

TRANSENERIX INC.  
Form 10-K  
February 20, 2015

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2014**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number 0-19437**

**TRANSENERIX, INC.**

**(Exact name of registrant as specified in its charter)**

|   |  |
|---|--|
| <b>Delaware</b><br>(State or other jurisdiction of<br>incorporation or organization)                            | <b>11-2962080</b><br>(I.R.S. Employer<br>Identification No.) |
| <b>635 Davis Drive, Suite 300, Morrisville, NC 27560</b><br>(Address of principal executive offices) (Zip Code) |  |

**Registrant's telephone number, including area code: (919) 765-8400**

**Securities registered pursuant to Section 12(b) of the Act:**

| <b>Title of each class</b>   | <b>Name of each exchange on which registered</b> |
|--|--|
| <b>Common Stock</b>  | <b>NYSE MKT</b>                                  |
| <b>\$0.001 par value per share</b>                                 |  |
| <b>Securities registered pursuant to Section 12(g) of the Act:</b> |  |

**None**

**(Title of class)**

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ☒.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes ☐ No ☒.

On June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value (based on the average bid and asked price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was \$144,527,730.

The number of shares outstanding of the registrant's common stock, as of February 16, 2015 was 63,379,939.

**TRANSENERIX, INC.**

**ANNUAL REPORT ON FORM 10-K**

**DECEMBER 31, 2014**

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## **FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K ( Annual Report ) contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). Such forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Many factors could cause our actual operations or results to differ materially from the operations and results anticipated in forward-looking statements. These factors include, but are not limited to:

our history of operating losses and uncertainty as to our ability to continue as a going concern;

our need to obtain additional funding to continue our operations;

our ability to successfully develop, clinically test and commercialize our products;

the timing and outcome of the regulatory review process for our products;

our ability to attract and retain key management, marketing and scientific personnel;

competition from existing and new market entrants;

our ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights;

our ability to successfully transition from a research and development company to a company focused on marketing, sales and distribution of our products in development;

changes in the health care and regulatory environments of the United States and other countries in which we intend to operate;

our ability to identify and pursue development of additional products; and

other factors contained in the section entitled Risk Factors contained in this Annual Report.

We do not undertake any obligation to update our forward-looking statements, except as required by applicable law.

## PART I

### ITEM 1. BUSINESS

#### Overview

TransEnterix, Inc. (the Company) is a medical device company that is focused on the development and future commercialization of a robotic-assisted surgical system called the SurgiBot System (the SurgiBot System). The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for three-dimensional (3-D) high definition vision technology.

On September 3, 2013, TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical), and SafeStitch Medical, Inc., a Delaware corporation (SafeStitch), consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the Merger). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. As used herein, the terms Company, we or us each refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger. The term SafeStitch refers to the historic business of SafeStitch Medical, Inc., prior to the Merger. The term TransEnterix Surgical refers to the historic business of TransEnterix Surgical, Inc., prior to the Merger. For a description of the Merger and related transactions, see the disclosure on page 41 of this Annual Report.

Prior to the Merger, each of TransEnterix Surgical and SafeStitch was focused on developing and/or commercializing other products, which product development and commercialization activities ceased in 2014. See the description below under the heading Product Overview - Prior Product Development Activities.

The Company operates in one business segment.

We believe that future outcomes of minimally invasive surgery will be enhanced through our combination of more advanced tools and robotic functionality which are designed to: (i) empower surgeons with improved precision, dexterity and visualization; (ii) improve patient satisfaction and enable a desirable post-operative recovery; and (iii) provide a cost-effective robotic system, compared to existing alternatives today, for a potentially wide range of clinical applications. Our strategy is to focus on the development and future commercialization of the SurgiBot System.

#### Market Overview

Over the past two decades laparoscopic surgery has emerged as a minimally invasive alternative to open surgery. In laparoscopic surgery, multiple incisions are spread over the body, carbon dioxide gas insufflation is used to create room in the body cavity, and long rigid instruments are introduced through ports placed in the incisions to perform surgical tasks. Millions of laparoscopic surgical procedures across a broad range of clinical applications are now performed each year worldwide, though many surgeries are still performed in an open fashion.

While laparoscopy has improved the invasive nature of many previously open procedures, it still has many limitations. Traditional, or rigid, laparoscopy still requires multiple incisions to achieve the visualization and instrument triangulation required to perform successful surgery. Rigid laparoscopy also creates physical challenges by forcing the surgeon's hands and arms into awkward angles, requiring the surgeon to hold instruments in fixed positions for long periods of time, and requiring an assistant to stabilize and move a laparoscopic camera. Another challenge associated with rigid laparoscopic surgery is the creation of a cumbersome and potentially tissue-damaging fulcrum at the patient's abdominal wall where instruments are manipulated. Nearly all laparoscopic instruments are rigid instruments that lack the internal articulation required to enhance dexterity in complex tasks. Most laparoscopic surgeries are performed with two-dimensional (2-D) visualization of the operative field, making depth perception difficult.

Robotic and computer controlled assistance have developed as technologies that offer the potential to improve upon many aspects of the laparoscopic surgical experience. Hundreds of thousands of robotic-assisted surgical procedures are now performed each year worldwide, but they still represent a small fraction of total laparoscopic procedures performed. While initial widespread adoption of robotic-assisted surgery was focused on urologic and gynecologic procedures that were primarily performed in an open fashion prior to robotics, recently developed robotic approaches have been applied to many other clinical applications, particularly in general surgery. Despite recent advances, we believe there remain many limitations created by current robotic-assisted surgery systems used in connection with laparoscopic surgeries. For example, existing robotic systems require a large capital investment. Moreover, existing robotic systems require the surgeon to sit outside of the sterile field, requiring the surgeon leave the operating room to scrub in should it become necessary to enter the sterile field. There are further challenges in maneuvering the patient once a large, multi-arm robotic system is fixed in place.

Both traditional laparoscopic surgery and robotic-assisted surgery have begun to migrate towards methods and technologies that may allow for fewer incisions in the patient. The first major attempts at reduced incision or single incision surgery were through access ports that utilized long, rigid instruments. These instruments were usually crowded in a small space, often at the patient's umbilicus, along with a laparoscopic camera for visualization. This configuration resulted in instrument collision, difficulty in establishing triangulation and working space for the instruments, and, often, difficulty associated with the crossing of instruments. More recent attempts at reduced incision surgery have leveraged robotic technology, but these efforts have diminished some of the benefits typically offered by robotic surgical systems and are plagued by some of the limitations of currently available robotic systems.

### **Product Overview**

We are addressing the challenges in laparoscopy and robotic-assisted surgery with innovative products and product candidates that leverage the best features of both approaches to minimally invasive surgery.

### **Current Products in Development**

#### ***SurgiBot System***

The SurgiBot System is currently in development and is designed as a single-incision, patient-side robotic-assisted surgery system. The system is intended to bring many of the advantages of robotic assistance to single-incision laparoscopic surgery while mitigating many of the drawbacks of existing robotic-assisted surgery systems.



The SurgiBot System is composed primarily of three key components:

**The SurgiBot Base:** a reusable robotic base that provides the platform of the system;

**The EndoDrive:** a single port, surgical access device for abdominal surgery that interfaces with the SurgiBot Base, which allows for the insertion of surgical instruments for the surgical procedures being performed; and

**The Positioning Arm:** a reusable arm that supports and repositions the SurgiBot Base at the operating table. Key design features of the SurgiBot System are:

**Patient side:** The SurgiBot System is positioned next to the operating table, thereby allowing the surgeon, as operator, to remain in the sterile field next to the patient;

**Precision with scaling:** The SurgiBot System allows the user to adjust the level of mechanized movement using scaled ratios;

**Strength:** The SurgiBot System features powered motion driven by motors controlled by the surgeon;

**Ergonomics:** The SurgiBot System stabilizes multiple instruments and a laparoscope and allows the surgeon to reposition their hands in an ergonomic fashion;

**Internal Triangulation:** The SurgiBot System utilizes a deployment mechanism to achieve triangulation of multiple instruments inside the body as contrasted with other single-port robotic systems that rely on crossing instruments at the patient's abdominal wall. The SurgiBot System allows for triangulation that can be repositioned in the surgical field during a procedure and be maintained at positions throughout a body cavity;

**Direct surgeon connection to the instruments:** The SurgiBot System allows the surgeon-operator to maintain human tactile feedback along several degrees of motion. Existing robotic systems lack any such tactile feedback; and

**Integration with 3-D Vision System:** The SurgiBot System integrates a three-dimensional scope and vision system for laparoscopic surgical visualization that can be viewed by all operating room personnel, not just the surgeon.

We believe the SurgiBot System will address the needs of the large and growing, yet underserved, population of physicians and hospitals who wish to offer the benefits of robotic-assisted surgery without the functional and economic challenges of current solutions. The SurgiBot System is designed for a potentially wide range of clinical

applications, and we believe the system will be particularly attractive for general, bariatric and gynecologic surgery. In addition, we believe that the SurgiBot System can be offered to hospitals and ambulatory surgery centers (ASCs) at a cost advantage relative to existing robotic surgery systems, and we expect hospitals, ASCs and physicians will be able to utilize existing laparoscopic procedure codes to receive reimbursement for procedures performed with the SurgiBot System.

### ***Surgical Instruments***

The Company has developed and manufactures, or has manufactured, flexible and rigid laparoscopic surgical instruments that are used in abdominal surgery, such as scissors, graspers, clip applicators, and suction and irrigation instruments. Such instruments were sold in limited volumes in connection with the SPIDER® System, described below, and have been adapted for use with the SurgiBot System.

In April 2014, we launched one such instrument for use with the SPIDER System, a flexible energy device. This product received 510(k) clearance in March 2013 from the U.S. Food and Drug Administration (FDA), and it provides surgeons with a flexible instrument that can be used to perform tissue ligation. We believe the flexibility of our instrument provides the surgeon with the ability to create proper angles for tissue ligation that cannot be achieved with the rigid products currently being sold.

### **Prior Product Development Activities**

#### ***SPIDER Surgical System***

Prior to the Merger, TransEnterix Surgical developed and commercialized the SPIDER Surgical System (the SPIDER System), a manual laparoscopic system, in the United States, Europe and the Middle East. The SPIDER System utilized flexible instruments and articulating channels that were controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System was cleared by the FDA in 2009 and CE Marked in August 2011. The Company also manufactured multiple instruments that could be deployed using the disposable SPIDER System.

The SPIDER System was commercially available in a limited release in select markets worldwide. It was distributed directly by TransEnterix Surgical in the United States. Outside of the United States, the SPIDER System was sold by distributors pursuant to distribution agreements. Based on input from customers and other surgeons, we determined that there was a greater market opportunity for a more fully-featured system (intended to be the SurgiBot System). As of December 31, 2014, we ceased all commercialization efforts with respect to the SPIDER System in order to fully focus our efforts on the SurgiBot System.

In the year ended December 31, 2014, we had one U.S. customer who accounted for 37% of the revenue of TransEnterix Surgical's products, including the SPIDER System. In the year ended December 31, 2013, we had one international customer who accounted for 37% of the revenue from TransEnterix Surgical's products, including the SPIDER System. The international customer was Al Danah Medical Co. W.L.L., a distributor of such products pursuant to a pre-release distribution agreement with TransEnterix Surgical dated June 10, 2012. Although these customers were the most significant purchasers of our commercialized products during 2014 and 2013, we do not believe we are dependent on such customers, as we ceased selling our SPIDER System products in 2014. The Company is continuing to consider alternatives to monetize the SPIDER System assets.

#### ***Intraluminal Gastroplasty Device (Gastroplasty Device)***

Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity, gastroesophageal reflux disease (GERD) and Barrett's Esophagus. SafeStitch had developed other surgical devices, including the SMART Dilator, to be utilized in treating obesity, GERD and esophageal strictures, but the Company ceased development of such other devices in 2013. In the second quarter of 2014, the Company determined to cease internal development of the Gastroplasty Device. The Company is evaluating strategic alternatives for the former SafeStitch products.

Prior to the Merger, SafeStitch also developed and was commercializing a surgical stapler called the AMID Hernia Fixation Device. The Company discontinued sales of the AMID Hernia Fixation Device in 2014.

## **Business Strategy**

Our strategy is to focus our resources on the development and commercialization of the SurgiBot System. We are planning to make the product available, subject to our obtaining the requisite regulatory and government clearances.

We believe that:

there are a number of hospitals and an increasing number of ambulatory surgery centers in the U.S. and internationally that could benefit from the addition of robotic-assisted minimally invasive surgery at a lower cost of entry than existing robotic-assisted surgery systems;

surgeons can benefit from the ease of use, 3-D visualization and precision of robotic-assisted surgery while remaining patient-side within the sterile field, consistent with current laparoscopic surgery procedures; and

patients will continue to seek a minimally invasive option, offering minimal scarring and fewer incisions, for many common general abdominal and gynecologic surgeries.

## **Research and Development**

We are focusing our research and development efforts on the SurgiBot System. Our experience with the SPIDER Surgical System has significantly advanced the development of certain components of the SurgiBot System. For example, the EndoDrive device portion of the SurgiBot System is very similar to the function and form of the SPIDER System that is inserted into the patient and features flexible articulating channels. The instruments used with both the SurgiBot System and the SPIDER System are long and flexible with many similar instrument tips and performance requirements. In addition to growing our internal expertise, we continue to collaborate extensively with outside experts in robotic systems and visualization technologies.

During the fiscal year ended December 31, 2013, the Company incurred research and development expenses of approximately \$12.7 million, primarily related to the SurgiBot System development. During the fiscal year ended December 31, 2014, we incurred research and development expenses of approximately \$27.9 million, primarily related to the SurgiBot System development. We fund, and SafeStitch and TransEnterix Surgical funded their respective research and development expenses prior to the Merger, primarily from proceeds raised from equity and debt financing transactions. We expect to continue to use equity and debt financing transactions to fund our research and development activities. No customers are obligated to pay any material portion of such research and development expenses.

## **Intellectual Property**

We believe that our intellectual property and expertise is an important competitive resource. Our experienced research and development team has created a substantial portfolio of intellectual property, including patents, patent applications, trade secrets and proprietary know-how. We maintain an active program of intellectual property protection, both to assure that the proprietary technology developed by us is appropriately protected and, where necessary, to assure that there is no infringement of our proprietary technology by competitive technologies.

The following summarizes our current patent and patent application portfolio.

*IP related to the SurgiBot System and the SPIDER System:* The Company holds four United States patents, two Japanese patents, and two Australian patents, and it has filed more than thirty patent applications in the United States and abroad. In each instance, we own all right, title and interest, and no licenses, security interests or other encumbrances have been granted on such patents and patent applications. Three of our United States patents resulted from filings relating to the SPIDER System and will remain in force until 2028, 2028 and 2032, respectively. The Japanese and Australian patents, which also resulted from filings relating to the SPIDER System, will expire in 2027. The patent applications relate to the SPIDER System, the SurgiBot System, and other instruments and systems for minimally invasive surgical procedures. We intend to seek further patent and other intellectual property protection in the United States and internationally, where available and when appropriate, as we continue our SurgiBot System product development efforts.

*IP related to the Gastroplasty Device:* We also have intellectual property from SafeStitch. We have exclusively licensed technology, know-how and patent applications from Creighton University (Creighton) for the Gastroplasty Device. These patent applications include systems and techniques for minimally invasive gastrointestinal procedures, a dilator for use with an endoscope, and bite blocks for use with an endoscope and for preserving airways of patients during endoscopy. In addition, we have certain rights to other Creighton intellectual property that we have not yet defined as products under development. In total, our intellectual property estate from SafeStitch includes six issued patents and four patent applications pending in the United States, including those that are exclusively licensed from Creighton. Four of the issued patents are owned by Creighton and relate to the Gastroplasty Device and related components. We include an evaluation of these intellectual property assets in our evaluation of strategic alternatives for the Gastroplasty Device.

