

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 8, 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:

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

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 each of January 8, 2020 and January 21, 2020, TransEnterix, Inc., a Delaware corporation (the “Company”), issued a press release announcing its entry into an agreement to lease its Senhance® System to an additional hospital customer.

On January 14, 2020, the Company issued a press release to announce it had filed a 510(k) submission with the U.S. Food and Drug Administration for its Intelligent Surgical Unit (ISU™) for use with the Senhance System. The Company believes it is the first such FDA submission seeking clearance for machine vision technology in abdominal robotic surgery. A copy of the press releases are filed herewith as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 8, 2020
99.2	Press Release, dated January 14, 2020
99.3	Press Release, dated January 21, 2020

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: January 22, 2020

/s/ Anthony Fernando

Anthony Fernando

President and Chief Executive Officer

TransEnterix Announces Ochsner Health System to Initiate Program with the Senhance Surgical System

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 8, 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 Ochsner Health System has entered into an agreement to lease and utilize a Senhance® System that has been installed at the Ochsner Baptist* facility. This placement is one of the two placements referenced in the Company's January 6, 2020 press release.

The Senhance System is the first new abdominal robotic surgery platform to receive FDA clearance since 2000. It is the first and only digital laparoscopic surgical platform designed to maintain laparoscopic MIS 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.

"We are pleased that Ochsner Baptist Medical Center is beginning its digital laparoscopy program using the Senhance Surgical System," said Anthony Fernando, president and chief executive officer at TransEnterix. "Our system is designed to minimize invasiveness, maximize control, and support responsible economics for the hospital. We look forward to partnering with the surgeons at Ochsner Baptist to advance patient care in ways that matter in today's value-based healthcare landscape."

"I'm excited to bring new minimally invasive technology to the patients at Ochsner Baptist," said Dr. George B. Morris, IV, chairman of OB/GYN at Ochsner Baptist. "We believe new technology, such as the Senhance Surgical System, will allow our skilled surgeons to maximize control, offer precise surgery, and minimize invasiveness for patients."

"As a health system, we are continuing to drive innovation as part of our mission to serve our patients," said Beth Walker, chief executive officer Ochsner Baptist. "We evaluated the Senhance Surgical System and believe it will be a welcome addition to our leading offering for patients seeking advanced minimally invasive and robotic surgery."

*Ochsner Baptist – a campus of Ochsner Medical Center

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, Japan and select other countries. For more information, visit www.transenterix.com.

About Ochsner Health System

Ochsner Health System is Louisiana's largest non-profit, academic, healthcare system. Driven by a mission to Serve, Heal, Lead, Educate and Innovate, coordinated clinical and hospital patient care is provided across the region by Ochsner's 40 owned, managed and affiliated hospitals and specialty hospitals, and more than 100 health centers and urgent care centers. Ochsner is the #1 ranked hospital in Louisiana by U.S. News & World Report and is recognized as a "Best Hospital" across two specialty categories caring for patients from all 50 states and more than 70 countries worldwide each year. Ochsner Hospital for Children is the only facility in Louisiana to be recognized as a top 50 children's hospital by U.S. News & World Report for three consecutive years. Ochsner employs nearly 25,000 employees and over 4,500 employed and affiliated physicians in over 90 medical specialties and subspecialties and conducts more than 700 clinical research studies. Ochsner Health System is proud to be a tobacco-free environment. For more information, please visit ochsner.org and follow us on Twitter and Facebook.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Ochsner Health System initiating a program with the Senhance 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 TransEnterix's partnering with the surgeons at Ochsner Health System will advance patient care in ways that matter in today's value-based healthcare landscape; whether surgeons at Ochsner Baptist, using the Senhance System, will maximize control, offer precise surgery and minimize invasiveness for patients; and whether the Senhance System will be a welcome addition to Ochsner Baptist's leading offering for patients seeking advanced minimally invasive and robotic surgery. 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, 2018, filed with the SEC on February 27, 2019 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.

Source: TransEnterix, Inc.

For TransEnterix, Inc.

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TransEnterix Announces Submission of 510(k) to FDA for First Machine Vision System in Robotic Surgery

New Technology Would Enable Augmented Intelligence with the Senhance Surgical System

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--January 14, 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 the Company filed a 510(k) submission with an Intelligent Surgical Unit (ISU™) that is designed to enable machine vision capabilities on the Senhance[®] Surgical System.

