

**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**

**January 19, 2021  
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:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
<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 January 19, 2021, TransEnterix, Inc., a Delaware corporation, issued a press release to announce that it had received CE Mark approval for the Intelligent Surgical Unit™ that enables vision capabilities on the Senhance® Surgical System.

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

Exhibit No.   Description

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99.1        [Press release dated January 19, 2021](#)

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.

**TRANSENERIX, INC.**

Date: January 19, 2021

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

# TransEnterix Receives CE Mark for Machine Vision System in Robotic Surgery

*The Intelligent Surgical Unit™ Enables Augmented Intelligence on the Senhance® Surgical System*

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- January 19, 2021-- 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 the Company received CE Mark approval for the Intelligent Surgical Unit™ (ISU™) that enables machine vision capabilities on the Senhance® Surgical System. This approval will provide Senhance digital laparoscopic programs in Europe access to this new technology, ushering them to the forefront of surgical innovation utilizing augmented intelligence.

“Augmented intelligence powered by machine vision will be one of the primary drivers in transforming surgery to enhance the capabilities of surgeons,” said Anthony Fernando, TransEnterix president and CEO. “We have already successfully implemented augmented intelligence in the U.S. with the Senhance System after receiving FDA clearance last year. We are pleased to expand this important capability to our broader global user base. ”

For the first time in surgery, the ISU’s machine vision capabilities provide the ability to recognize certain objects and locations in the surgical field. This new capability enhances visualization and camera control over currently available surgical technologies, and provides the foundation for additional augmented intelligence capabilities. Additionally, the ISU improves surgical team collaboration by seamlessly sharing the surgeon’s console view in real-time across the entire operating room. Future augmented intelligence features may include 3D point-to-point measurement and anatomical structure identification, further enhancing the digital laparoscopic experience with Senhance.

“Real-time augmented intelligence is a powerful new capability made possible by digitizing surgery,” said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center and the first surgeon to utilize the ISU in augmented surgery with Senhance. “I’ve been able to benefit from the new capabilities of the Senhance System in over 40 surgeries, to seamlessly move the camera to specific points in the surgical field and track with my instruments as I perform delicate tasks. This new technology is interpreting and analyzing information from the surgery, and the additional possibilities of this platform are very exciting.”

This Intelligent Surgical Unit is compatible with both the global installed base of Senhance Surgical Systems and with third-party vision systems that are currently supported by Senhance.

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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/>.

## **Forward-Looking Statements**

This press release includes statements relating to the Senhance Surgical System and the Company receiving CE Mark approval for its Intelligent Surgical Unit (ISU) that enables machine vision capabilities on the Senhance Surgical System. 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 ISU approval will provide Senhance digital laparoscopic programs in Europe access to this new technology, ushering them to the forefront of surgical innovation utilizing augmented intelligence and whether augmented intelligence powered by machine vision will be one of the primary drivers in transforming surgery to enhance the capabilities of surgeons. 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.

For TransEnterix, Inc.

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