Pursuant to our exclusive license and development agreement with Creighton (the Creighton Agreement), we own all inventions conceived of and reduced to practice solely by our employees and agents related to the SafeStitch products, and all patent applications and patents related to the SafeStitch products claiming such inventions developed without the use of any licensed patent rights or associated know-how from Creighton. Creighton owns all inventions conceived of and reduced to practice solely by Dr. Charles Filipi, who was formerly our chief medical officer, or any Creighton employees or agents who work directly with Dr. Filipi in the course of performing duties for us, and all patent applications and patents claiming such inventions, which inventions, patent applications and all resulting licensed patent rights are subject to the Creighton Agreement. Together with Creighton, we jointly own all inventions conceived of and reduced to practice jointly by Dr. Filipi, and/or any Creighton employees or agents who work directly with him, and our employees or agents. Notwithstanding the foregoing, Creighton owns all inventions conceived of or reduced to practice under its research and development budget, and all patent applications and patents claiming such inventions, even if conceived of solely by our employees or agents, and such inventions, patent applications and all resulting licensed patent rights are subject to the Creighton Agreement. The Company has seven years after the later of the effective date of the Creighton Agreement or the disclosure and acceptance of a licensed patent and associated know-how (each as defined in the Creighton Agreement) to commence development of the licensed patent or commercially exploit the licensed products developed. We believe the Company's work in developing the Gastroplasty Device has satisfied this requirement; however, if necessary, such seven-year term can be extended by the Company by payment, per licensed patent, of a term extension fee. If the Company fails to develop or commercially exploit a licensed patent and associated know-how within such term, the licensed patent and associated know-how revert back to Creighton. Otherwise, no specific term is established under the Creighton Agreement. Our obligation to pay royalties ends when the last valid claim (as defined in the Creighton Agreement) expires.

Dr. Filipi served as our Chief Medical Officer until June 30, 2014.

### **Competition**

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more established and developed than ours.

There are many competitive offerings in the field of minimally invasive surgery. Several companies have launched devices that enable reduced incision or single incision laparoscopic surgery with or without robotic assistance. Our surgical competitors include, but are not limited to: Applied Medical, Medtronic plc, Intuitive Surgical, and Johnson & Johnson.

In addition to surgical competitors, there are many products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. These products and therapies may impact the overall volume of surgical procedures and negatively impact our business.

In addition, our ability to compete may be affected by the failure to fully educate physicians in the use of our products and products in development, or by the level of physician expertise. This may have the effect of making our products less attractive. Among the products with which we will directly compete, we expect to differentiate on the basis of internal triangulation, positioning of the surgeon within the sterile field, as well as lower cost, in most cases. Several medical device companies are actively engaged in research and development of robotic systems or other medical devices and tools used in minimally invasive surgery procedures. We cannot predict the basis upon which we will compete with new products marketed by others.

### **Government Regulation of our Product Development Activities**

The U.S. government regulates the medical device industry through various agencies, including but not limited to, the FDA, which administers the Federal Food, Drug and Cosmetic Act (the FDCA). The design, testing, manufacturing, storage, labeling, distribution, advertising, and marketing of medical devices are subject to extensive regulation by federal, state, and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any device product that we develop must receive all requisite regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country.

#### **Device Development, Marketing Clearance and Approval**

Medical devices are subject to varying levels of pre-market regulatory controls. The FDA classifies medical devices into one of three classes: (i) Class I devices are relatively simple and can be manufactured and distributed with general controls; (ii) Class II devices are somewhat more complex and require greater scrutiny; and (iii) Class III devices are new, high risk devices, and frequently are permanently implantable or help sustain life.

In the United States, a company generally can obtain permission to distribute a new medical device in one of two ways. The first applies to any device that is substantially equivalent to a device first marketed prior to May 1976, or to another device marketed after that date, but which was substantially equivalent to a pre-May 1976 device. These devices are either Class I or Class II devices. To obtain FDA clearance to distribute the medical device, a company generally must submit a Section 510(k) notification, and receive an FDA order finding substantial equivalence to a predicate device (pre-May 1976 device or post-May 1976 device that was substantially equivalent to a pre-May 1976 device) and permitting commercial distribution of that medical device for its intended use. A 510(k) notification must provide information supporting a claim of substantial equivalence to the predicate device. If clinical data from human experience are required to support the 510(k) notification, these data must be gathered in compliance with investigational device exemption (IDE) regulations for investigations performed in the United States. The 510(k) process is normally used for products of the type that we are developing and propose to market and sell. The FDA review process for premarket notifications submitted pursuant to Section 510(k) takes, pursuant to statutory requirements, 90 days, but it can take substantially longer if the FDA has questions regarding the regulatory submission. It is possible for Section 510(k) clearance procedures to take from six to twenty-four months, depending on the concerns raised by the FDA and the complexity of the device. There is no guarantee that the FDA will clear a medical device for marketing, in which case the device cannot be distributed in the United States. There is also no guarantee that the FDA will deem the applicable device subject to the 510(k) process, as opposed to the more time-consuming, resource-intensive and problematic, pre-market approval (PMA) process described below. In 2011, the FDA issued a series of draft guidance documents designed to reform the 510(k) clearance process. Similarly, the Medical Device User Fee Amendments of 2012 authorized the FDA to collect user fees for the review of certain pre-market submissions received on or after October 1, 2012, including 510(k) notifications. These fees are intended to improve the medical device review process, but the actual impact on the industry is still unknown.

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a pre-1976 product or that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices. For example, most implantable devices are subject to the approval process. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to approval, as opposed to clearance, as a Class III device. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device. These regulations permit a company to undertake a clinical study of a non-significant risk device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. Second, the FDA must review the company's PMA application, which contains, among other things, clinical information acquired under the IDE. Additionally, devices subject to PMA approval may be subject to a panel review to obtain marketing approval and are required to pass a factory inspection in accordance with the current good manufacturing practices standards in order to obtain approval. The FDA will approve the PMA application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process, approximately one to two years or more. However, in some instances the FDA may find that a device is new and not substantially equivalent to a predicate device but is also not a high risk device as is generally the case with Class III PMA devices. In these instances FDA may allow a device to be down classified from Class III to Class I or II. The de novo classification option is an alternate pathway to classify novel devices of low to moderate risk that had automatically been placed in Class III after receiving a not substantially equivalent (NSE) determination in response to a 510(k) notification. The FDCA has also been amended to allow a sponsor to submit a de novo classification request to the FDA for novel low to moderate risk devices without first being required to submit a 510(k) application. These types of applications are referred to as Evaluation of Automatic Class III Designation or de novo. In instances where a device is deemed not substantially equivalent to a Class II predicate device, the candidate device may be filed as a de novo application which may lead to delays in regulatory decisions by the FDA. FDA review of a de novo application may lead the FDA to identify the device as either a Class I or II device and worthy of either an exempt or 510(k) regulatory pathway.





We believe that the SurgiBot System-related products are Class II devices, and we are in the process of pursuing Section 510(k) clearance for such products. The FDA might not agree with our assessment that the SurgiBot System is eligible for the 510(k) process or that the SurgiBot System is a Class II device. If that were to occur, we would be required to undertake the more complex and costly PMA process or perhaps be considered for a de novo reclassification. However, for either the 510(k), de novo, or the PMA process, the FDA could require us to conduct clinical trials, which would take more time, cost more money and pose certain other risks and uncertainties.

We have participated in discussions with, and intend to continue to engage in discussions with, the FDA regarding the appropriate regulatory pathway for our products, with primary emphasis directed toward confirming the regulatory pathway for the SurgiBot System. While clinical trial data for Class II devices are generally not required, we have received information from the FDA that clinical trial data may be required for the SurgiBot System to enable market clearance. Should a clinical study be required to support a 510(k) submission, the Company would seek FDA advisement on study design, endpoints and statistical methods. Additionally, clinical data is required to support a CE Mark filing, but a clinical trial may not be required. The Company is pursuing regulatory guidance on the requirements related to the clinical evaluation to support a CE Mark.

Even when a clinical study has been approved by the FDA or deemed approved, the study is subject to factors beyond a manufacturer's control, including, but not limited to, the fact that the institutional review board (IRB) at a specified clinical site might not approve the study, might decline to renew approval, or might suspend or terminate the study before its completion. There is no assurance that a clinical study at any given site will progress as anticipated. In addition, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA that the product is safe and effective, a prerequisite for FDA approval of a PMA, or substantially equivalent in terms of safety and effectiveness to a predicate device, a prerequisite for clearance under Section 510(k). Even if the FDA approves or clears a device, it may limit its intended uses in such a way that manufacturing and distribution of the device may not be commercially feasible.

After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval of the device, or require changes to a device, its manufacturing process or its labeling or require additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the PMA process is not permitted to make changes to the device which affects its safety or effectiveness without first submitting a supplement application to its PMA and obtaining FDA approval for that supplement, prior to marketing the modified device. In some instances, the FDA may require clinical trials to support a supplement application. A manufacturer of a device cleared through the 510(k) process must submit an additional premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source, labeling or manufacturing process. Any change in the intended uses of a PMA device or a 510(k) device requires an approval supplement or new cleared premarket notification. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

### Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include:

establishment registration and device listing with the FDA;

quality system regulations, which require manufacturers to follow stringent design, testing;

process control, documentation and other quality assurance procedures;

labeling regulations, which prohibit the promotion of products for unapproved, i.e. off label, uses and impose other restrictions on labeling;

MDR regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and

requirements to conduct postmarket surveillance studies to establish continued safety data.

We are required to, and have, registered with the FDA and ISO as medical device manufacturers and must obtain all necessary permits and licenses to operate our business. As manufacturers, we and our suppliers are subject to announced and unannounced inspections by the FDA to determine our compliance with the Quality System Regulation, or QSR, and other regulations.

In Europe, we need to comply with the requirements of the Medical Devices Directive, or MDD, and appropriately affix the CE Mark on our products to attest to such compliance. To achieve compliance, our products must meet the

Essential Requirements of the MDD relating to safety and performance and we must successfully undergo verification of our regulatory compliance, or conformity assessment, by a notified body selected by us. The level of scrutiny of such assessment depends on the regulatory class of the product. We are subject to continued surveillance by our notified body and will be required to report any serious adverse incidents to the appropriate authorities. We also must comply with additional requirements of individual countries in which our products are marketed. In the European Community, we are required to maintain certain International Organization for Standardization (ISO) certifications in order to sell products. These regulations require us or our manufacturers to manufacture products and maintain documents in a prescribed manner with respect to design, manufacturing, testing, labeling and control activities.

### Impact of Regulation

Failure to comply with the applicable regulatory requirements can result in enforcement action by the FDA, which may include, among other things, any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refund or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or premarket approval of new products or modifications to existing products;

withdrawing or suspending clearances or approvals that are already granted; and

criminal prosecution.

Further, the levels of revenues and profitability of medical device companies like us may be affected by the continuing efforts of government and third party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. Therefore, we cannot assure you that any of our products will be considered cost effective, or that, following any commercialization of our products, coverage and reimbursement will be available or sufficient to allow us to manufacture and sell them competitively and profitably.

#### Health Care Regulation

Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

In the United States, there have been, and we expect there to continue to be, a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. At the current time, our products are not defined as durable medical equipment (DME). Non-DME devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. Instead, the hospital or health care provider is reimbursed based on the procedure performed and the inpatient or outpatient stay. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage as hospitals, ASCs and health care providers attempt to negotiate lower prices for products such as the ones we develop and sell.

In March 2010, President Obama signed into law both the Patient Protection and Affordable Care Act (the Affordable Care Act) and the reconciliation law known as Health Care and Education Reconciliation Act (the Reconciliation Act, and, with the Affordable Care Act, the 2010 Health Care Reform Legislation). The constitutionality of the 2010 Health Care Reform Legislation was confirmed on June 28, 2012 by the Supreme Court of the United States. Specifically, the Supreme Court upheld the individual mandate and included changes regarding the extension of medical benefits to those who currently lack insurance coverage. Thus, the 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying

the methodology for reimbursing medical services, drugs and devices, such as our products. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid or some combination of both, as well as other changes.

The 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. This excise tax will likely increase our expenses in the future.

Further, the 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires certain manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or transfers of value provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. We provided our first reports under the Open Payments Act to the Centers for Medicare & Medicaid Services, or CMS, during 2014 and the first public disclosure of the Open Payments data by CMS occurred in September 2014. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

Regulations under the 2010 Health Care Reform Legislation have been, and are expected to continue to be, drafted, released and finalized throughout the next several years. The full impact of the 2010 Health Care Reform Legislation, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

#### **International Regulation and Potential Impact**

The Company intends to pursue continued expansion into international markets. Some of these markets maintain unique regulatory requirements outside of or in addition to those of the U.S. FDA and the European Union. Due to the variations in regulatory requirements within territories, the Company may be required to perform additional safety or clinical testing or fulfill additional agency requirements for specific territories. The Company may also be required to apply for registration using third parties within those territories and may be dependent upon the third parties' successful regulatory processes to file, register and list the product applications and associated labeling. These additional requirements may result in delays in international registrations and commercialization of our products in certain countries.

#### **Employees**

As of December 31, 2014, we had 100 employees, including 98 full time employees. The Company considers its relationships with its employees to be good.

#### **Corporate Information**

The Company's principal executive offices are located at 635 Davis Drive, Suite 300, Morrisville, NC 27560. TransEnterix Surgical was originally incorporated under the laws of the State of Delaware on July 12, 2006. On September 3, 2013, TransEnterix Surgical merged with and into a SafeStitch merger subsidiary and became a wholly owned subsidiary of SafeStitch. SafeStitch was originally incorporated on August 19, 1988 as NCS Ventures Corp. under the laws of the State of Delaware. Its name was changed to Cellular Technical Services Company, Inc. on May 31, 1991. On September 4, 2007, SafeStitch acquired SafeStitch LLC, and, in January 2008, changed its name to SafeStitch Medical, Inc. On December 6, 2013, SafeStitch's name was changed to TransEnterix, Inc.





### **Available Information**

The Company maintains a website at [www.transenterix.com](http://www.transenterix.com). Our Code of Business Conduct and Ethics, as reviewed and updated on February 18, 2014, is available on our website. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website as soon as practicable after electronic filing of such material with, or furnishing it to, the U.S. Securities and Exchange Commission (the SEC). This information may be read and copied at the Public Reference Room of the SEC at 100 F Street, N.E., Washington D.C. 20549. The SEC also maintains an internet website that contains reports, proxy statements, and other information about issuers, like TransEnterix, Inc., who file electronically with the SEC. The address of the site is <http://www.sec.gov>.

### **ITEM 1A. RISK FACTORS**

***We have a history of operating losses, and we may not be able to achieve or sustain profitability. In addition, we may be unable to continue as a going concern.***

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. Substantial doubt exists about our ability to continue as a going concern as a result of recurring losses and an accumulated deficit. We continue to incur research and development and general and administrative expenses related to our operations. Our net loss for the year ended December 31, 2014 was \$37.7 million, and our accumulated deficit as of December 31, 2014 was \$135.9 million. We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will not be sufficient to meet our anticipated cash needs through December 31, 2015.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products and product candidates. If our products fail in development or do not gain regulatory clearance or approval, or if our products do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that, if needed, we will seek capital from other sources, such as equity offerings. Absent a significant increase in revenue or additional equity or debt financing, we may not be able to sustain our ability to continue as a going concern. We have filed shelf registration statements which have been declared effective by the Securities and Exchange Commission ( SEC ). As of December 31, 2014, we had \$143.6 million available for future financings. However, we cannot assure you that we will be successful in obtaining such additional financing on terms acceptable to the Company or at all.

***We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.***

The net proceeds of recent financings, including the public offering of our common stock completed in April 2014, will not be sufficient to support development of our products and product candidates and provide us with the necessary resources to commercialize these products and product candidates. While we are currently focused on our SurgiBot System product in development, we intend to advance multiple additional products through clinical and pre-clinical development in the future. We will likely need to raise substantial additional capital in order to continue our operations and achieve our business objectives.

Our future funding requirements will depend on many factors, including, but not limited to:

the costs of our SurgiBot System development activities;

the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals;

the costs associated with establishing a sales force and commercialization capabilities;

the costs associated with the expansion of our manufacturing capabilities;

our need to expand our research and development activities;

the rate of progress and cost of future clinical testing;

the costs of acquiring, licensing or investing in businesses, products and technologies;

the economic and other terms and timing of our existing licensing arrangement and any collaboration, licensing or other arrangements into which we may enter in the future;

our need and ability to hire additional management, scientific, medical and sales and marketing personnel;

the effect of competing technological and market developments;

our need to implement additional internal systems and infrastructure, including financial and reporting systems, quality systems and information technology systems; and

our ability to maintain, expand and defend the scope of our intellectual property portfolio.

Until we generate a sufficient amount of product revenue to finance our cash requirements, which may never occur, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical studies or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution; and debt financing, if available, may involve restrictive covenants that limit our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our products or grant licenses on terms that may not be favorable to us.



