



TransEnterix Announces FDA 510(k) Submission for Senhance Ultrasonic Instrument System

September 6, 2018

Filed 510(k) submission for Senhance Ultrasonic, broadening the potential applicability of Senhance surgery in the U.S.

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Sep. 6, 2018-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between surgeons and patients to improve minimally invasive surgery, today announced the Company filed a FDA 510(k) submission for its Senhance Ultrasonic Instrument System.

Advanced energy devices, including ultrasonic devices, represent some of the most versatile and critical tools for surgeons in minimally invasive surgery. These instruments deliver controlled energy to effectively ligate and divide tissue, and minimize thermal injury to surrounding structures.

"Advanced energy devices are an important tool within laparoscopic surgery because of their applicability within a wide range of procedures," said Todd M. Pope, TransEnterix CEO. "Once approved, we believe the addition of the Senhance Ultrasonic will be a useful tool for surgeons and help drive broader penetration of Senhance and help advance digital laparoscopy in the U.S."

"Advanced energy devices, such as the one now developed for Senhance, represent the most common tools that surgeons utilize when performing challenging tissue dissections," said Dr. Guy Orangio, FACS, FASCRS, Chief Section of Colorectal Surgery at LSU Health New Orleans, and Past President of the American Society of Colon and Rectal Surgeons. "Adding such capability to a digital laparoscopic platform will further enable wide clinical use."

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.

Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System and the Senhance Ultrasonic Instrument System and our current regulatory and commercialization plans for this product. 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 Senhance Ultrasonic Instrument System will be approved, whether the Senhance Ultrasonic will be a useful tool for surgeons and help drive broader penetration of Senhance and help advance digital laparoscopy in the U.S., and whether the addition of the ultrasonic energy device to a digital laparoscopic platform will further enable wide clinical use. 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 8, 2018 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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