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TransEnterix Submits 510(k) Application to FDA for SurgiBot System

-- First Patient-Side Robotically Enhanced Laparoscopic Surgery Platform --

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- TransEnterix, Inc. (NYSE MKT:TRXC), a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery, today announced the submission of its 510(k) application with the U.S. Food and Drug Administration (FDA) for clearance of the company's SurgiBot™ System.

"TransEnterix is pleased to deliver on our commitment to file for 510(k) clearance for the SurgiBot System by mid-2015," said TransEnterix President and CEO, Todd M. Pope. "Robotically enhanced laparoscopy with the SurgiBot System represents the first surgical platform designed to address economic and clinical challenges associated with current laparoscopic and robotic options. We view the SurgiBot as a market-expanding technology with a compelling value for a wide variety of surgical facilities with the potential to deliver critical benefits to surgeons, hospitals and patients. We look forward to continuing our preparation to bring this innovative technology to the market upon FDA clearance."

The SurgiBot System is the first patient-side, robotically enhanced laparoscopy platform. Our goal is to usher in the next wave of minimally invasive surgery by delivering excellent instrument dexterity and precision, surgeon comfort, and minimize patient incisions. The system is also designed to be mobile, minimize reliance on additional staff, and be cost-effective for many types of surgical facilities.

The surgical approach and motions used with the SurgiBot are intended to mimic established laparoscopic surgical techniques. The system utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, from within the sterile field. The flexible nature of the system allows multiple instruments to be introduced and deployed through a single incision.

About TransEnterix

TransEnterix is a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery by addressing the economic and clinical challenges associated with current laparoscopic and robotic options. The company is focused on the development and commercialization of the SurgiBot system, a robotically enhanced laparoscopic surgical platform that allows the surgeon to be patient-side within the sterile field. For more information, visit the company's website at www.transenterix.com.

Forward Looking Statements

This press release includes statements relating to the SurgiBot System, and our current regulatory and commercialization plans for these products. 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, including whether we will be able to successfully commercialize the SurgiBot System and whether the SurgiBot System will be able to be utilized in a wide variety of surgical facilities with the potential to deliver critical benefits to surgeons, hospitals and patients. Factors that could cause our results to differ materially from those described include, but are not limited to, whether the SurgiBot System's 510(k) application will be cleared by the U.S. FDA. For a discussion of the most significant 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, 2014 filed on February 20, 2015 as amended, and other filings we make with the Securities and Exchange Commission. 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 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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