***We have a substantial amount of indebtedness, which may adversely affect our financial resources and our ability to operate our business.***

We are party to, and jointly and severally liable with our subsidiaries for, \$10.0 million of outstanding debt of a Loan and Security Agreement, originally dated January 17, 2012, as amended, with Silicon Valley Bank (SVB) and Oxford Finance LLC (Oxford), as Lenders, which agreement was amended and restated on September 26, 2014 (the Amended and Restated Loan Agreement). Under the Amended and Restated Loan Agreement, the Lenders have agreed to make certain term loans in an aggregate principal amount of up to \$25,000,000, with the first tranche adding to the outstanding principal amount of the then existing term loan borrowed by the Company from the Lenders under the original loan agreement for an aggregate of \$10,000,000 in borrowings as of September 26, 2014. Two additional tranches are to be made available as follows. The second tranche of \$5,000,000 will be available at any time prior to one year after the closing date when the Company files a 510(k) application for its SurgiBot System, and completes an offering of its equity securities at or above \$35 million. The third tranche of \$10,000,000, will be made available to the Company at any time prior to two years after the closing date upon recognition of at least \$10,000,000 of trailing six-month revenues from the SurgiBot System and SurgiBot-related products. The Company is entitled to make interest-only payments for 12 months from the closing date, which interest-only period is extended to 18 months if the Company receives 510(k) clearance for its SurgiBot System at any time before October 31, 2015. The maturity date of the Term Loans is April 1, 2018 without the interest-only extension and October 1, 2018 with the interest-only extension. Our resulting substantial level of indebtedness and other financial obligations increase the possibility that we may be unable to pay, when due, the principal of, interest on, or other amounts due in respect of, our indebtedness.

Further, under the Amended and Restated Loan Agreement, we are subject to certain restrictive covenants that, among other things, may limit our ability to obtain additional financing for working capital requirements, product development activities, debt service requirements, and general corporate or other purposes. These restrictive covenants include, without limitation, restrictions on our ability to: (1) change the nature of our business; (2) incur additional indebtedness; (3) incur liens; (4) make certain investments; (5) make certain dispositions of assets; (6) merge, dissolve, consolidate or sell all or substantially all of our assets; and (7) enter into transactions with affiliates.

If we breach any of these restrictive covenants or are unable to pay our indebtedness under the Amended and Restated Loan Agreement when due, this could result in a default under the Amended and Restated Loan Agreement. In such event, SVB and/or Oxford, as the case may be, may elect (after the expiration of any applicable notice or grace periods) to declare all outstanding borrowings, together with accrued and unpaid interest and other amounts payable under the Amended and Restated Loan Agreement, to be immediately due and payable. Any such occurrence would have an immediate and materially adverse impact on our business and results of operations. The Amended and Restated Loan Agreement is secured by a security interest in all assets of the Company and its current and future subsidiaries, including a security interest in intellectual property proceeds, but excluding a current security interest in intellectual property.

***Some of our technologies are in an early stage of development and not yet proven. Further, our related product research and development activities may not lead to our technologies and products being commercially viable.***

We are engaged in the research and development of minimally invasive surgical devices, robotic surgical devices, and medical devices that manipulate tissues for the treatment of certain intraperitoneal abnormalities. The effectiveness of our technologies is not well known in, or may not be accepted generally by, the clinical medical community. Further, our products are prone to the risks of failure inherent in medical device product development. In particular, any of our products may fail to show desired efficacy and safety traits. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results at earlier points. The occurrence of any such events would have a material adverse effect on our business.



***The results of previous clinical experience with our devices and devices similar to those that we are developing may not be indicative of future results and may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.***

Positive results from limited in vivo and ex vivo animal trials and other early development work we have conducted or early clinical experience with the test articles or with similar devices should not be relied upon as evidence that later-stage clinical experience will be successful.

Further, our products may not be cleared or approved, as the case may be, even if the clinical data are satisfactory and support, in our view, clearance or approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of the clinical data. Any of these regulatory authorities may change requirements for the clearance or approval of a product even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA approval. These regulatory authorities may also clear or approve a product for fewer or more limited uses than we request. In addition, the FDA or other non-U.S. regulatory authorities may not approve or clear the labeling claims necessary or desirable for the successful commercialization of our products.

***We are highly dependent on the success of the SurgiBot System, and we cannot give any assurance that it will receive regulatory clearance or that it or future products will be successfully commercialized.***

We are highly dependent on the success of our products, especially the SurgiBot System. We cannot give any assurance that the FDA will grant regulatory clearance for the SurgiBot System, or will not require the more burdensome PMA submission and approval, nor can we give any assurance that the SurgiBot System or any of our other products will be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically effective or cost-effective alternatives, or failure in our sales and marketing efforts. Any failure to obtain clearance or approval of our products or to successfully commercialize them would have a material and adverse effect on our business.

***If we cannot achieve sufficient margins for our SurgiBot System, we may not be able to grow our revenues sufficiently to sustain our business.***

The commercial viability of our SurgiBot System is a significant focus of our product development efforts. Competition in our industry is intense and we need to provide a commercially sustainable product. Although we expect our initial gross margins to be lower as we ramp up manufacturing, we need to produce a product with sufficient gross margins. Additionally, our SurgiBot System is designed with reusable and limited-life components, and we may not be able to meet reusability targets for applicable components at launch. If we are not successful, our revenue growth may be slower than expected and it could have a material adverse impact on our business.

***If our competitors develop and market products that are more effective, safer or less expensive than our products and future products, our commercial opportunities will be negatively impacted.***

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address minimally invasive and robotic-assisted surgery. We are currently developing and commercializing medical devices that will compete with other medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other medical devices and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical device companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than we do. Some of the medical device companies we expect to compete with include Applied Medical, Medtronic plc, Intuitive Surgical, Johnson & Johnson, and a number of minimally invasive surgical device, robotic surgical device manufacturers and

providers of products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many other universities and private and public research institutions are or may become active in research involving surgical devices for minimally invasive and robotic-assisted surgery.

We believe that our ability to successfully compete will depend on, among other things:

the efficacy, safety and reliability of our products;

the speed at which we develop our products;

our ability to commercialize and market any of our products that may receive regulatory clearance or approval;

our ability to design and successfully execute appropriate clinical trials;

the cost of our products in relation to alternative devices;

the timing and scope of regulatory clearances or approvals;

whether our competitors substantially reduce the cost of ownership of an alternative device;

our ability to protect and defend intellectual property rights related to our products;

our ability to have our partners manufacture and sell commercial quantities of any approved products to the market;

the availability of adequate coverage and reimbursement by third-party payors for the procedures in which our products are used;

the effectiveness of our sales and marketing efforts; and

acceptance of future products by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than our products or future products, or that reach the market sooner than our products, we may not achieve commercial success. In addition, the medical device industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or products obsolete or less competitive.





***Our product development activities could be delayed or stopped.***

We do not know whether our current product development activities will result in products that meet necessary standards and performance criteria and whether the development will be completed on schedule. Delays could occur based on a number of issues that could arise. For example, should clinical trials be required, the commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

delay or failure to obtain sufficient supplies of the product for our clinical trials;

limited number of, and competition for, suitable patients that meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;

limited number of, and competition for, suitable sites to conduct our clinical trials, and delay or failure to obtain FDA approval, if necessary, to commence a clinical trial;

requirements to provide the medical device required in our clinical trial at cost, which may require significant expenditures that we are unable or unwilling to make;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and

delay or failure to obtain IRB approval or renewal to conduct a clinical trial at a prospective or accruing site, respectively.

The completion of our clinical trials, if required, could also be substantially delayed or prevented by several factors, including:

lack of efficacy evidenced during clinical trials;

slower than expected rates of patient recruitment and enrollment;

failure of patients to complete the clinical trial;

unforeseen safety issues;

termination of our clinical trials by one or more clinical trial sites;

inability or unwillingness of patients or medical investigators to follow our clinical trial protocols or allocate sufficient resources to complete our clinical trials; and

inability to monitor patients adequately during or after treatment.

In addition other issues, such as the need to investigate third party patents and potential infringement matters, although not currently an issue, could arise thereby delaying our development efforts.

***Any failure or significant delay in completing clinical trials for our products could materially harm our financial results and the commercial prospects for our products.***

Certain of our future products, such as the SurgiBot System, may require the approval of a PMA. Initiating and completing clinical trials necessary to support a PMA application, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, can be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. Conducting successful clinical studies requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, proximity of patients to clinical sites, patient ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, results of operations and prospects.

***The results of clinical trials may not support future product candidates or claims or may result in the discovery of adverse side effects.***

In the future, we may need to conduct clinical trials to support approval of new products, and any future clinical trial activities that we undertake will be subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies intended to support a 510(k) or PMA must be conducted in compliance with the FDA's Good Clinical Practice regulations and similar requirements in foreign jurisdictions. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and Notified Bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of associated product submissions and, ultimately, our ability to commercialize products requiring submission of clinical data. It is also possible that patients enrolled in a clinical trial will experience adverse side effects that are not currently part of the product candidate's safety profile, which could cause us to delay or abandon development of such product.



***The regulatory approval and clearance processes are expensive, time-consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals or clearances, as the case may be, for the commercialization of some or all of our products.***

The product development and design, testing, manufacturing, labeling, approval, clearance, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our products in the United States until we receive a clearance letter under the 510(k) process or approval of a PMA from the FDA, depending on the nature of the device. While we believe we understand, from our discussions with the FDA, the regulatory pathway for our SurgiBot System, we cannot be certain of the regulatory pathway we will need to follow until we file for 510(k) clearance. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews a premarket notification in 90 days, there is no guarantee that our future products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, even if a device is reviewed under the 510(k) premarket notification process, that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. In the past the Company has been successful in receiving 510(k) clearance within the 90 day review period, but it can take longer (six to eighteen months) to obtain 510(k) clearance for a Class II device. If the FDA fails to provide clearance for a product candidate, such as the SurgiBot System, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product.

Regulatory approval of a PMA, PMA supplement or clearance pursuant to a 510(k) premarket notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive, uncertain and may, especially in the case of the PMA application, take several years. The FDA also has substantial discretion in the medical device clearance process or approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional development, standardized testing, pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA clearance or approval varies depending on the medical device candidate, the disease or condition that the medical device candidate is designed to address, and the regulations applicable to any particular medical device candidate. The FDA or other non-U.S. regulatory authorities can delay, limit or deny clearance or approval of a medical device candidate for many reasons, including:

a medical device candidate may not be deemed safe or effective, in the case of a PMA application;

a medical device candidate may not be deemed to be substantially equivalent to a device lawfully marketed either as a grandfathered device or one that was cleared through the 510(k) premarket notification process;

a medical device candidate may not be deemed to be in conformance with applicable standards and regulations;

FDA or other regulatory officials may not find the data from pre-clinical studies and clinical trials sufficient;

the FDA might not approve our processes or facilities or those of any of our third-party manufacturers for our Class III PMA devices;



other non-U.S. regulatory authorities may not approve our processes or facilities or those of any of our third-party manufacturers, thereby restricting export; or

the FDA or other non-U.S. regulatory authorities may change clearance or approval policies or adopt new regulations.

***Once our products are cleared or approved, modifications to our products may require new 510(k) clearances, premarket approvals or new or amended CE Certificates of Conformity, and may require us to cease marketing or recall the modified products until clearances, approvals or the relevant CE Certificates of Conformity are obtained.***

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review such determinations. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determinations for any future changes, or prior changes to previously marketed products, as the case may be, we may be required to cease marketing or to recall the modified products until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. In July and December 2011, respectively, the FDA issued draft guidance documents addressing when to submit a new 510(k) due to modifications to 510(k) cleared products and the criteria for evaluating substantial equivalence. The July 2011 draft guidance document was ultimately withdrawn as the result of the FDASIA, and as a result, the FDA's original guidance document regarding 510(k) modifications, which dates back to 1997, remains in place. It is uncertain when the FDA will seek to issue new guidance on product modifications. Any efforts to do so could result in a more rigorous review process and make it more difficult to obtain clearance for device modifications.

***Even if we obtain regulatory clearances or approvals for our products, the terms thereof and ongoing regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate anticipated revenues.***

Once regulatory clearance or approval has been granted, the cleared or approved product and its manufacturer are subject to continual review. Any cleared or approved product may be promoted only for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities clear or approve any of our products, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with the FDA's QSR, which includes requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation as well as other quality system requirements and regulations from non-U.S. regulatory authorities. Further, regulatory agencies must approve our manufacturing facilities for Class III devices before they can be used to manufacture our products, and all manufacturing facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA, either before or after clearance or approval, or other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

restrictions on the products, manufacturers or manufacturing process;





adverse inspectional observations (Form 483), warning letters, non-warning letters incorporating inspectional observations;

civil or criminal penalties or fines;

injunctions;

product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory clearances or approvals;

total or partial suspension of production;

imposition of restrictions on operations, including costly new manufacturing requirements;

refusal to clear or approve pending applications or premarket notifications; and

import and export restrictions.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, the FDA and other non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory clearance or approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future products and we may not achieve or sustain profitability.

***Even after clearance or approval for our products is obtained, we are subject to extensive post-market regulation by the FDA. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.***

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States. The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation

and the perceived safety and efficacy of our products.

We are also required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products. The FDA enforces the QSR through periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and/or customers may require specific packaging of sterile products, which could increase our costs and the price of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

***If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations. Even though we are currently not marketing a number of our cleared products, such as the SPIDER, because these products are still in the marketplace, we are required to handle complaints and submit MDRs for any events meeting the reportability requirements.

All manufacturers bringing medical devices to market in the European Economic Area (EEA) are legally bound to report any incident that led or might have led to the death or serious deterioration in the state of health of a patient, user or other person, and which the manufacturer's device is suspected to have caused, to the competent authority in whose jurisdiction the incident occurred. In such case, the manufacturer must file an initial report with the relevant competent authority, which would be followed by further evaluation or investigation of the incident and a final report indicating whether further action is required.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

***A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.***

The FDA and similar foreign governmental authorities such as the competent authorities of the EEA countries have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

Any future recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

***U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the Refuse to Accept guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

***We may be subject, directly or indirectly, to federal and state anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

***Current legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.***

In the United States, there have been, and we expect there to continue to be, a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. While many of the proposed policy changes require congressional approval to implement, we cannot assure you that reimbursement payments under governmental and private third-party payor programs to health care providers will remain at levels comparable to present levels or will be sufficient to cover the costs allocable to patients eligible for reimbursement under these programs. Any changes that lower reimbursement rates under Medicare, Medicaid or private payor programs could negatively affect our business.

To the extent that any of our products are deemed to be durable medical equipment (DME), they may be subject to distribution under Medicare's Competitive Acquisition regulations, which could adversely affect the amount that we can seek from payors. Non-DME devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage as hospitals and health care providers attempt to negotiate lower prices for products such as the ones we develop and sell.

Most significantly, in March 2010, President Obama signed into law both the Patient Protection and Affordable Care Act (the Affordable Care Act) and the reconciliation law known as Health Care and Education Reconciliation Act (the Reconciliation Act, and, with the Affordable Care Act, the 2010 Health Care Reform Legislation). The constitutionality of the 2010 Health Care Reform Legislation was confirmed on June 28, 2012 by the Supreme Court of the United States. Specifically, the Supreme Court upheld the individual mandate included changes regarding the extension of medical benefits to those who currently lack insurance coverage. Thus, the 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, or some combination of both, as well as other changes.

Beyond coverage and reimbursement changes, the 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. Although there are current bills in Congress to repeal this excise tax, it remains current law. This excise tax will likely increase our expenses in the future.

Further, the 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires certain manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or transfers of value provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. We provided our first reports under the Open Payments Act to the Centers for Medicare & Medicaid Services, or CMS, during 2014 and the first public disclosure of the Open Payments data by CMS occurred in September 2014. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

Regulations under the 2010 Health Care Reform Legislation have been, and are expected to continue to be, drafted, released and finalized throughout the next several years. The full impact of the 2010 Health Care Reform Legislation, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

Finally, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. Any cost containment measures or other health care system reforms that are adopted could have a material and adverse effect on our ability to commercialize our existing and future products successfully.

Even if we receive regulatory clearance or approval to market our products, the market may not be receptive to our products, which could undermine our financial viability.

Even if our products obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. To date, we have experienced minimal sales of the SPIDER System and AMID HFD stapler (both products were discontinued in 2014) and have not made any sales of the SurgiBot System. We believe that the degree of market acceptance will depend on a number of factors, including:

timing of market introduction of competitive products;

safety and efficacy of our products;

physician training in the use of our products;

prevalence and severity of any side effects;

potential advantages or disadvantages over alternative treatments;

strength of marketing and distribution support; and

price of our future products, both in absolute terms and relative to alternative treatments.

If applicable, availability of coverage and reimbursement from government and other third-party payors can also impact the acceptance of our product offerings.

***If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our products.***

We will need to effectively manage our managerial, operational, financial, development, marketing and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and

future products. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our senior management, particularly Todd M. Pope and Joseph P. Slattery, could delay or prevent the development or commercialization of our products. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. We employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing organization.



