Conference Call

TransEnterix will release first quarter 2016 financial and operating results after the market closes on Tuesday, May 10, 2016. Todd M. Pope, President & Chief Executive Officer and Joseph P. Slattery, Executive Vice President and Chief Financial Officer will host a conference call to discuss these results starting at 4:30 pm Eastern Time the same day. The call will be concurrently webcast.

To listen to the conference call on your telephone, please dial, 888-427-9419 for domestic callers and 719-457-1035 for international callers and reference TransEnterix Call approximately ten minutes prior to the start time. 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 development and commercialization of the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform, and the ALF-X® 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 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 U.S. For more information, visit TransEnterix online 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. 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.

Contacts

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