



February 14, 2018

## **TransEnterix Announces FDA 510(k) Submission for Senhance Indication Expansion to More than Double Addressable Market in the U.S. and Provides Commercial Update**

*Filed 510(k) submission for indication expansion into laparoscopic hernia and laparoscopic cholecystectomy procedures*

*Announces second Senhance sale in the first quarter of 2018*

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 the Company has filed a FDA 510(k) submission to expand the indication for use of its Senhance™ Surgical System, and provided an update about commercial results thus far for the quarter ending March 31, 2018.

The Company recently filed a FDA 510(k) submission to include laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery in the indicated list of covered procedures. The clearance for these indications would allow the Senhance to be used for the most common abdominal surgeries in the U.S. in general surgery, gynecology and colorectal surgery. In collecting the data submitted, the Company leveraged its broad CE mark that includes full use in the abdominal and pelvic cavities, and specific uses in the thoracic cavity. The Company expects to achieve FDA clearance for these expanded indications by mid-year 2018.

"Clinicians are now successfully using Senhance outside of the United States to address a multitude of procedures and specialties. Collecting human clinical data from these experiences to drive expanded applicability of the system is a key element of our strategy," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "This FDA filing is an excellent example of this strategy in action; once cleared by the FDA, our addressable market in the United States will more than double to approximately three million procedures."

The Senhance System is currently cleared for use in the U.S. for laparoscopic colorectal surgery and laparoscopic gynecologic surgery, accounting for approximately 1.5 million procedures in the U.S. annually. There are approximately 760,000 inguinal hernia and 1.2 million laparoscopic cholecystectomy procedures performed annually in the U.S. Upon clearance, the Senhance System's total addressable procedures in the U.S. will more than double to approximately three million.

"We have performed more than 150 Senhance surgeries across a wide range of general surgery and colorectal cases since we purchased a Senhance System less than a year ago." said Dr. Dietmar Stephan, Head of Minimally Invasive and Robotic Surgery at St. Marien Hospital in Siegen, Germany. "Our clinical experience, and those of other European hospitals, was used in showing the results of Senhance in hernia and gallbladder surgery. We are continuing to generate clinical data and are successfully expanding our utilization of Senhance in laparoscopic surgery."

### **Commercial Update**

Thus far in the quarter ending March 31, 2018, the Company has delivered one Senhance System and has received an additional order that it expects to deliver and recognize revenue for in the quarter ending March 31, 2018. Both of these sales have come from sales to end user hospitals by distributors in the Company's EMEA (Europe, Middle East, and Africa) region.

### **About TransEnterix, Inc.**

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](http://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 expansion of the indications for use of the Senhance System to include laparoscopic inguinal hernia and laparoscopic cholecystectomy will be approved by mid-year 2018, if at all, and whether, upon clearance the Senhance System's total addressable procedures in the U.S. will more than double to approximately three million procedures. 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 6, 2017 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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