
**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 6, 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>
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 January 6, 2021, TransEnterix, Inc., a Delaware corporation (the “Company”), issued a press release announcing an update with preliminary financial results for the fourth quarter and full year ended December 31, 2020.

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	Press release dated January 6, 2021
104	Cover Page Interactive Data File (formatted in inline XBRL)

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: January 6, 2021

TRANSENERIX, INC.

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

TransEnterix Provides Preliminary 2020 Year-End Corporate Update

January 6, 2021

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 6, 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 provided a preliminary 2020 year-end corporate update.

Recent Highlights

- Senhance® Surgical System received its registration certificate by the Russian medical device regulatory agency, Roszdravnadzor, allowing for its sale and utilization throughout the Russian Federation
- Southern Surgical Hospital, a hospital based in Louisiana, entered into an agreement to lease and utilize a Senhance Surgical System
- First pediatric cases utilizing Senhance completed in October, representing the first time that 3mm instruments were used in robotic pediatric surgery
- First surgical procedures successfully completed using the Intelligent Surgical Unit™ (ISU™), leveraging augmented intelligence and machine vision capabilities on the Senhance Surgical System

Year-End Highlights

- In 2020, ten Senhance Systems were installed under operating leases, nine clinical programs were initiated, and over 1,450 procedures were performed globally
- At December 31, 2020, the Company had approximately \$17.5 million in cash, cash equivalents and restricted cash. The Company currently expects to have cash to support operations into the third quarter of 2021
- Fourth quarter revenue is expected to be approximately \$1.1 million
- Full year 2020 revenue is expected to be approximately \$3.0 - \$3.2 million

“Looking at 2020 as a whole we are pleased with the momentum generated across our organization during these challenging times. We continued to expand our global footprint with new system installations and procedure volumes rebounded in the back half of the year across each of our geographies. In addition, we had a number of regulatory and portfolio expansion milestones including the introduction of machine vision and augmented intelligence which enable the promise of digital laparoscopy,” said Anthony Fernando, President and CEO of TransEnterix. “We built a great foundation in 2020 and we are planning to continue to execute on our strategy in 2021, bringing transformative technology to surgeons, hospitals and patients across the globe.”

Upcoming 2021 Milestones

During the first half of 2021, the Company expects to achieve the following regulatory milestones:

- Receive CE Mark approval for the ISU in Europe
- Receive FDA 510(k) clearance for General Surgery indication expansion
- File for FDA 510(k) clearance for articulating instruments
- File for FDA 510(k) clearance for the next generation ISU features

During the first half of 2021, the Company expects to publish clinical papers in peer reviewed journals on the following subjects:

- Health economic studies comparing Senhance Digital Laparoscopy, laparoscopy, and robotic surgery
- Clinical performance when utilizing the Senhance Surgical System
- Operating room efficiency and surgeon ergonomics when utilizing Senhance Surgical System

Market Development

2020 Senhance Surgical System Placements

Throughout 2020, the Company initiated ten clinical programs: three in the US, four in Europe, and three in Asia.

In December 2020, the Company announced that Southern Surgical Hospital, a hospital based in Louisiana, has signed an agreement to initiate a Senhance Digital Laparoscopic program. This will represent the third Senhance Surgical program initiated in the state of Louisiana since 2018 (May 2018 - LSU Health's University Medical Center New Orleans, January 2020 - Ochsner Baptist Medical Center). LSU Health, in addition to utilizing a Senhance system in their Digital Laparoscopy program, is home to one of the Senhance Surgical training centers in the southeast United States.

Training Sites

In the third quarter, the Company established the first training center for the Senhance Surgical System in the Asia-Pacific region in Japan at the Saitama Medical University International Medical Center in the Greater Tokyo Area. The Asia-Pacific region has been a major contributor of new system placements and surgical cases utilizing the Senhance Surgical System and the Asia-Pacific laparoscopy device market is expected to grow from \$1.26 billion in 2019 to \$1.87 billion by 2024, according to Market Data Forecast, Inc. The training center is expected to drive increased utilization of our eight system installations in the Asia-Pacific region and encourage further adoption of our technology in additional hospitals.

Procedure Volumes

In 2020, surgeons performed over 1,450 procedures utilizing the Senhance Surgical System, representing a 10% decrease over the previous year, which was less than our goal as a result of the COVID-19 pandemic. These procedures included general surgery, gynecology, urology, colorectal and bariatric surgical cases.