"TransEnterix is the first company to seek FDA clearance for machine vision technology in abdominal robotic surgery. Rather than simply passing a video signal to the surgeon, the Intelligent Surgical Unit for Senhance will initially have the ability to actually visualize the surgical field to guide movement and capture information," said Anthony Fernando, TransEnterix president and CEO. "This technology advance is an important first step towards enabling augmented intelligence and we believe it will support continued machine vision driven advances in surgery performed with the Senhance Digital Laparoscopy Platform."

The initial features of the Intelligent Surgical Unit (ISU) are designed to increase control in visualization beyond what has previously been available in digital laparoscopy or robotic surgery. The cleared Senhance System already features unique eye-tracking camera control and the new technology would enable machine vision driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field. The ISU hardware is also designed to be compatible with planned future augmented intelligence features such as scene cognition and surgical image analytics that are expected to continue to drive meaningful innovations in digital laparoscopy with Senhance.

"Many of us that perform and teach surgery firmly believe that the care of patients will be transformed by augmented intelligence and machine vision capabilities in the future," said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center and a participant in the design and usability studies conducted in support of the 510(k) submission of the ISU. "Imagine if a computer could be the best assistant you've ever had in surgery by anticipating and moving a camera effortlessly to maximize control of the visual field. I'm very excited about this new addition to the Senhance System."

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

Senhance Indication for use

In the U.S., The Senhance[®] Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization and retraction. The Senhance Surgical System is intended for use in laparoscopic gynecological surgery, colorectal surgery, cholecystectomy, and inguinal hernia repair. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the Instructions for Use. The device is restricted to sale by or on the order of a physician.

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 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 System is available for sale in the US, the EU, Japan and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Company's 510(k) submission with an Intelligent Surgical Unit that is designed to enable 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 FDA will clear TransEnterix's 510(k) submission; whether the 510(k) submission will support continued machine vision driven advances in surgery performed with the Senhance Digital Laparoscopy Platform; and whether the ISU hardware with planned future augmented intelligence features will continue to drive meaningful innovations in digital laparoscopy with Senhance. 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, 2018, filed with the SEC on February 27, 2019 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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Exhibit 99.3

TransEnterix Announces Klinikum Esslingen to Initiate a Senhance Surgical System Program

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 21, 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 Klinikum Esslingen, a hospital in southern Germany close to Stuttgart, has entered into an agreement to lease and utilize a Senhance[®] System. The Senhance System has been installed at the hospital facility and cases are expected to begin shortly. This placement is one of the two placements referenced in the Company's January 6, 2020 press release.

Klinikum Esslingen is a major German hospital that serves as the academic teaching hospital of the University of Tübingen. The facility has more than 660 beds and performs more than 9,000 surgical interventions each year.

The Senhance[®] Surgical System is the first and only digital laparoscopic platform designed to maintain laparoscopic MIS 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.

"We are committed to support and grow the outstanding minimally invasive surgical program of Klinikum Esslingen with the addition of a Senhance System," said Anthony Fernando, president and chief executive officer at TransEnterix. "We continue to see strong momentum in Germany, and the expansion into such a prestigious hospital as the Klinikum Esslingen is a significant milestone in the advancement of digital laparoscopy with Senhance in Europe."

"We have created a strong, multidisciplinary program in minimally invasive surgery at our hospital," said Professor Dr. Ludger Staib, chief physician of the clinic for general and visceral surgery at the Klinikum Esslingen. "We believe modern technology can help offer our patients the most precise and least invasive surgery possible, and we appreciate the ability to build on our strong existing minimally invasive program with the Senhance that will allow for maximum precision, visualization and control during delicate surgeries."

About TransEnterix

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Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Klinikum Esslingen hospital initiating a program with the Senhance 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 TransEnterix will continue to see strong momentum in Germany, whether the expansion of the Senhance System into Klinikum Esslingen will serve as a significant milestone in the advancement of digital laparoscopy in Europe, and whether the use of a Senhance System in the minimally invasive program at Klinikum Esslingen will allow for maximum precision, visualization and control during delicate surgeries. 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, 2018, filed with the SEC on February 27, 2019 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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