We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among medical device and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

***Because our design, development and manufacturing capabilities are limited, we may rely on third parties to design, develop, manufacture or supply some of our products. An inability to find additional or alternate sources for these services and products could materially and adversely affect our financial condition and results of operations.***

In 2014, we used third-party design and development sources to assist in the design and development of our SurgiBot system. In the future, we may choose to use additional third-party sources for the design and development of our products. If these design and development partners are unable to provide their services in the timeframe or to the performance level that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the manner that we require.

In 2014 we operated manufacturing facilities for production of the SPIDER System and maintained manufacturing facilities for the AMID HFD product (both products were discontinued in 2014). In the future, we may choose to use a third-party manufacturer for our other products. In addition, certain product component parts are likely to come from third-party suppliers. If these manufacturing partners are unable to produce our products or component parts in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require.

Our products require precise, high quality manufacturing. We and our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with QSR, current good manufacturing practices and other applicable government regulations and corresponding standards. If we or our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure by us or on the part of our design and development partners or contract manufacturers could delay product development or regulatory clearance or approval of our products, or commercialization of our products and future products, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on any third party for design, development or manufacturing could adversely affect our future profit margins. Our ability to replace any then-existing manufacturer may be difficult because the number of potential manufacturers is limited and, in the case of Class III devices, the FDA must approve any replacement manufacturer before manufacturing can begin. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

***We may become subject to potential product liability claims, and we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the design, testing, manufacture, sale and distribution of our products and each of our product candidates that we are seeking to introduce to the market. Surgical medical devices involve significant risks of serious complications, including bleeding, nerve injury, paralysis, infection, and even death. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. If longer-term patient results and experience indicate that our products or any component of a product causes tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management's attention from managing our business.

***We currently have a limited sales, marketing and distribution organization. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our products.***

We currently have limited marketing, sales and distribution capabilities. We intend to distribute our products through direct sales and independent contractor and distribution agreements with companies possessing established sales and marketing operations in the medical device industry, but there can be no assurance that we will be successful in building our sales capabilities. To the extent that we enter into co-promotion or other arrangements, our product revenue is likely to be lower than if we directly market or sell our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our existing and future products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***If we or our licensors are unable to obtain and enforce patent protection for our products, our business could be materially harmed.***

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. We have numerous patent applications that are in process. For example, with respect to the SPIDER System and the SurgiBot System, we have three issued patents and we have filed over 30 patent applications in the United States and abroad. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.



Our strategy depends on our ability to promptly identify and seek patent protection for our discoveries. In addition, we will rely on third-party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time-consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to develop and use information that we regard as proprietary.

The issuance of a patent provides a presumption, but does not guarantee that it is valid. Any patents we have obtained, or obtain in the future, may be challenged or potentially circumvented. Moreover, the United States Patent and Trademark Office (the USPTO) may commence interference proceedings involving our patents or patent applications. Any such challenge to our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, future court decisions may introduce uncertainty in the enforceability or scope of any patent, including those owned by medical device companies.

Our pending patent applications may not result in issued patents. The patent position of medical device companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties.

We cannot assure you that any patents that will issue, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our products, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our future products.

***If we or our licensors are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade

secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

***If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts, any of which could materially adversely affect our liquidity, business prospects and results of operations.***

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third-party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***Our business may become subject to economic, political, regulatory and other risks associated with domestic and international operations.***

Our business is subject to risks associated with conducting business domestically and internationally, in part due to some of our suppliers being located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

difficulties in compliance with U.S. and non-U.S. laws and regulations;

changes in U.S. and non-U.S. regulations and customs;

changes in non-U.S. currency exchange rates and currency controls;

changes in a specific country's or region's political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;

negative consequences from changes in tax laws; and

difficulties associated with staffing and managing foreign operations, including differing labor relations.

***We may be required to recognize impairment charges for our goodwill and other intangible assets.***

As of December 31, 2014, the net carrying value of our goodwill and other intangible assets totaled approximately \$93.8 million, which was 69% of total assets. In accordance with generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

***Our stockholders have experienced dilution of their percentage ownership of our stock and may experience additional dilution in the future.***

As a result of the Merger, we issued new shares of common stock to certain former TransEnterix Surgical stockholders, representing approximately 65% of the total outstanding voting power of all our stockholders immediately following the closing of the Merger. The issuance of these shares caused existing stockholders at the time of the Merger to experience immediate and significant dilution in their percentage ownership of our outstanding common stock. In addition, the private placement issuance of our Series B Preferred Stock in September 2013 caused substantial dilution to our stockholders, as each share of Series B Preferred Stock was converted into ten shares of our common stock on December 6, 2013, and our stockholders experienced additional dilution in our April 2014 \$56 million common stock public offering.





We will likely need to raise substantial additional capital in order to continue our operations and achieve our business objectives. The future issuance of the Company's equity securities will further dilute the ownership of our outstanding common stock.

***The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.***

During the two years ended December 31, 2014, the market price of our common stock fluctuated from a high of \$14.00 per share to a low of \$0.22 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

the announcement of new products or product enhancements by us or our competitors;

developments concerning intellectual property rights and regulatory approvals;

variations in our and our competitors' results of operations;

changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;

developments in the medical device industry;

the results of product liability or intellectual property lawsuits;

future issuances of common stock or other securities;

the addition or departure of key personnel;

announcements by us or our competitors of acquisitions, investments or strategic alliances; and

general market conditions and other factors, including factors unrelated to our operating performance. Further, the stock market in general, and the market for medical device companies in particular, has recently experienced extreme price and volume fluctuations. The volatility of our common stock is further exacerbated due to its low trading volume. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all of your investment.

***Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price.***

Trading of our common stock is currently conducted on the NYSE MKT. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all. As of December 31, 2014, approximately 41% of the issued and outstanding shares of our common stock were held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

Sales by stockholders of substantial amounts of our shares of common stock, the issuance of new shares of common stock by us or the perception that these sales may occur in the future could materially and adversely affect the market price of our common stock, and you may lose all or a portion of your investment in our common stock.

***Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in the best interests of our stockholders.***

Our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 47% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

In connection with the Merger, we entered into a voting and lock-up agreement with certain of our stockholders pursuant to which such stockholders agreed to vote to approve certain corporate actions following the Merger.

In connection with the Merger and the related private placement transaction, stockholders holding an aggregate of 93% of our common stock on the effective date of the Merger, and members of our Board of Directors, entered into lock-up and voting agreements (each, a Voting Agreement), pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company's securities held by them (collectively, Covered Securities) for one year following the Merger closing date. The Voting Agreements provide that such persons may sell, transfer or convey: (i) up to 50% of their respective Covered Securities commencing on September 3, 2014, the one-year anniversary of the Merger closing date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on March 3, 2015, the eighteen-month anniversary of the Merger closing date. The restrictions on transfer contained in the Voting Agreements cease to apply to the Covered Securities on September 3, 2015, the second anniversary of the Merger closing date. In accordance with a Registration Rights Agreement dated September 3, 2013, we included many of these stockholders as selling stockholders on a shelf registration statement we filed in November 2014. On such shelf registration statement we registered, for the account of such selling stockholders, the Covered Securities that were released from the transfer restrictions of the Voting Agreement on September 3, 2014. Sales of our common stock by such selling stockholders could have a negative impact on the trading price of our common stock and increase the volatility of our common stock trading price.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our principal corporate office and the manufacturing facilities are located at 635 Davis Drive, Suite 300, Morrisville, North Carolina. We lease these facilities, which consist of 37,328 square feet, for a five-year term, under a lease that commenced on April 1, 2010. An amendment to this lease was signed on June 13, 2014, extending the lease term until June 30, 2018. Pursuant to a lease entered into on October 24, 2013, we also lease 24,000 square feet of warehouse and office space in Durham, North Carolina. That lease commenced in January 2014 and has a 52-month term, with a six-year renewal option. Prior to that we leased 5,093 square feet of warehouse space in Durham, North Carolina pursuant to a lease that expired in January 2014.

We also leased approximately 6,800 square feet of office and warehouse space at 4400 Biscayne Blvd., Miami, Florida on a month-to-month basis from Frost Real Estate Holdings, LLC, which is a company controlled by Dr. Phillip Frost, one of our principal stockholders and a former director. The Company terminated the SafeStitch lease effective August 15, 2014.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Since April 2, 2014, our common stock has been listed on the NYSE MKT under the symbol TRXC. From December 9, 2013 to April 1, 2014, our common stock was quoted on the OTCBB under the symbol TRXC. From August 25, 2011 to December 6, 2013, our common stock was quoted on the OTCBB under the symbol SFES. The table below sets forth, for the respective periods indicated, the high and low bid prices for our common stock on the NYSE MKT or in the over-the-counter market as reported on the OTCBB, as applicable. The bid prices represent inter-dealer transactions, without adjustments for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

On March 31, 2014, the Company effectuated a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1 for 5 (the Reverse Stock Split). As a result of the Reverse Stock Split, the Company's issued and outstanding stock decreased from 244,276,923 to 48,855,255 shares of common stock, all with a par value of \$0.001. All information related to common stock, stock options, RSUs, warrants and earnings per share for prior periods has been retroactively adjusted in this Annual Report to give effect to the Reverse Stock Split, except for the reference to the Merger Exchange Ratio of 1.1533.

|   | Bid Prices |          |
|---|------------|----------|
|   | High       | Low      |
| <b>2015</b>                               |            |          |
| First Quarter (through February 19, 2015) | \$ 3.50    | \$ 2.66  |
| <b>2014</b>                               |            |          |
| First Quarter                             | \$ 2.59    | 1.51     |
| Second Quarter                            | 14.00      | 1.87     |
| Third Quarter                             | 5.50       | 3.43     |
| Fourth Quarter                            | 4.54       | 1.40     |
| <b>2013</b>                               |            |          |
| First Quarter                             | \$ 2.50    | \$ 1.275 |
| Second Quarter                            | 3.275      | 1.75     |
| Third Quarter                             | 8.60       | 1.80     |
| Fourth Quarter                            | 8.80       | 6.45     |

As of February 16, 2015, there were approximately 266 record holders of our common stock (counting all shares held in single nominee registration as one stockholder).

We paid no dividends or made any other distributions in respect of our common stock during our fiscal years ended December 31, 2014 and 2013, and we have no plans to pay any dividends or make any other distributions in the future.

#### Securities Authorized for Issuance Under Equity Compensation Plans.

The Company currently has one equity compensation plan under which it makes awards, the TransEnterix, Inc. 2007 Incentive Compensation Plan, as amended (the 2007 Plan). In connection with the Merger, SafeStitch assumed all of TransEnterix Surgical's options that were issued and outstanding immediately prior to the Merger at the Exchange Ratio, which are now exercisable for approximately 3,136,155 shares of common stock. Such options were granted

under the TransEnterix, Inc. 2006 Stock Plan (the 2006 Plan) which was assumed by the Company in the Merger. The 2006 Plan is maintained solely for the purpose of the stock options granted under such 2006 Plan that remain outstanding; no future awards are authorized to be made under the 2006 Plan. The 2007 Plan was originally approved by the Board of Directors and adopted by the majority of our stockholders on November 13, 2007, and amended and restated and approved by the Board of Directors and approved by the majority of our stockholders on October 29, 2013 to increase the number of shares of common stock authorized under the 2007 Plan to 4,940,000 shares, and to make other changes. The 2007 Plan is used for plan-based awards for officers, other employees, consultants, advisors and non-employee directors.

The following table gives information about the Company's common stock that may be issued upon the exercise of options and other equity awards as of December 31, 2014:

| Plan Category  | Number of securities to be                      | Weighted average exercise price of outstanding options | Number of securities remaining available for future issuance (2) |
|--|---|--|--|
|  | issued upon exercise of outstanding options (1) |  |  |
| Equity compensation plans approved by security holders         | 5,563,741                                       | \$ 4.96  | 2,186,360  |
| Equity compensation plans not approved by security holders (3) | 2,829,735                                       | \$ 0.66  | 0  |
| Total  | 8,393,476                                       |  | 2,186,360  |

- (1) Includes 5,557,075 shares underlying outstanding stock options awarded under the 2007 Plan and 6,666 restricted stock units awarded under the 2007 Plan.
- (2) These shares are all available for future awards under the 2007 Plan.
- (3) Represents 2,696,401 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger, and 133,334 restricted stock units remaining under a new hire award to our Chief Financial Officer.

#### Unregistered Sales of Equity Securities and Use of Proceeds.

The Company issued no unregistered securities during the fourth quarter of 2014.

#### ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company as defined in Rule 12b-2 of the Exchange Act, we are not required to include information otherwise required by this Item.

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## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with our Risk Factors and our consolidated financial statements and the related notes to our consolidated financial statements included in this Annual Report. The following discussion contains forward-looking statements. See cautionary note regarding Forward-Looking Statements at the beginning of this Annual Report.*

### Overview

We are a medical device company that is focused on the development and future commercialization of a robotic-assisted surgical system called the SurgiBot System (the SurgiBot System). The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for three-dimensional (3-D) high definition vision technology. We have commercialized the SPIDER<sup>®</sup> Surgical System, (the SPIDER System) a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilizes flexible instruments and articulating channels that are controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System has been cleared by the U.S. Food and Drug Administration (FDA). We also manufactured multiple instruments that could be deployed using the SPIDER System, and which are being adapted for use with the SurgiBot System. In April 2014, we launched the Flex Ligating Shears (FLS) which is an advanced energy device used with the existing SPIDER Surgical System. The FLS device is designed to deliver controlled energy to effectively ligate and divide tissue. We intend to offer a similar device in the future for the SurgiBot System. We have chosen to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014. We discontinued sales of the SPIDER System on December 31, 2014.

During the second quarter of 2014, we determined to cease internal development of the SafeStitch Gastroplasty Device. We are evaluating strategic alternatives for the former SafeStitch products.

We believe that future outcomes of minimally invasive surgery will be enhanced through our combination of more advanced tools and robotic functionality which are designed to: (i) empower surgeons with improved precision, dexterity and visualization; (ii) improve patient satisfaction and post-operative recovery; and (iii) provide a cost-effective robotic system, compared to existing alternatives today, for a potentially wide range of clinical applications.

Our strategy is to focus our resources on the development and future commercialization of the SurgiBot System. We are planning to make the product available subject to our obtaining the requisite regulatory and government clearances.

We believe that:

there are a number of hospitals and an increasing number of ambulatory surgery centers in the U.S. and internationally that could benefit from the addition of robotic-assisted minimally invasive surgery at a lower cost of entry than existing robotic-assisted surgery systems;



surgeons can benefit from the ease of use, 3-D visualization and precision of robotic-assisted surgery while remaining patient-side within the sterile field, consistent with current laparoscopic surgery procedures; and

patients will continue to seek a minimally invasive option, offering minimal scarring and fewer incisions, for many common general abdominal and gynecologic surgeries.

From our inception, we devoted a substantial percentage of our resources to research and development and start-up activities, consisting primarily of product design and development, clinical studies, manufacturing, recruiting qualified personnel and raising capital.

Since inception, we have been unprofitable. As of December 31, 2014 we had an accumulated deficit of \$135.9 million.

We expect to continue to invest in research and development and related clinical studies, and increase selling, general and administrative expenses as we grow. As a result, we will need to generate significant revenue in order to achieve profitability.

In 2013, we incurred \$2.9 million of Merger related expenses, which were included in operating expenses, as of December 31, 2013.

We operate in one business segment.

## **2014 Events**

### **Reverse Stock Split**

On March 31, 2014, we effectuated a reverse stock split of our issued and outstanding shares of common stock at a ratio of 1 for 5 (the Reverse Stock Split). As a result of the Reverse Stock Split, our issued and outstanding stock decreased from 244,276,923 to 48,855,255 shares of common stock, all with a par value of \$0.001. All information related to common stock, stock options, RSUs, warrants and earnings per share for prior periods has been retroactively adjusted to give effect to the Reverse Stock Split.

### **Public Offering**

On April 14, 2014, we sold 12,500,000 shares of common stock at a public offering price of \$4.00 per share for aggregate gross proceeds of \$50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of common stock to cover over-allotments. Certain of our existing stockholders that are affiliated with certain of our directors purchased \$10.0 million of common stock in the public offering. The common stock was offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-193235) registering an aggregate of \$100.0 million of our designated securities (the Shelf Registration Statement). The Shelf Registration Statement was declared effective by the SEC on April 2, 2014. The closing of the public offering occurred on April 21, 2014. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of \$4.00 per share for aggregate additional gross proceeds of \$6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were \$52.4 million, net of issuance costs of \$4.0 million.

In connection with the public offering, our common stock was eligible to be listed on the NYSE MKT and began trading on such exchange on April 1, 2014.

