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

May 29, 2018
Date of Report (date of earliest event reported)

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

Delaware	0-19437	11-2962080
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

635 Davis Drive, Suite 300
Morrisville, North Carolina 27560
(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 8.01 Other Items.

On May 29, 2018, TransEnterix, Inc. (the "Company") announced that it has received U.S. Food and Drug Administration's ("FDA") 510(k) clearance for expanded indications for use of the Company's Senhance™ Surgical System. The additional indications are for laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release, issued May 29, 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.

TransEnterix, Inc.

Date: May 29, 2018

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

Exhibit 99.1

May 29, 2018

TransEnterix Announces FDA Clearance for Expanded Indications for Senhance Surgical System

Receives FDA 510(k) clearance for laparoscopic inguinal hernia and laparoscopic cholecystectomy procedures

Doubles total addressable market in the U.S. to over three million annual procedures

RESEARCH TRIANGLE PARK, N.C.—(BUSINESS WIRE)— TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced that the Company has received FDA 510(k) clearance for expanded indications of its Senhance Surgical System.

The Company received FDA 510(k) clearance for laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery. There are approximately 760,000 inguinal hernia and 1.2 million laparoscopic cholecystectomy procedures performed annually in the U.S. With this clearance, Senhance System's total addressable annual procedures in the U.S. has more than doubled to over three million.

"This indication expansion immediately doubles the addressable market for Senhance in the US and validates our regulatory strategy to successfully add to our indications for use," said Todd M. Pope, president and chief executive officer of TransEnterix. "These expanded procedures are commonly performed at over 95% of hospitals in the United States. We believe this indication expansion will significantly increase the applicability of Senhance to more institutions, particularly those with a busy general surgery practice."

In the U.S., Senhance is now cleared for laparoscopic colorectal, gynecologic, inguinal hernia and cholecystectomy surgery. This enables Senhance to be used for some of the most common abdominal surgeries, including procedures in general surgery and gynecology.

"We have utilized Senhance broadly across a wide range of general surgery, upper GI surgery and colorectal procedures at our institution," said Professor Dr. Frank Willeke, Chief of Surgery at St. Marien Hospital in Siegen, Germany. "We believe this procedural expansion for the US will allow surgeons there to incorporate the Senhance, as we have, as a highly-efficient, enabling and very promising technology that can impact the vast majority of surgeries commonly performed by general surgeons and their sub-specialties."

About TransEnterix

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 contains "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, which 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 indication expansion will significantly increase the applicability of Senhance to more institutions, particularly those with a busy general surgery practice and whether the procedural expansion for the US will allow US surgeons to incorporate the Senhance as a highly-efficient, enabling and very promising technology that can impact the vast majority of surgeries commonly performed by general surgeons and their sub-specialties. We cannot assure you that our expectations will be realized. 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.

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