Foundational Sites

As of December 31, 2020, the Company had 11 foundational sites, up from 7 at the start of 2020. Foundational sites are hospitals that are performing clinical procedures with the Senhance Surgical System at an annualized rate of greater than 100 procedures per year.

Clinical Validation

During 2020, there were 15 peer-reviewed clinical papers published providing further support of the clinical utility of the Senhance Surgical System across gynecology, general surgery, urology and colorectal procedures demonstrating the utility breadth and the complexity of procedures being performed.

Portfolio Expansion

Intelligent Surgical Unit™(ISU™)

The Company received 510(k) clearance for the ISU that enables machine vision capabilities on the Senhance Surgical System. On September 23, 2020, the Company announced the first surgical procedures successfully completed using the ISU.

Pediatric Indication

The Company received CE Mark approval for an expanded indication to treat pediatric patients. During the fourth quarter of 2020, the Company announced the first pediatric surgical cases with Senhance Surgical System at Maastricht University Medical Center+ in the Netherlands.

General Surgery Indication

The Company submitted an application for 510(k) approval for an expanded General Surgery indication for use for the Senhance Surgical System to the FDA.

Russian Regulatory Approval

During the fourth quarter of 2020, the Company received approval for the Senhance Surgical System in the Russian Federation allowing for its sale and utilization throughout the Russian Federation. We believe that the Russian robotic surgery market is underserved and provides an opportunity to grow Senhance Surgical System placements and sales.

Fourth Quarter and Full Year 2020 Revenue

During the quarter ended December 31, 2020, the Company expects preliminary unaudited revenue of approximately \$1.1 million. For the full year, preliminary unaudited 2020 revenue is expected to be approximately \$3.0 - \$3.2 million, representing revenues from Senhance Surgical System leasing and related revenues from instruments, accessories and services.

Balance Sheet

As of December 31, 2020, the Company had preliminary unaudited cash, cash equivalents and restricted cash of approximately \$17.5 million, and there were approximately 116.2 million shares of common stock outstanding.

On October 9, 2020, the Company filed a prospectus supplement, relating to an “at the market” offering (ATM Offering) of up to an aggregate of \$40.0 million of shares of the Company’s common stock, through Cantor Fitzgerald & Co. (Cantor), as sales agent under an existing Sales Agreement. During the quarter ended December 31, 2020, the Company raised gross proceeds of approximately \$9.3 million, and net proceeds of approximately \$9.0 million under the ATM Offering.

As a result of the restructuring completed in the first quarter of 2020, cost optimization efforts, and equity financings, together with anticipated cash received from operating activities, including cash from system sales and leases, instruments and accessories, and services, we believe that cash on hand will be sufficient to meet our anticipated cash needs into the third quarter of 2021.

COVID-19 Pandemic

The COVID-19 pandemic continues to have a significant impact on the Company’s operations, primarily due to the temporary cessation of elective surgical procedures in many markets, and the challenges and restrictions caused by stay-at-home orders, social distancing requirements and travel restrictions. The Company’s business and customers were negatively impacted by the COVID-19 pandemic, which suspended many elective surgical procedures globally, curtailed travel and necessarily diverted the attention of hospital customers. The Company has taken steps, and continues to take further actions, to minimize the impact of the COVID-19 pandemic on its business. A variety of travel restrictions have caused delays in product installation and training activities. Since the second quarter of 2020, the Company has seen elective surgical procedures recommence in the United States, Europe and Japan, but not, to date, to the levels seen before the COVID-19 pandemic. This has significantly impacted its ability to implement its market development activities to place its Senhance Systems, provide training, and increase the use of the Senhance Systems in place. Given the dynamic nature of this health emergency, the full impact of the COVID-19 pandemic on ongoing business, results of operations and overall financial performance cannot be reasonably estimated at this time.

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 System and our preliminary 2020 results. 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 we will be able to continue to progress our strategic plan in 2021; whether 2020 fourth quarter revenue will be approximately \$1.1 million; whether 2020 revenue for the full year will be approximately \$3.0 - \$3.2 million; whether cash, cash equivalents and restricted cash will be \$17.5 million as of December 31, 2020; whether the Russian robotic surgery market is underserved and provides an opportunity to grow Senhance Surgical System placements and sales; whether we can continue to increase Senhance System placements and sales, whether we can continue to add foundational sites and receive regulatory clearances and approvals that we seek, whether our cash on hand will be sufficient to meet our anticipated cash needs into the third quarter of 2021 and whether we can continue to support our operations through capital raising transactions. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (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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