### **2013 Merger Transaction and Related Events**

On September 3, 2013, TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical), and SafeStitch Medical, Inc., a Delaware corporation (SafeStitch), consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the Merger). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc.

Pursuant to the Merger Agreement, each share of TransEnterix Surgical's capital stock issued and outstanding immediately preceding the Merger was converted into the right to receive 1.1533 shares (the Exchange Ratio) of SafeStitch's common stock, par value \$0.001 per share, other than those shares of TransEnterix Surgical's common stock held by non-accredited investors, which shares were instead converted into the right to receive an amount in cash per share of SafeStitch common stock equal to \$1.08, without interest, which was the volume-weighted average price of a share of SafeStitch common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one business day prior to the effective date of the Merger). Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, SafeStitch assumed all of TransEnterix Surgical's options and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

Following the announcement of the Merger on August 14, 2013, the common stock price increased prior to the Merger closing date of September 3, 2013, generating additional goodwill. As of December 31, 2014, the net carrying value of our goodwill and other intangible assets totaled approximately \$93.8 million. In accordance with generally accepted accounting principles, we annually assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized. We performed our annual impairment analysis as of December 31, 2014. Based upon the results of our analysis, we determined that no impairment of goodwill existed as of this date.

### **Lock-Up and Voting Agreement**

In connection with the Merger Agreement and the Private Placement, certain of TransEnterix Surgical's and SafeStitch's former stockholders, agreed to enter into Lock-up and Voting Agreements, pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company's securities held by them (collectively, Covered Securities) for one year following the September 3, 2013 closing date (the Closing Date). The Lock-up and Voting Agreements provide that such persons may sell, transfer or convey: (i) up to 50% of their respective Covered Securities during the period commencing on the one-year anniversary of the Closing Date and ending on the eighteen-month anniversary of the Closing Date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on the eighteen-month anniversary of the Closing Date and ending on the two-year anniversary of the Closing Date. The restrictions on transfer contained in the Lock-up and Voting Agreements cease to apply to the Covered Securities following the second anniversary of the Closing Date.

Additionally, pursuant to the Lock-up and Voting Agreements, each person party thereto has agreed, for the period commencing on the Closing Date and ending on the one-year anniversary of the Closing Date, to vote all of such person's Covered Securities in favor of: (i) amending the Company's Amended and Restated Certificate of Incorporation to change the legal name of the Company to TransEnterix, Inc.; (ii) effecting a reverse stock split of the common stock on terms approved by the Company's Board; and (iii) amending the Company's 2007 Incentive Compensation Plan in order to increase the number of shares of common stock available for issuance thereunder. All three events were approved and completed by February 2014.

### **Registration Rights Agreement**

In connection with the Merger Agreement and the Private Placement, the Company and the Investors entered into the Registration Rights Agreement. Pursuant to the Registration Rights Agreement, the Company is obligated to provide registration rights and certain other standard expense reimbursement and indemnification rights for the benefit of the Investors. After two years, the Company is required to file a registration statement on Form S-3, subject to the Company's eligibility to use such form, to register for resale certain shares of common stock held by the Investors, and the Company is required to maintain the effectiveness of such registration statement until the earlier of: (i) the sale of all securities covered by the registration statement; or (ii) 36 months. After one year, if the Company registers a primary offering of its securities, the Registration Rights Agreement also requires that the Company include securities owned by the Investors in such registered primary offering, subject to certain restrictions including customary underwriter cutbacks. The Registration Rights Agreement terminates upon the earlier of: (a) with respect to any holder, when all of its securities have been sold by such holder; (b) a change of control of the Company, in which the registrable securities are sold or can be sold immediately after the change of control; and (c) five years following the Closing Date.

The foregoing description of the Purchase Agreement, the Lock-Up and Voting Agreement and the Registration Rights Agreement is only a summary and is qualified in its entirety by reference to the complete text of the Purchase Agreement, the form of Lock-up and Voting Agreement and the Registration Rights Agreement, which are filed as Exhibit 10.1, Exhibit 10.2 and Exhibit 10.10, respectively, to the Form 8-K dated September 6, 2013, and incorporated by reference herein.

### **Results of Operations**

Our results of operations include the acquired SafeStitch operations from the Merger date, September 3, 2013, forward.

### **Revenue**

We derived sales from the SPIDER System and other distributed products through limited direct sales in the United States and international distributors. The Company records revenue when persuasive evidence of an arrangement exists, delivery has occurred which is typically at shipping point, the fee is fixed and determinable and collectability is reasonably assured. Shipping and handling costs billed to customers are included in revenue.

Sales for the year ended December 31, 2014 decreased 72% to \$0.4 million compared to \$1.4 million for the year ended December 31, 2013. The \$1.0 million decrease was primarily the result of our decision to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014. We discontinued sales of the SPIDER System on December 31, 2014.

### **Cost of Goods Sold**

Cost of goods sold consists of materials, labor and overhead incurred internally to produce our products and the impairment and write off of excess and obsolete inventory. Shipping and handling costs incurred by the Company are included in cost of goods sold.

Cost of goods sold for the year ended December 31, 2014 decreased 77% to \$1.1 million as compared to \$4.8 million for the year ended December 31, 2013. The \$3.7 million decrease was primarily the result of our reduction in sales as we limited sales of our SPIDER System to our existing customers, the discontinuation of production of our SPIDER System and the transfer of employees from our manufacturing and quality departments to research and development and regulatory functions.

### **Research and Development**

Research and development (R&D) expenses primarily consist of engineering, product development and regulatory expenses incurred in the design, development, testing and enhancement of our products and legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products. In future periods, we expect R&D expenses to remain consistent or be modestly higher as we continue to invest in basic research, clinical studies, product development and intellectual property supporting the evolution of our SurgiBot System. R&D expenses are expensed as incurred.

R&D expenses for the year ended December 31, 2014 increased 120% to \$27.9 million as compared to \$12.7 million for the year ended December 31, 2013. The \$15.2 million increase resulted primarily from increased contract engineering services, consulting and other outside services of \$5.3 million related to product development of our SurgiBot System, increased personnel related expenses of \$4.3 million as we increased the headcount and transferred employees from our manufacturing and quality departments to research and development and regulatory functions, increased supplies expense of \$3.0 million, and increased other expenses of \$1.7 million. In addition, R&D expenses incurred for development of SafeStitch products for the year ended December 31, 2014 were \$0.9 million.

### **Sales and Marketing**

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshow, marketing clinical studies and consulting expenses. In 2015, we expect sales and marketing expenses to increase modestly as we begin the early stages of commercialization. We expect sales and marketing expenses to increase significantly in 2016 in support of our anticipated SurgiBot System product launch. We cannot assure you that the SurgiBot System will be cleared by the FDA, or that we will meet our anticipated product launch target in 2016.

Sales and marketing expenses for the year ended December 31, 2014 decreased 11% to \$1.7 million compared to \$1.9 million for the year ended December 31, 2013. The \$0.2 million decrease was primarily related to lower personnel-related costs of \$61,000 and travel-related expenses of \$85,000 and reduced expenditures for demonstration product and tradeshows and other marketing expenses of \$54,000.

### **General and Administrative**

General and administrative expenses consist of personnel costs related to the executive, finance and human resource functions, as well as professional service fees, legal fees, accounting fees, insurance costs, amortization of intellectual property and general corporate expenses. In future periods, we expect general and administrative expenses to increase to support our sales, marketing, research and development efforts.

General and administrative expenses for the year ended December 31, 2014 increased 48% to \$6.2 million compared to \$4.2 million for the year ended December 31, 2013. The \$2.0 million increase was primarily due to increased personnel costs of \$0.3 million, increased stock compensation costs of \$0.9 million, increased legal, accounting, and investor relation fees and other public company costs of \$0.8 million, and increased insurance costs of \$0.2 million, offset by decreased other expenses of \$0.2 million.

### **Merger Expenses**

Merger expenses consist primarily of legal, investment banking, accounting and other professional fees related to the Merger. We incurred \$2.9 million of Merger related expenses for the year ended December 31, 2013.

### **Impairment Loss on Disposal of Property and Equipment**

Impairment loss on disposal of property and equipment for the year ended December 31, 2013, was the result of an impairment charge of \$0.4 million for a change in the estimate of the useful lives for certain manufacturing property and equipment that we do not anticipate using in the future.

### **Other Expense, Net**

Other expense is primarily composed of interest expense on long-term debt and the remeasurement of fair value of preferred stock warrant liability.

Other expense for the year ended December 31, 2014 decreased to \$1.0 million compared to \$2.8 million for the year ended December 31, 2013. The \$1.8 million decrease was related to the remeasurement of fair value of the preferred stock warrant liability immediately preceding the Merger.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

Since our inception we have incurred significant losses and, as of December 31, 2014, we had an accumulated deficit of \$135.9 million. We have not yet achieved profitability and we cannot assure investors that we will achieve profitability with our existing capital resources. Our recurring losses raise substantial doubt about our ability to continue as a going concern. As a result, the Company's independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the years ended December 31, 2014 and 2013 with respect to this uncertainty. We expect to continue to fund research and development, sales and marketing and general and administrative expenses at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash have

been proceeds from private placements of common and preferred stock, incurrence of debt and the sale of equity securities held as investments.

In January 2014, we filed the Shelf Registration Statement with the SEC which was declared effective on April 2, 2014 (the January Registration Statement). The January Registration Statement allows us to raise up to \$100.0 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof. On April 14, 2014, we sold 12,500,000 shares of common stock at a public offering price of \$4.00 per share for aggregate gross proceeds of \$50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of common stock to cover over-allotments. Certain of our existing stockholders that are affiliated with certain of our directors purchased \$10.0 million of common stock in the public offering. The common stock was offered and sold pursuant to the January Registration Statement. The closing of the public offering occurred on April 21, 2014. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of \$4.00 per share for aggregate additional gross proceeds of \$6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were from the offering were \$52.4 million, net of issuance costs of \$4.0 million. In addition, on November 7, 2014, we filed a Shelf Registration Statement with the SEC which was declared effective on December 19, 2014 (the November Registration Statement and collectively with January Registration Statement, the Shelf Registration Statements). The November Registration Statement allows us to raise up to \$100.0 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof. As of December 31, 2014, we had the ability to raise an additional \$143.6 million from the Shelf Registration Statements.

At December 31, 2014, we had cash and cash equivalents of approximately \$34.8 million. Our cash and cash equivalents increased by approximately \$24.8 million during the year ended December 31, 2014, primarily as a result of proceeds from the issuance of common stock, net of issuance costs, of \$52.4 million, proceeds from the sale and maturities of investments of \$6.2 million, and proceeds from the issuance of debt of \$4.3 million, proceeds from the exercise of options and warrants of \$0.1 million, offset by net cash used in operating activities of \$33.2 million, purchases of property and equipment of \$2.2 million, and payments on term debt of \$2.9 million.

## **Cash Flows**

### **Net Cash Used in Operating Activities**

Net cash used in operating activities was \$33.2 million during the year ended December 31, 2014. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation and amortization, and stock-based compensation, plus the net change in operating assets and liabilities for the year ended December 31, 2014, which consisted primarily of increases in accrued expenses and decreases in restricted cash, inventory, interest receivable and accounts receivable.

### **Net Cash Provided by Investing Activities**

Net cash provided by investing activities was \$4.0 million during the year ended December 31, 2014. This amount reflected the net cash proceeds from the sale and maturities of investments of \$6.2 million offset by cash paid for the purchases of property and equipment of \$2.2 million.

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**Net Cash Provided by Financing Activities**

Net cash provided by financing activities during the year ended December 31, 2014 of \$53.9 million was primarily related to proceeds from the issuance of common stock, net of issuance costs, of \$52.4 million, and proceeds from the issuance of debt of \$4.3 million, offset by payments on debt of \$2.9 million.

**Operating Capital and Capital Expenditure Requirements**

We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will not be sufficient to meet our anticipated cash needs through December 31, 2015. We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will need to pursue a plan to license or sell our assets, cease operations and/or seek bankruptcy protection.

During August 2013, TransEnterix Surgical issued promissory notes (the "Bridge Notes") in the aggregate principal amount of \$2.0 million. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the term loan evidenced by the loan and security agreement between TransEnterix Surgical, Inc. and Silicon Valley Bank and Oxford Finance LLC, as lenders (the "Lenders"). The Bridge Notes were converted into the Company's Series B Preferred Stock at the effective time of the Merger.

On September 3, 2013, we consummated a private placement (the "Private Placement") transaction in which we issued and sold shares of our Series B Convertible Preferred Stock, par value \$0.01 per share (the "Series B Preferred Stock") to finance our operations following the merger. The Private Placement was done pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with accredited investors (the "Investors"), the majority of which were considered related parties as existing investors in SafeStitch and TransEnterix Surgical, pursuant to which the Investors agreed to purchase an aggregate of 7,544,704.4 shares of the Series B Preferred Stock, each share of which was convertible, subject to certain conditions, into two shares of common stock, for a purchase price of \$4.00 per share of Series B Preferred Stock, which was paid in cash, cancellation of certain indebtedness of TransEnterix Surgical or a combination thereof. In accordance with the Purchase Agreement, we issued and sold an additional 25,000 shares of Series B Preferred Stock on September 17, 2013. Proceeds from the issuance of the Series B Preferred Stock, net of issuance costs, were \$28.2 million.

In connection with the Merger, we assumed and became the borrower under TransEnterix Surgical's outstanding credit facility (the "Original Loan Agreement"). On September 26, 2014, we entered into an amended and restated loan and security agreement (the "Amended and Restated Loan Agreement") with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders have agreed to make certain term loans (the "Term Loans") in an aggregate principal amount of up to \$25.0 million, with the first tranche adding to the outstanding principal amount of the existing term loan, which was \$5.6 million, borrowed by the Company from the Lenders under the Original Loan Agreement for an aggregate of \$10.0 million in borrowings as of September 26, 2014. Two additional tranches are to be made available as follows. The second tranche of \$5.0 million will be available at any time prior to one year after the closing date when we file a 510(k) application for the SurgiBot System, and complete an offering of equity securities at or above \$35.0 million. The third tranche of \$10.0 million, will be made available to us at any time prior to two years after the closing date upon recognition of at least \$10.0 million of trailing six-month revenues from the SurgiBot System and SurgiBot-related products. We are entitled to make interest-only payments for 12 months from the closing date, which



interest-only period is extended to 18 months if we receive 510(k) clearance for the SurgiBot system at any time before October 31, 2015. The maturity date of the Term Loans is April 1, 2018 without the interest-only extension and October 1, 2018 with the interest-only extension.

The Term Loans bear interest at a fixed rate equal to 7.50% per annum, subject to adjustment at funding for subsequent tranches on an increase in LIBOR above a designated rate. The Term Loans will be required to be prepaid if the Term Loans are accelerated following an event of default. In addition, we are permitted to prepay the Term Loans in full at any time upon 10 days' written notice to the Lenders. Upon the earliest to occur of the maturity date, acceleration of the term loans, or prepayment of Term Loans, we are required to make a final payment equal to 5.45% of the original principal amount of each Term Loan without the interest-only extension or 6.75% with the interest-only extension (the Final Payment Fee). Any prepayment, whether mandatory or voluntary, must include the Final Payment Fee, interest at the default rate (which is the rate otherwise applicable plus 5%) with respect to any amounts past due, and the Lenders' expenses and all other obligations that are due and payable to the Lenders.

In connection with the entry into the Amended and Restated Loan Agreement, we became obligated to make a payment equal to the accrued portion of the 3.33% final payment fee due under the Original Amended Loan Agreement plus a facility fee payment of \$75,000. In addition, in connection with the first tranche borrowings, we issued warrants to the Lenders to purchase shares of our common stock. Additional common stock warrants will be issued if additional tranche Term Loans are made under the Amended and Restated Loan Agreement. The warrants expire seven years from their respective issue date.

The Amended and Restated Loan Agreement is secured by a security interest in all assets of the Company and its current and future subsidiaries, including a security interest in intellectual property proceeds, but excluding a current security interest in intellectual property. The Amended and Restated Loan Agreement contains customary representations (tested on a continual basis) and covenants that, subject to exceptions, restrict our ability to do the following things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business.

#### Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2014 (in millions):

|                               | Total   | Payments due by period |              |              |
|-------------------------------|---------|------------------------|--------------|--------------|
|                               |         | Less than<br>1 year    | 1 to 3 years | 3 to 5 years |
| Long-term debt obligations    | \$ 11.5 | \$ 0.7                 | \$ 10.8      |              |
| Operating leases              | \$ 2.1  | \$ 0.5                 | \$ 1.6       | \$           |
| Total contractual obligations | \$ 13.6 | \$ 1.2                 | \$ 12.4      | \$           |

Long-term debt obligations include future payments under the Amended Loan Agreement.

