

# **TransEnterix Announces Completion of GLP Studies**

# SurgiBot<sup>TM</sup> system FDA 510(k) filing on track for mid-2015 submission

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- <u>TransEnterix</u>, Inc. (NYSE MKT: <u>TRXC</u>), a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery, today announced the successful completion of its GLP Studies using the SurgiBot system, its patient-side robotic surgery system. Management also commented that the Company remains on track to submit its FDA 510(k) filing in mid-2015.

"We are pleased to have completed our GLP Studies, one of the key remaining steps prior to the upcoming 510(k) submission for the SurgiBot system. Our GLP studies included multiple procedures performed by surgeons from varying specialties to demonstrate the system's ability to handle the critical tasks commonly performed in laparoscopy," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "Importantly, we continue to be in position for a mid-2015 submission."

Dr. Michel Gagner of Montreal, Canada and President of the 2014 World Congress of the International Federation for the Surgery of Obesity & Metabolic Disorders was one of the investigators for the study. "The SurgiBot system proved to be capable of effectively performing surgery in this completed study," said Dr. Gagner. "The system provided articulating vision and multiple instruments through a single incision. The user experience keeps the surgeon in the sterile field with familiar laparoscopic movement. I prefer to be at the patient's side during surgery, and appreciate maintaining the approach and movement of gold standard laparoscopic surgery while adding the features of robotic assistance."

### **Analyst Event**

The Company will host an Analyst Event featuring an expert panel of laparoscopic surgeons at 10:00am CT / 11:00am ET on Friday, April 17, 2015. The event will take place at the Gaylord Opryland Resort and Convention Center in Nashville, TN, and a live webcast will be accessible using the following link: <a href="http://ir.transenterix.com/events.cfm">http://ir.transenterix.com/events.cfm</a>. A replay will be available on the company's website.

## **About SurgiBot**

The SurgiBot system, currently in development, is a minimally invasive, patient-side robotic surgery system. The system utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, at the patient's bedside. The flexible nature of the system allows for multiple instruments to be introduced and deployed through a single incision. The SurgiBot system has not been cleared by the FDA for use the in United States.

#### **About TransEnterix**

TransEnterix is a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery. The company is focused on the development and commercialization of the SurgiBot system, a minimally invasive surgical robotic system that allows the surgeon to be patient-side within the sterile field. For more information, visit the company's website at <a href="https://www.transenterix.com">www.transenterix.com</a>.

#### **Forward Looking Statements**

This press release includes statements relating to the SurgiBot system, our flexible energy device 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 successfully submit our SurgiBot system regulatory filings in mid-2015, 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 procedures. 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 (s) 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.

### **Investor Contact:**

Westwicke Partners
Mark Klausner, 443-213-0501
transenterix@westwicke.com

## **Media Contact:**

TransEnterix, Inc.
Mohan Nathan, 919-917-6559
mnathan@transenterix.com

Source: TransEnterix, Inc.

News Provided by Acquire Media