

**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**

**December 16, 2020  
Date of Report (date of earliest event reported)**

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

**Delaware  
(State or other jurisdiction of  
incorporation or organization)**

**0-19437  
(Commission  
File Number)**

**11-2962080  
(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))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading symbol</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock \$0.001 par value per share</b>	<b>TRXC</b>	<b>NYSE American</b>

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 Events.**

On December 16, 2020, TransEnterix, Inc., a Delaware corporation, issued a press release to announce that it has received its registration certificate by Roszdravnadzor, the Russian medical device regulatory agency allowing for its sale and utilization throughout the Russian Federation.

A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibit

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated December 16, 2020</a>
104	Cover Page Interactive Data File (formatted in inline XBRL)

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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, thereunto duly authorized.

Date: December 16, 2020

**TRANSENERIX, INC.**

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

## Exhibit 99.1

### **TransEnterix Announces Approval of Senhance® Surgical System in Russian Federation** *Approval allows for marketing and sale of Senhance Surgical System for digital laparoscopy*

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--December 16, 2020-- 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 Senhance® Surgical System has received its registration certificate by Roszdravnadzor, the Russian medical device regulatory agency allowing for its sale and utilization throughout the Russian Federation.

“Russian regulatory approval is an important milestone for TransEnterix, and this is an underserved market for robotic surgery,” said Anthony Fernando, President and Chief Executive Officer of TransEnterix. “Russia has rapidly developed expertise and adoption of minimally invasive surgery over the past 10 years, but robotic surgery remains extremely limited in the region due to high per-procedure costs and the success of laparoscopic approaches. Senhance helps address these adoption hurdles. We have worked with BOWA previously to launch four Senhance programs in the Commonwealth of Independent States (CIS) region, and look forward to partnering to leverage this recent success in entering the largest CIS market.”

TransEnterix has been partnering with BOWA-electronic GmbH & Co. KG (BOWA), based in Germany, to commercialize the Senhance Surgical System in the CIS region over the past three years. BOWA, together with its wholly-owned subsidiary OOO “BOWA Eurasia”, have an established commercial and support presence in this region. They are well equipped to drive medical device sales and provide aftersale support to hospitals in the CIS region, including Russia, for the Senhance and BOWA’s own complementary surgical device portfolio of products.

The Senhance Surgical System is the first and only digital laparoscopic platform designed to maintain laparoscopic minimally invasive surgery standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including 3 mm microlaparoscopic instruments, eye-sensing camera control, and reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy. TransEnterix also recently launched the first machine vision system in robotic surgery in the US. This first-of-its-kind augmented intelligence capability is powered by the new Intelligent Surgical Unit™ on the Senhance Surgical System. Not all features are currently available in every market.

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## **About TransEnterix**

At TransEnterix, Inc., we are digitizing the interface between the surgeon and the patient to improve minimally invasive surgery (MIS) through a new category of care called Digital Laparoscopy. Digitizing the interface enables the use of advanced capabilities like augmented intelligence, connectivity and robotics in laparoscopy, and allows us to address the current clinical, cognitive and economic shortcomings in surgery. The system features the first machine vision system for use in robotic surgery which is powered by the new Intelligent Surgical Unit™ (ISU™) that enables augmented intelligence in surgery. The Senhance Surgical System brings the benefits of Digital Laparoscopy to patients around the world while staying true to the principles of value-based healthcare. Learn more about Digital Laparoscopy with the Senhance Surgical System here: <https://Senhance.com/>. Now available for sale in the US, the EU, Japan, Russia, and select other countries. For a complete list of indications for use, please visit: <https://www.transenterix.com/indications-for-use/>.

## **About BOWA Medical**

BOWA develops and produces high-specification medical-technology solutions, and since 1977 has continuously developed into a leading technological supplier of energy-based surgical systems. With its three cutting-edge production sites in Gomaringen, Germany, Poznan, Poland, and Ashburton, UK, the core of the company is in the heart of Europe. International branches and sales offices in the Middle East, Russia, Brazil, Kazakhstan, Ukraine and additional countries across Asia guarantee global support for their customers. To find out more about, visit at [www.bowa-medical.com](http://www.bowa-medical.com).

## **Forward-Looking Statements**

This press release includes statements relating to the Senhance Surgical System and that TransEnterix has received its registration certificate by the Russian medical device regulatory agency allowing for the Senhance System's sale and utilization throughout the Russian Federation. 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 includes whether the Senhance Surgical System will help address the high-procedure costs of minimally invasive surgery in Russia. 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, 2019, filed with the SEC on March 16, 2020 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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or

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