Operating lease amounts include future minimum lease payments under all our non-cancelable operating leases with an initial term in excess of one year. We rent office space under an operating lease which expires in 2018, with options to extend the lease through 2021. We also rent space for a warehouse facility which expires in 2018, with options to extend the lease through 2024. This table does not include obligations for any lease extensions.

### **Off-Balance Sheet Arrangements**

As of December 31, 2014, we did not have any off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations set forth above under the headings Results of Operations and Liquidity and Capital Resources have been prepared in accordance with U.S. GAAP and should be read in conjunction with our financial statements and notes thereto appearing in Item 8 of this Annual Report. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our critical accounting policies and estimates, including identifiable intangible assets and goodwill, stock-based compensation, inventory, intellectual property and long-lived assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note 2 in the Notes to the Financial Statements set forth in our financial statements for the years ended December 31, 2014 and 2013, which are attached as Item 8 of this Annual Report. Actual results may differ from these estimates under different assumptions and conditions.

While all accounting policies impact the financial statements, certain policies may be viewed as critical. Critical accounting policies are those that are both most important to the portrayal of financial condition and results of operations and that require management's most subjective or complex judgments and estimates. Our management believes the policies that fall within this category are the policies on accounting for identifiable intangible assets and goodwill, stock-based compensation, intellectual property and long-lived assets and inventory.

### **Identifiable Intangible Assets and Goodwill**

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 10 years. We periodically evaluate identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists by performing either a qualitative evaluation or a two-step quantitative test. The qualitative evaluation is an assessment of factors, including industry, market and general economic conditions, market value, and future projections to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. The Company may elect to bypass this qualitative assessment and perform a two-step quantitative test. The quantitative goodwill impairment test is performed by comparing the estimated fair value of the associated reporting unit to its carrying value.

### **Accounting for Stock-Based Compensation**

We recognize as expense, the grant-date fair value of stock options and other stock based compensation issued to employees and non-employee directors over the requisite service periods, which are typically the vesting periods. We use the Black-Scholes-Merton model to estimate the fair value of our stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies. The expected term of options granted by the Company has been determined based upon the simplified method, because we do not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield is assumed to be zero. We estimates forfeitures based on our historical experience and adjust the estimated forfeiture rate based upon actual experience.

### **Intellectual Property and Long-Lived Assets**

Intellectual property consists of purchased patent rights. Amortization is recorded using the straight-line method over the estimated useful life of the patents of ten years. We review our long-lived assets including purchased intellectual property and property and equipment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine the recoverability of our long-lived assets, we evaluate the probability that future estimated undiscounted net cash flows will be less than the carrying amount of the assets. If such estimated cash flows are less than the carrying amount of the long-lived assets, then such assets are written down to their fair value. Our estimates of anticipated cash flows and the remaining estimated useful lives of long-lived assets could be reduced in the future, resulting in a reduction to the carrying amount of long-lived assets.

### **Inventory**

Inventory, which includes material, labor and overhead costs, is stated at standard costs which approximates actual cost, determined on a first-in, first-out basis, not in excess of market value. We record reserves, when necessary, to reduce the carrying value of inventory to their net realizable value. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

### **Recent Accounting Pronouncements**

See Note 2. Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements in Item 8. Financial Statements and Supplementary Data of this Annual Report for a full description of recent accounting pronouncements including the respective expected dates of adoption and effects on Consolidated Balance Sheets and Consolidated Statements of Operations and Comprehensive Loss.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company as defined in Rule 12b-2 of the Exchange Act, we are not required to include information otherwise required by this Item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

TransEnterix, Inc.

Morrisville, North Carolina

We have audited the accompanying consolidated balance sheets of TransEnterix, Inc. (the Company) as of December 31, 2014 and 2013 and the related consolidated statements of operations and comprehensive loss, preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of TransEnterix, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), TransEnterix, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 20, 2015 expressed an unqualified opinion thereon.

/s/BDO USA, LLP

BDO USA, LLP

Raleigh, North Carolina

February 20, 2015

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

TransEnterix, Inc.

Morrisville, North Carolina

We have audited TransEnterix, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). TransEnterix, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, TransEnterix, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of TransEnterix, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2014 and our report dated February 20, 2015 expresses an unqualified opinion thereon.

/s/BDO USA, LLP

BDO USA, LLP

Raleigh, North Carolina

February 20, 2015



**TransEnterix, Inc.****Consolidated Balance Sheets****(in thousands, except share amounts)**

|   | December 31,<br>2014 | December 31,<br>2013 |
|---|----------------------|----------------------|
| <b>Assets</b>   |                      |                      |
| Current Assets  |                      |                      |
| Cash and cash equivalents   | \$ 34,766            | \$ 10,014            |
| Short-term investments  |                      | 6,191                |
| Accounts receivable, net  | 133                  | 188                  |
| Interest receivable   | 1                    | 68                   |
| Inventory, net  |                      | 701                  |
| Other current assets  | 789                  | 593                  |
| <b>Total Current Assets</b>   | <b>35,689</b>        | <b>17,755</b>        |
| Restricted cash   | 250                  | 375                  |
| Property and equipment, net   | 3,120                | 1,864                |
| Intellectual property, net  | 2,241                | 2,741                |
| Trade names, net  | 7                    | 10                   |
| Goodwill  | 93,842               | 93,842               |
| Other long term assets  | 62                   | 127                  |
| <b>Total Assets</b>   | <b>\$ 135,211</b>    | <b>\$ 116,714</b>    |
| <b>Liabilities and Stockholders' Equity</b>   |                      |                      |
| Current Liabilities   |                      |                      |
| Accounts payable  | \$ 1,768             | \$ 1,804             |
| Accrued expenses  | 1,769                | 1,406                |
| Note payable - current portion  | 610                  | 3,879                |
| <b>Total Current Liabilities</b>  | <b>4,147</b>         | <b>7,089</b>         |
| Long Term Liabilities   |                      |                      |
| Note payable - less current portion, net of debt discount   | 9,275                | 4,602                |
| <b>Total Liabilities</b>  | <b>13,422</b>        | <b>11,691</b>        |
| <b>Commitments and Contingencies</b>  |                      |                      |
| <b>Stockholders' Equity</b>   |                      |                      |
| Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2014 and 2013; and 63,182,806 and 48,841,417 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively (1) | 63                   | 49                   |
| Additional paid-in capital  | 257,642              | 203,238              |

|  |            |            |
|--|------------|------------|
| Accumulated deficit                        | (135,916)  | (98,264)   |
| Total Stockholders' Equity                 | 121,789    | 105,023    |
| Total Liabilities and Stockholders' Equity | \$ 135,211 | \$ 116,714 |

*See accompanying notes to consolidated financial statements.*

(1) Adjusted for 1:5 reverse stock split on March 31, 2014.

**TransEnterix, Inc.****Consolidated Statements of Operations and Comprehensive Loss****(in thousands)**

|  | Years ended<br>December 31, |             |
|--|-----------------------------|-------------|
|  | 2014                        | 2013        |
| Sales  | \$ 401                      | \$ 1,431    |
| Operating Expenses   |                             |             |
| Cost of goods sold   | 1,095                       | 4,810       |
| Research and development   | 27,944                      | 12,700      |
| Sales and marketing  | 1,727                       | 1,943       |
| General and administrative                                       | 6,244                       | 4,221       |
| Impairment loss on property and equipment                        |                             | 450         |
| Merger expenses  |                             | 2,911       |
| Total Operating Expenses   | 37,010                      | 27,035      |
| Operating Loss   | (36,609)                    | (25,604)    |
| Other Expense  |                             |             |
| Remeasurement of fair value of preferred stock warrant liability |                             | (1,800)     |
| Interest expense, net  | (1,043)                     | (954)       |
| Total Other Expense, net   | (1,043)                     | (2,754)     |
| Net Loss   | \$ (37,652)                 | \$ (28,358) |
| Other comprehensive income (loss)                                |                             |             |
| Comprehensive loss   | \$ (37,652)                 | \$ (28,358) |
| Net loss per share - basic and diluted                           | \$ (0.64)                   | \$ (2.23)   |
| Weighted average common shares outstanding - basic and diluted   | 58,714                      | 12,731      |

*See accompanying notes to consolidated financial statements.*

## TransEnterix, Inc.

## Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit)

(in thousands)

|                               | Series A |           | Preferred Stock<br>Series B |           | Series B-1 |           | Preferred Stock<br>Series B |          | Common Stock (1) |        | Additional<br>Paid-in<br>Capital<br>(1) | Accumulated<br>Deficit |
|-------------------------------|----------|-----------|-----------------------------|-----------|------------|-----------|-----------------------------|----------|------------------|--------|---|------------------------|
|                               | Shares   | Amount    | Shares                      | Amount    | Shares     | Amount    | Shares                      | Amount   | Shares           | Amount |   |                        |
| Balance at January 1, 2017    | 5,696    | \$ 19,885 | 11,490                      | \$ 40,016 | 45,998     | \$ 15,104 |                             | \$       | 1,078            | \$ 1   | \$ 1,292                                | \$ (69,906)            |
| Issuance of common stock      |          |           |                             | 31        |            | 9         |                             |          |                  |        |   | (40)                   |
| Conversion of preferred stock |          |           |                             |           |            |           |                             |          |                  |        | 941                                     |                        |
| Repurchase of common stock    |          |           |                             |           |            |           |                             |          | 68               |        | 54                                      |                        |
| Exercise of warrants          |          |           |                             |           |            |           |                             |          | 167              |        | 90                                      |                        |
| Conversion of preferred stock | (5,696)  | (19,885)  | (11,490)                    | (40,047)  | (45,998)   | (15,113)  |                             |          | 32,444           | 33     | 168,810                                 |                        |
| Exercise of common stock      |          |           |                             |           |            |           |                             |          |                  |        |   |                        |
| Conversion of preferred stock |          |           |                             |           |            |           |                             |          | (54)             |        |   |                        |
| Conversion of preferred stock |          |           |                             |           |            |           |                             |          |                  |        | 1,909                                   |                        |
| Conversion of preferred stock |          |           |                             |           |            |           | 7,570                       | 30,197   |                  |        |   |                        |
| Conversion of preferred stock |          |           |                             |           |            |           | (7,570)                     | (30,197) | 15,139           | 15     | 30,182                                  |                        |
| Conversion of preferred stock |          |           |                             |           |            |           |                             |          |                  |        |   | (28,358)               |

|            |    |    |    |    |        |       |            |              |
|------------|----|----|----|----|--------|-------|------------|--------------|
| 1,         | \$ | \$ | \$ | \$ | 48,842 | \$ 49 | \$ 203,238 | \$ (98,264)  |
| on         |    |    |    |    |        |       | 1,840      |              |
| ck,<br>nce |    |    |    |    | 14,110 | 14    | 52,419     |              |
| s<br>d     |    |    |    |    | 221    |       | 75         |              |
|            |    |    |    |    | 10     |       | 16         |              |
|            |    |    |    |    |        |       | 54         |              |
|            |    |    |    |    |        |       |            | (37,652)     |
| 1,         | \$ | \$ | \$ | \$ | 63,183 | \$ 63 | \$ 257,642 | \$ (135,916) |

*See accompanying notes to consolidated financial statements. See Note 19 for information on the Reverse Merger and the applicable conversion ratio applied to historical common stock amounts.*

(1) Adjusted for 1:5 reverse stock split on March 31, 2014.

**TransEnterix, Inc.****Consolidated Statements of Cash Flows****(in thousands)**

|  | Years ended<br>December 31, |             |
|--|-----------------------------|-------------|
|  | 2014                        | 2013        |
| <b>Operating Activities</b>  |                             |             |
| Net loss   | \$ (37,652)                 | \$ (28,358) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities: |                             |             |
| Depreciation and amortization  | 1,310                       | 1,483       |
| Amortization of debt discount  | 14                          |             |
| Amortization of debt issuance costs  | 69                          | 103         |
| Remeasurement of fair value of preferred stock warrant liability                                 |                             | 1,800       |
| Accretion/amortization of bond discount/premium  |                             | 52          |
| Stock-based compensation   | 1,840                       | 941         |
| Loss on disposal of property and equipment   | 86                          | 31          |
| Impairment loss on property and equipment  |                             | 450         |
| Changes in operating assets and liabilities:   |                             |             |
| Accounts receivable  | 55                          | 402         |
| Interest receivable  | 67                          | (52)        |
| Inventory  | 701                         | 731         |
| Other current and long term assets   | (170)                       | (328)       |
| Restricted cash  | 125                         |             |
| Accounts payable   | (36)                        | 641         |
| Accrued expenses   | 363                         | 868         |
| Net cash and cash equivalents used in operating activities                                       | (33,228)                    | (21,236)    |
| <b>Investing Activities</b>  |                             |             |
| Purchase of investments  |                             | (6,240)     |
| Proceeds from sale and maturities of investments   | 6,191                       | 904         |
| Cash received in acquisition of a business, net of cash paid                                     |                             | 246         |
| Purchase of property and equipment   | (2,174)                     | (1,377)     |
| Proceeds from sale of property and equipment   | 25                          |             |
| Net cash and cash equivalents provided by (used in) investing activities                         | 4,042                       | (6,467)     |
| <b>Financing Activities</b>  |                             |             |
| Proceeds from issuance of debt, net of debt discount   | 4,321                       | 1,998       |
| Payment of debt  | (2,877)                     | (1,519)     |
| Proceeds from issuance of common stock, net of issuance costs                                    | 52,433                      |             |
| Proceeds from issuance of preferred stock, net of issuance costs                                 |                             | 28,199      |
| Debt issuance costs  | (30)                        |             |
| Proceeds from exercise of stock options and restricted stock units                               | 75                          |             |

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|  |           |           |
|--|-----------|-----------|
| Proceeds from exercise of warrants                             | 16        | 143       |
| Net cash and cash equivalents provided by financing activities | 53,938    | 28,821    |
| Net increase in cash and cash equivalents                      | 24,752    | 1,118     |
| Cash and Cash Equivalents, beginning of year                   | 10,014    | 8,896     |
| Cash and Cash Equivalents, end of year                         | \$ 34,766 | \$ 10,014 |

Supplemental Disclosure for Cash Flow Information

|               |        |        |
|---------------|--------|--------|
| Interest paid | \$ 904 | \$ 824 |
|---------------|--------|--------|

Supplemental Schedule of Noncash Investing and Financing Activities

|   |       |           |
|---|-------|-----------|
| Issuance of common stock warrants                               | \$ 54 | \$        |
| Conversion of bridge notes to preferred stock                   | \$    | \$ 1,998  |
| Conversion of preferred stock warrants to common stock warrants | \$    | \$ 1,909  |
| Conversion of preferred stock to common stock                   | \$    | \$ 30,197 |

*See accompanying notes to consolidated financial statements.*

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**TransEnterix, Inc.**

**Notes to Financial Statements**

**1. Organization and Capitalization**

TransEnterix, Inc. (the Company) is a medical device company that is focused on the development and future commercialization of a robotic assisted surgical system called the SurgiBot System (the SurgiBot System). The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System would allow for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once in the body. The SurgiBot System also allows for three-dimensional (3-D) high definition vision technology. The Company previously commercialized the SPIDER<sup>®</sup> Surgical System, (the SPIDER System) a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilizes flexible instruments and articulating channels that are controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System has been cleared by the U.S. Food and Drug Administration (FDA). The Company also manufactured multiple instruments that can be deployed using the SPIDER System, and which are being adapted for use with the SurgiBot System. The Company has discontinued sales of the SPIDER System as of December 31, 2014.

On September 3, 2013, TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical) and SafeStitch Medical, Inc., a Delaware corporation (SafeStitch) consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the Merger). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. As used herein, the term Company refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, the term SafeStitch refers to the historic business of SafeStitch Medical, Inc. prior to the Merger, and the term TransEnterix Surgical refers to the historic business of TransEnterix Surgical, Inc. prior to the Merger.

On December 6, 2013, the Company filed an Amended and Restated Certificate of Incorporation (the Restated Certificate) to change its name to TransEnterix, Inc. and to increase the authorized shares of common stock from 225,000,000 to 750,000,000, and to authorize 25,000,000 shares of preferred stock, par value \$0.01 per share. The Company's Board of Directors has the authority to fix the designations, powers, preferences and relative participating, optional and other special rights of shares of any series of preferred stock designated by them, and the qualifications, limitations or restrictions of such preferred stock.

Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity, gastroesophageal reflux disease (GERD) and Barrett's Esophagus. In the second quarter of 2014, the Company determined to cease internal development of the Gastroplasty Device. The Company is evaluating strategic alternatives for the former SafeStitch products.

The Company operates in one business segment.



## **2. Summary of Significant Accounting Policies**

### **Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has accumulated a deficit of \$135.9 million, including a net loss of \$37.7 million for the year ended December 31, 2014, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

### **Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SafeStitch LLC, and TransEnterix Surgical, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ( U.S. GAAP ) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include identifiable intangible assets and goodwill, the valuation of common stock for purposes of determining stock compensation expense, excess and obsolete inventory reserves, allowance for uncollectible accounts, and deferred tax asset valuation allowances.

### **Reverse Merger**

On September 3, 2013, TransEnterix Surgical and SafeStitch, consummated the Merger whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the Merger. As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its corporate name to TransEnterix, Inc.

The Reverse Merger has been accounted for as a reverse acquisition under which TransEnterix Surgical was considered the acquirer of SafeStitch. As such, the financial statements of TransEnterix Surgical are treated as the historical financial statements of the combined company, with the results of SafeStitch being included from September 3, 2013.

As a result of the Reverse Merger with SafeStitch, historical common stock amounts and additional paid in capital have been retroactively adjusted using an Exchange Ratio of 1.1533.

## **Reverse Stock Split**

On March 31, 2014, the Company effectuated a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1 for 5 (the Reverse Stock Split). As a result of the Reverse Stock Split, the Company's issued and outstanding stock decreased from 244,276,923 to 48,855,255 shares of common stock, all with a par value of \$0.001. All information related to common stock, stock options, restricted stock units, warrants and earnings per share for prior periods has been retroactively adjusted to give effect to the Reverse Stock Split, except for the reference to the Merger Exchange Ratio of 1.1533.

## **Cash and Cash Equivalents, Restricted Cash, and Short-Term Investments**

The Company considers all highly liquid investments with original maturities of 90 days or less at the time of purchase to be cash equivalents and investments with original maturities of between 91 days and one year to be short-term investments. In order to manage exposure to credit risk, the Company invests in high-quality investments rated at least A2 by Moody's Investors Service or A by Standard & Poor.

Restricted cash, consisting of a money market account used as collateral securing a letter of credit under the terms of the corporate office operating lease that commenced in 2010, was \$250,000 and \$375,000 as of December 31, 2014 and 2013, respectively.

The Company's investments at December 31, 2013 consisted of corporate bonds and were classified as available for sale. Investments classified as available for sale are measured at fair value, and net unrealized gains and losses are recorded as a component of accumulated other comprehensive income (loss) on the balance sheet until realized. Realized gains and losses on sales of investment securities are determined based on the specific-identification method and are recorded in interest expense, net. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization and accretion is included in interest expense, net. The Company held no investments as of December 31, 2014 as it sold all its investment securities during 2014. There were no gross realized gains or losses for the years ended December 31, 2014 and 2013. There have been no unrealized gains or losses reclassified to accumulated other comprehensive income (loss).

## **Accounts Receivable**

Accounts receivable are recorded at net realizable value, which includes an allowance for estimated uncollectable accounts. The allowance for uncollectible accounts was determined based on historical collection experience.

## **Fair Value of Financial Instruments**

The carrying values of cash equivalents, accounts receivable, interest receivable, accounts payable, and certain accrued expenses at December 31, 2014 and 2013, approximate their fair values due to the short-term nature of these items. The Company's debt balance approximates fair value as of December 31, 2014 and 2013.

## **Concentrations and Credit Risk**

The Company's principal financial instruments subject to potential concentration of credit risk are cash and cash equivalents and investments held in money market accounts. The Company places cash deposits with a federally insured financial institution. The Company maintains its cash at banks and financial institutions it considers to be of high credit quality; however, the Company's cash deposits may at times exceed the FDIC insured limit. Balances in excess of federally insured limitations may not be insured. The Company has not experienced losses on these accounts, and management believes that the Company is not exposed to significant risks on such accounts.



The Company had one customer who constituted 74% of the Company's net accounts receivable at December 31, 2014 and one customer who constituted 61% of the Company's net accounts receivable at December 31, 2013. The Company had two customers who accounted for 37% and 10% of sales in 2014 and one customer who accounted for 37% of sales in 2013.

### **Inventory**

Inventory, which includes material, labor and overhead costs, is stated at standard costs which approximates actual cost, determined on a first-in, first-out basis, not in excess of market value. The Company records reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

### **Identifiable Intangible Assets and Goodwill**

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed at December 31, 2014 or 2013.

Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at December 31<sup>st</sup> or when events or changes in circumstances indicate evidence of potential impairment exists, using a fair value based test. No impairment existed at December 31, 2014 or 2013.

### **Debt Issuance Costs**

The Company capitalizes costs associated with the issuance of debt instruments and amortizes these costs to interest expense over the term of the related debt agreement using the effective yield amortization method. Unamortized debt issuance costs will be charged to operations when indebtedness under the related credit facility is repaid prior to maturity.

### **Business Acquisitions**

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification (ASC) 805, Business Combinations. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, Fair Value Measurements, as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price, which may be different than the amount of consideration assumed in the pro forma financial statements. Under ASC 805, acquisition related costs (i.e., advisory, legal, valuation and other professional fees) and certain acquisition-related restructuring charges impacting the target company are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

### **Risk and Uncertainties**

The Company is subject to a number of risks similar to other similarly-sized companies in the medical device industry. These risks include, without limitation, the historical lack of profitability, our ability to raise additional capital, our ability to successfully develop, clinically test and commercialize our products, the timing and outcome of the regulatory review process for our products, changes in the health care and regulatory environments of the United States and other countries in which we intend to operate, our ability to attract and retain key management, marketing and scientific personnel, competition from new entrants, our ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights, our ability to successfully transition from a research and development company to a marketing, sales and distribution concern, and our ability to identify and pursue development of additional products.

### **Property and Equipment**

Property and equipment consists primarily of machinery, manufacturing equipment, computer equipment, furniture, and leasehold improvements, which are recorded at cost.

Depreciation is recorded using the straight-line method over the estimated useful lives of the assets as follows:

|                                       |                                       |
|---------------------------------------|---------------------------------------|
| Machinery and manufacturing equipment | 5 years                               |
| Computer equipment                    | 3 years                               |
| Furniture                             | 5 years                               |
| Leasehold improvements                | Lesser of lease term or 3 to 10 years |

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

### **Intellectual Property**

Intellectual property consists of purchased patent rights. Amortization is recorded using the straight-line method over the estimated useful life of the patents of 10 years. This method approximates the period over which the Company expects to receive the benefit from these assets.

### **Long-Lived Assets**

The Company reviews its long-lived assets including property and equipment and purchased intellectual property, for possible impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine the recoverability of its long-lived assets, the Company evaluates the probability that future estimated undiscounted net cash flows will be less than the carrying amount of the assets. If such estimated cash flows are less than the carrying amount of the



long-lived assets, then such assets are written down to their fair value. The Company's estimates of anticipated cash flows and the remaining estimated useful lives of long-lived assets could be reduced in the future, resulting in a reduction to the carrying amount of long-lived assets.

### **Preferred Stock Warrant Liability**

In January and December 2012, TransEnterix Surgical entered into promissory notes with two lenders and issued preferred stock warrants to each lender in connection with the issuance of the promissory notes. At December 31, 2012, TransEnterix Surgical accounted for these freestanding warrants to purchase TransEnterix Surgical Series B-1 Convertible Preferred Stock as liabilities at fair value. The warrants were subject to re-measurement at each balance sheet date prior to the Merger, and the change in fair value through the Merger date was recognized as other income (expense). TransEnterix Surgical used the Monte Carlo simulation method to value the warrants prior to the Merger which is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of TransEnterix Surgical's future expected stock prices and minimizes standard error. In connection with the Merger, the warrants, which previously were convertible into shares of TransEnterix Surgical Series B-1 Convertible Preferred Stock, were amended to be convertible into warrants to purchase the Company's common stock. Upon conversion of the warrants as a consequence of the Merger, the preferred stock warrant liability was reclassified into additional paid-in capital.

### **Revenue Recognition**

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, delivery has occurred which is typically at shipping point, the fee is fixed or determinable and collectability is reasonably assured. Shipping and handling costs billed to customers are included in revenue.

### **Cost of Goods Sold**

Cost of goods sold consists of materials, labor and overhead incurred internally to produce the products. Shipping and handling costs incurred by the Company are included in cost of goods sold.

### **Research and Development Costs**

Research and development expenses primarily consist of engineering, product development and regulatory expenses, incurred in the design, development, testing and enhancement of our products and legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products. Research and development costs are expensed as incurred.

### **Stock-Based Compensation**

The Company follows ASC 718 ( Stock Compensation ) and ASC 505-50 ( Equity-Based Payments to Non-employees ), which provide guidance in accounting for share-based awards exchanged for services rendered and requires companies to expense the estimated fair value of these awards over the requisite service period. The Company determines the fair value of the stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either of (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (2) the date at which the counterparty's performance is complete.





The Company records as expense the fair value of stock-based compensation awards, including stock options and restricted stock units. Compensation expense for stock-based compensation was \$1,840,000 and \$941,000 for the years ended December 31, 2014 and 2013, respectively.

## Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets or liabilities for the temporary differences between financial reporting and tax basis of the Company's assets and liabilities, and for tax carryforwards at enacted statutory rates in effect for the years in which the asset or liability is expected to be realized. The effect on deferred taxes of a change in tax rates is recognized in income during the period that includes the enactment date. In addition, valuation allowances are established when necessary to reduce deferred tax assets and liabilities to the amounts expected to be realized.

## Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss is equal to its net loss for all periods presented.

## Impact of Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The Standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the Standard in 2017.

In June 2014, the FASB issued ASU 2014-12 *Compensation - Stock Compensation: Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved after the Requisite Service Period*, which provides explicit guidance for the accounting treatment for these types of awards. The ASU requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. This update is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. The Company does not expect this ASU will have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). The amendments in ASU 2014-15 are intended to define management's responsibility to evaluate whether there is substantial doubt about an



organization's ability to continue as a going concern and to provide related footnote disclosures. Under U.S. GAAP, financial statements are prepared under the presumption that the reporting organization will continue to operate as a going concern, except in limited circumstances. The going concern basis of accounting is critical to financial reporting because it establishes the fundamental basis for measuring and classifying assets and liabilities. Currently, U.S. GAAP lacks guidance about management's responsibility to evaluate whether there is substantial doubt about the organization's ability to continue as a going concern or to provide related footnote disclosures. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not expect this ASU will have a material impact on its consolidated financial statements.

### 3. Cash, Cash Equivalents, Restricted Cash, and Short-term Investments

Cash, cash equivalents, restricted cash, and short-term investments consist of the following:

|  | <b>December 31</b> |                  |
|--|--------------------|------------------|
|  | <b>2014</b>        | <b>2013</b>      |
|  | (In thousands)     |                  |
| Cash                                   | \$ 1,511           | \$ 930           |
| Money market                           | 33,255             | 9,084            |
| <b>Total cash and cash equivalents</b> | <b>\$ 34,766</b>   | <b>\$ 10,014</b> |
| Corporate bonds                        | \$                 | \$ 6,191         |
| <b>Total short-term investments</b>    | <b>\$</b>          | <b>\$ 6,191</b>  |
| Total restricted cash                  | \$ 250             | \$ 375           |
| <b>Total</b>                           | <b>\$ 35,016</b>   | <b>\$ 16,580</b> |

### 4. Fair Value

The Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets and liabilities include available for sale securities classified as cash equivalents and a preferred stock warrant liability, respectively. ASC 820-10 ( Fair Value Measurement Disclosure ) requires the valuation using a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data and therefore, are based primarily upon estimates, are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

As prescribed by U.S. GAAP, the Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy.

The determination of where an asset or liability falls in the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures and based on various factors, it is possible that an asset or liability may be classified differently from period to period. However, the Company expects changes in classifications between levels will be rare.

The following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2014 and 2013, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

| Description                         | December 31, 2014<br>(In thousands)                                     |  |  |  | Total<br>December 31, 2014 |
|-------------------------------------|---|--|--|--|----------------------------|
|                                     | Quoted Prices in<br>Active Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Observable<br>Inputs<br>(Level 2) | Other<br>Observable<br>Inputs<br>(Level 3) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |                            |
|                                     | (Level 1)   | (Level 2)  | (Level 3)                                  | (Level 3)  |                            |
| Assets measured at fair value       |   |  |  |  |                            |
| Cash and Cash Equivalents           | \$ 34,766   | \$   | \$   | \$   | 34,766                     |
| Restricted Cash                     | 250   |  |  |  | 250                        |
| Total Assets measured at fair value | \$ 35,016   | \$   | \$   | \$   | 35,016                     |

| Description                         | December 31, 2013<br>(In thousands)                                     |  |  |  | Total<br>December 31, 2013 |
|-------------------------------------|---|--|--|--|----------------------------|
|                                     | Quoted Prices in<br>Active Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Observable<br>Inputs<br>(Level 2) | Other<br>Observable<br>Inputs<br>(Level 3) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |                            |
|                                     | (Level 1)   | (Level 2)  | (Level 3)                                  | (Level 3)  |                            |
| Assets measured at fair value       |   |  |  |  |                            |
| Cash and Cash Equivalents           | \$ 10,014   | \$   | \$   | \$   | 10,014                     |
| Restricted Cash                     | 375   |  |  |  | 375                        |
| Short-term investments              |   | \$ 6,191   |  | \$   | 6,191                      |
| Total Assets measured at fair value | \$ 10,389   | \$ 6,191   | \$   | \$   | 16,580                     |

The change in the fair value of the Level 3 preferred stock warrant liability is summarized below:

|   | December 31,<br>2013<br>(In thousands) |
|---|--|
| Fair value at beginning of year                                   | \$ 109                                 |
| Issuances   |  |
| Change in fair value recorded in other expense                    | 1,800                                  |
| Reclassification to additional paid-in capital upon the<br>Merger | (1,909)                                |
| Fair value at end of year   | \$                                     |

The Company utilized the Monte Carlo simulation to value the liability related to the preferred warrants, which requires significant unobservable, or Level 3, inputs. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices and minimizes standard error.

## 5. Investments

The aggregate fair values of investment securities along with unrealized gains and losses determined on an individual investment security basis are as follows:

|                          | (In thousands) |                 |                   |            |
|--------------------------|----------------|-----------------|-------------------|------------|
|                          | Amortized Cost | Unrealized Gain | Unrealized (Loss) | Fair Value |
| <i>December 31, 2013</i> |                |                 |                   |            |
| Corporate bonds          | \$ 6,191       | \$              | \$                | \$ 6,191   |

None of the securities have contractual maturities of more than one year and therefore do not have continuous unrealized losses greater than 12 months. The Company held no investments at December 31, 2014 as it sold all its investment securities during 2014. There were no realized gains or losses for the years ended December 31, 2014 and 2013.

## 6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

|                                      | December 31,<br>2014 | December 31,<br>2013 |
|--------------------------------------|----------------------|----------------------|
|                                      | (In thousands)       |                      |
| Gross accounts receivable            | \$ 221               | \$ 220               |
| Allowance for uncollectible accounts | (88)                 | (32)                 |

|                                |        |        |
|--------------------------------|--------|--------|
| Total accounts receivable, net | \$ 133 | \$ 188 |
|--------------------------------|--------|--------|

## 7. Inventories

The following table presents the components of inventories:

|   | December 31,<br>2014 | December 31,<br>2013 |
|---|----------------------|----------------------|
|   | (In thousands)       |                      |
| Finished goods                            | \$ 358               | \$ 896               |
| Reserve for excess and obsolete inventory | (358)                | (195)                |
| Total inventories                         | \$                   | \$ 701               |

During the year ended December 31, 2013, the reserve for excess and obsolete inventory was increased by approximately \$803,000 primarily to reserve for raw materials that the Company no longer anticipates selling. Of this amount, approximately \$718,000 was written-off and removed from inventory, resulting in an increase in the reserve for excess and obsolete inventory of approximately \$85,000. During 2014, the Company discontinued the sale of the SPIDER System. As a result, the inventory balance was fully reserved at December 31, 2014, as we increased the reserve for excess and obsolete inventory by approximately \$163,000.

## 8. Property and Equipment

Property and equipment consisted of the following:

|   | December 31,<br>2014 | December 31,<br>2013 |
|---|----------------------|----------------------|
|   | (In thousands)       |                      |
| Machinery and manufacturing equipment     | \$ 3,797             | \$ 2,453             |
| Computer equipment                        | 1,710                | 1,327                |
| Furniture                                 | 358                  | 287                  |
| Leasehold improvements                    | 1,405                | 1,249                |
| <b>Total property and equipment</b>       | <b>7,270</b>         | <b>5,316</b>         |
| Accumulated depreciation and amortization | (4,150)              | (3,452)              |
| <b>Property and equipment, net</b>        | <b>\$ 3,120</b>      | <b>\$ 1,864</b>      |

Depreciation expense was \$810,000 and \$983,000, for the years ended December 31, 2014 and 2013, respectively.

During the year ended December 31, 2013, an impairment charge of \$450,000 was incurred for a charge in the estimate of the useful lives for certain manufacturing property and equipment that the Company does not anticipate using in the future.

## 9. Intellectual Property

In 2009, the Company purchased certain patents from an affiliated company for \$5 million in cash and concurrently terminated a license agreement related to the patents. Intellectual Property consisted of the following:

|                                   | December 31,<br>2014 | December 31,<br>2013 |
|-----------------------------------|----------------------|----------------------|
|                                   | (In thousands)       |                      |
| Patents                           | \$ 5,000             | \$ 5,000             |
| Accumulated amortization          | (2,759)              | (2,259)              |
| <b>Intellectual property, net</b> | <b>\$ 2,241</b>      | <b>\$ 2,741</b>      |



Amortization expense was \$500,000 for the years ended December 31, 2014 and 2013. At December 31, 2014, the estimated amortization expense for each of the four succeeding years is approximately \$500,000 per year, with a final year of estimated amortization expense of \$241,000. The remaining amortization period is 4.5 years. The patent expiration dates begin in 2027.

#### **10. Debt Issuance Costs**

In connection with the issuance of notes payable, TransEnterix Surgical incurred debt acquisition costs of \$183,000. TransEnterix Surgical capitalizes these costs and is amortizing them over the life of the debt, using the straight-line method of amortization which approximates the effective-interest method. Amortization expense for the debt issuance costs was \$38,000 and \$65,000 for the years ended December 31, 2014 and 2013, respectively.

In January 2012, TransEnterix Surgical recorded \$63,000 of debt issuance costs related to the issuance to the lenders of warrants to purchase Series B-1 Convertible Redeemable Preferred Stock. The preferred stock warrants were issued in conjunction with a promissory note issued to the lenders. At that time, TransEnterix Surgical began amortizing the debt issuance costs over the four year term of the promissory note. Amortization expense for the debt issuance costs was \$15,000 and \$16,000 for the years ended December 31, 2014 and 2013, respectively.

In December 2012, TransEnterix Surgical recorded \$65,000 of debt issuance costs related to the issuance of warrants to purchase Series B-1 Convertible Redeemable Preferred Stock to lenders. The preferred stock warrants were issued in conjunction with a promissory note issued to the lender. At that time, TransEnterix Surgical began amortizing the debt issuance costs over the three year term of the promissory note. Amortization expense for the debt issuance costs was \$16,000 and \$22,000 for the years ended December 31, 2014 and 2013, respectively.

Total amortization expense related to issuance of warrants was \$31,000 and \$38,000 for the years ended December 31, 2014 and 2013, respectively. Total accumulated amortization for the warrant issuance costs was \$80,000 and \$49,000 at December 31, 2014 and 2013, respectively. Debt issuance costs, net of amortization, are recorded within other assets on the consolidated balance sheets.

#### **11. Income Taxes**

No income tax expense or benefit has been recorded for the years ended December 31, 2014 or December 31, 2013. This is due to the establishment of a valuation allowance against the deferred tax assets generated during those periods. The valuation allowance was recorded due to management's assessment of the likelihood that said deferred tax assets will be realized in future periods.

Significant components of the Company's deferred tax assets consist of the following at December 31 (in thousands):

|   | 2014     | 2013     |
|---|----------|----------|
| Current deferred tax assets:                    |          |          |
| Inventory reserves                              | \$ 537   | \$ 71    |
| Accrued expenses                                | 373      | 331      |
| Deferred rent                                   | 17       | 14       |
| Allowance for uncollectible accounts receivable | 32       | 12       |
| Valuation allowance                             | (959)    | (428)    |
| Net current deferred tax asset                  |          |          |
| Noncurrent deferred tax assets:                 |          |          |
| Stock-based compensation                        | 1,154    | 1,170    |
| Contribution carryforward                       | 2        | 2        |
| Research credit carryforward                    | 3,200    | 2,307    |
| Fixed assets                                    | 278      | 235      |
| Capitalized start up costs                      | 4,233    | 4,676    |
| Net operating loss carryforwards                | 51,145   | 38,286   |
|   | 60,012   | 46,676   |
| Valuation allowance                             | (60,009) | (46,672) |
| Net noncurrent deferred tax asset               | 3        | 4        |
| Noncurrent deferred tax liability               |          |          |
| Purchase accounting intangibles                 | (3)      | (4)      |
| Net deferred tax asset (liability)              | \$       | \$       |

The Merger transaction described in Note 1 was in the form of a tax-free reorganization under Internal Revenue Code Sec. 368. The transaction qualifies as a Business Combination under ASC 740. The goodwill recorded under U.S. GAAP purchase accounting is not deductible for tax purposes.

At December 31, 2014 and 2013, the Company has provided a full valuation allowance against its net deferred assets, since realization of these benefits is not more likely than not. The valuation allowance increased approximately \$13.9 million from the prior year. At December 31, 2014, the Company had federal and state net operating loss tax carryforwards of approximately \$140.6 million and \$98.1 million, respectively. These net operating loss carryforwards expire in various amounts starting in 2027 and 2018, respectively. The Company's federal and state net operating loss carryforwards include approximately \$0.4 million of excess tax benefits related to deductions from the exercise of stock options. The tax benefit of these deductions has not been recognized in deferred tax assets. If utilized, the benefits from these deductions will be recorded as adjustments to additional paid-in capital. At December 31, 2014, the Company had federal research credit carryforwards in the amount of \$3.2 million. These carryforwards begin to expire in 2027. The utilization of the federal net operating loss carryforwards and credit carryforwards will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.



The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2014, the Company had gross unrecognized tax benefits of approximately \$0.6 million. As of December 31, 2013, the Company had not recorded any amounts associated with unrecognized tax benefits. Of the total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next twelve months. Furthermore, the Company does not expect any cash settlement with the taxing authorities as a result of these unrecognized tax benefits as the Company has sufficient unutilized carryforward attributes to offset the tax impact of these adjustments.

The following is a tabular reconciliation of the Company's change in gross unrecognized tax positions (in thousands):

|   |        |
|---|--------|
| Balance at December 31, 2013              | \$     |
| Gross increases related to current period | 606    |
| Gross decreases related to current period |        |
| Balance at December 31, 2014              | \$ 606 |

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2014, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to United States Federal, state, and local tax examinations by tax authorities for years before 2011, although carryforward attributes that were generated prior to 2011 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

Taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision for income taxes as follows for the years ended December 31:

|  | 2014        |                            | 2013       |                            |
|--|-------------|----------------------------|------------|----------------------------|
|  | Amount      | Percent of Pretax Earnings | Amount     | Percent of Pretax Earnings |
| United States federal tax statutory rate                                   | \$ (12,801) | 34.0%                      | \$ (9,642) | 34.0%                      |
| State taxes (net of deferred benefit)                                      | (786)       | 2.0%                       | (662)      | 2.3%                       |
| Non-deductible expenses  | 253         | (0.7)%                     | 1,556      | (5.5)%                     |
| Research & Development Credits   | (1,532)     | 4.1%                       |            | 0.0%                       |
| Change in unrecognized tax benefits  | 606         | (1.6)%                     |            | 0.0%                       |
| Change in valuation allowance  | 13,868      | (36.8)%                    | 20,733     | (73.1)%                    |
| Adjustment for valuation allowance recorded as part of purchase accounting |             | 0.0%                       | (11,785)   | 41.6%                      |
| Other, net   | 392         | (1.0)%                     | (200)      | 0.7%                       |
| Provision for income taxes   | \$          | 0.0%                       | \$         | 0.0%                       |

## 12. Related-Person Transactions

Synecor, LLC and its shareholders and officers collectively owned approximately 9% and 12% of the Company's common stock at December 31, 2014 and 2013, respectively. Various research and development services were purchased from Synecor LLC and its wholly owned subsidiary Synchrony Labs LLC and totaled approximately \$66,000 and \$90,000 for the years ended December 31, 2014 and 2013, respectively.

The Company's director, Dr. Hsiao, and a former director, Dr. Frost, are significant stockholders and/or directors of Non-Invasive Monitoring Systems, Inc. ( NIMS ), a publicly-traded medical device company, Tiger X Medical, Inc. ( Tiger X ) (formerly known as Cardo Medical, Inc.), a publicly-traded medical device company, and Tiger Media, Inc. ( Tiger Media ) (formerly known as SearchMedia Holdings Limited), a publicly-traded media company operating primarily in China. Director Richard Pfenniger is also a shareholder of NIMS. The Company's Chief Legal Officer serves under a Board-approved cost sharing arrangement as Corporate Counsel of Tiger Media and as the Chief Legal Officer of each of NIMS and Tiger X. Additionally, the Company's former Chief Financial Officer, until October 2, 2013, also served as the Chief Financial Officer and supervised the accounting staff of NIMS under a Board-approved cost sharing arrangement whereby the salaries of the accounting staffs of the companies are shared. The Company has recorded reductions to general and administrative expenses for the years ended December 31, 2014 and 2013 of approximately \$125,000 and \$55,000, respectively, to account for the sharing of accounting and legal administrative costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X and TigerMedia were approximately \$24,000 and \$14,000 as of December 31, 2014 and 2013, respectively, and are included in other current assets.

SafeStitch entered into a month to month lease for office space in Miami, Florida with a company controlled by Dr. Frost. The Company recorded approximately \$89,000 and \$48,000 of rent expense related to the Miami lease for the years ended December 31, 2014 and 2013, respectively. The Company terminated the SafeStitch lease effective August 15, 2014.

### 13. Stock-Based Compensation

The Company's stock-based compensation plans include the TransEnterix, Inc. 2007 Incentive Compensation Plan, previously named the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan (the 2007 Plan), as well as options outstanding under the TransEnterix, Inc. Stock Option Plan (the 2006 Plan). As part of the Merger, options outstanding, whether vested or unvested, under the 2006 Plan were adjusted by the Exchange Ratio of 1.1533, and assumed by the Company concurrent with the closing of the Merger.

The 2007 Plan was approved by the majority of the SafeStitch's stockholders on November 13, 2007. The 2007 Plan was amended on June 19, 2012 to increase the number of shares of common stock available for issuance to 1,000,000 and was amended on October 29, 2013 to (a) increase the number of shares of common stock authorized for issuance under the 2007 Plan from 1,000,000 shares of common stock to 4,940,000 shares of common stock, (b) increase the per-person award limitations for options or stock appreciation rights from 200,000 to 1,000,000 shares and for restricted stock, deferred stock, performance shares and/or other stock-based awards from 100,000 to 500,000 shares, and (c) change the name of the 2007 Plan to reflect the change to the TransEnterix, Inc. 2007 Incentive Compensation Plan. Under the 2007 Plan, which is administered by the Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock and/or deferred stock to employees, officers, directors, consultants and vendors. The exercise price of stock options or stock appreciation rights may not be less than the fair market value of the Company's shares at the date of grant. Additionally, no stock options or stock appreciation rights granted under the 2007 Plan may have a term exceeding ten years.

The 2006 Plan was adopted in September 2006 and provided for the granting of up to 80,000 stock options to employees, directors, and consultants. Under the 2006 Plan, both employees and non-employees were eligible for such stock options. In 2009, the 2006 Plan was amended to increase the total options pool to 1,110,053. In 2011, the 2006 Plan was amended to increase the total options pool to 3,378,189. The Board of Directors had the authority to administer the plan and determine, among other things, the exercise price, term and dates of the exercise of all options at their grant date. Under the 2006 Plan, options become vested generally over four years, and expire not more than 10 years after the date of grant. As part of the Merger, options outstanding under the 2006 Plan were adjusted by the Conversion Ratio, and remain in existence as options in the combined entity.

During the years ended December 31, 2014 and 2013, the Company recognized \$1,840,000 and \$941,000, respectively, of stock-based compensation expense, including stock options and restricted stock units. During 2014, the Company granted options with performance-based features. As of December 31, 2014, the Company determined that achievement of the pre-defined corporate performance goals was not probable and no expense was recognized during the year.

The Company recognizes as expense, the grant-date fair value of stock options and other stock based compensation issued to employees and non-employee directors over the requisite service periods, which are typically the vesting periods. The Company uses the Black-Scholes-Merton model to estimate the fair value of its stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies. The expected term of options granted by the Company has been determined based upon the simplified method, because the Company does not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate





is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero. The Company estimates forfeitures based on the historical experience of the Company and adjusts the estimated forfeiture rate based upon actual experience.

The fair value of options granted were estimated using the Black-Scholes-Merton option pricing model based on the assumptions in the table below:

| <i>Year ended December 31,</i> | 2014          | 2013          |
|--------------------------------|---------------|---------------|
| Expected dividend yield        | 0%            | 0%            |
| Expected volatility            | 46%-63%       | 62%-63%       |
| Risk-free interest rate        | 1.60% - 2.30% | 1.64% - 1.98% |
| Expected life (in years)       | 5.2 7.0       | 5.7 6.1       |

The Company is also required to estimate the fair value of the common stock underlying the stock-based awards when performing the fair value calculations with the Black-Scholes-Merton option-pricing model. The fair value of the common stock underlying the stock-based awards for the common stock before the Company was public was estimated on each grant date by the Board of Directors, with input from management. The Board of Directors is comprised of a majority of non-employee directors with significant experience in the medical device industry. Given the absence of a public trading market of the Company's common stock prior to the Merger, and in accordance with the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, the Board of Directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the common stock, including among other things, the rights, preferences and privileges of the redeemable convertible preferred stock, business performance, present value of future cash flows, likelihood of achieving a liquidity event, illiquidity of the Company's capital stock, management experience, stage of development, industry information and macroeconomic conditions. In addition, the Company's Board of Directors utilized independent valuations performed by an unrelated third-party specialist to assist with the valuation of the common stock; however, the Company and the Board of Directors have assumed full responsibility for the estimates. The Board of Directors utilized the fair values of the common stock derived in the third-party valuations to set the exercise price for options granted prior to the Merger in 2013.

The following table summarizes the Company's stock option activity, including grants to non-employees, for the years ended December 31, 2014 and 2013:

|   | Number of<br>Shares | Weighted-<br>Average<br>Exercise Price | Weighted-<br>Average<br>Remaining<br>Contractual<br>Term (Years) |
|---|---------------------|--|--|
| Options outstanding at December 31, 2012          | 2,584,554           | \$ 0.40                                | 8.70   |
| Options assumed through merger with<br>SafeStitch | 709,550             | 3.75                                   |  |
| Granted   | 603,139             | 2.20                                   |  |
| Forfeited   | (6,129)             | 0.40                                   |  |
| Exercised   | (68,227)            | 0.80                                   |  |
| Options outstanding at December 31, 2013          | 3,822,887           | \$ 1.30                                | 7.95   |

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|  |           |         |      |  |
|--|-----------|---------|------|--|
| Granted                                  | 2,422,309 | 5.40    |      |  |
| Forfeited                                | (670,065) | 3.95    |      |  |
| Exercised                                | (151,390) | 0.49    |      |  |
| Options outstanding at December 31, 2014 | 5,423,741 | \$ 2.82 | 7.79 |  |

The following table summarizes information about stock options outstanding at December 31, 2014:

|   | Number of<br>Shares | Weighted-<br>Average<br>Exercise Price | Weighted-<br>Average<br>Remaining<br>Contractual<br>Term (Years) |
|---|---------------------|--|--|
| Exercisable at December 31, 2014                | 2,721,164           | \$ 1.47                                | 6.65   |
| Vested or expected to vest at December 31, 2014 | 4,864,038           | \$ 2.38                                | 7.63   |

The aggregate intrinsic value of stock options outstanding, exercisable, and vested or expected to vest at December 31, 2014 was approximately \$6.2 million, \$4.8 million, and \$6.2 million, respectively. This amount is before applicable income taxes and represents the closing market price of the Company's common stock at December 31, 2014 less the grant price, multiplied by the number of stock options that had a grant price that is less than the closing market price. This amount represents the amount that would have been received by the optionees had these stock options been exercised on that date.

The following table summarizes the unvested stock option activity:

|   | Number of Shares | Weighted-Average<br>Fair Value |
|---|------------------|--------------------------------|
| Unvested options at December 31, 2012                   | 1,707,536        | \$ 0.40                        |
| Unvested options assumed through merger with SafeStitch | 223,200          | 2.45                           |
| Granted   | 603,139          | 0.95                           |
| Vested  | (711,818)        | 1.25                           |
| Forfeited   | (5,490)          | 0.20                           |
| Unvested options at December 31, 2013                   | 1,816,566        | \$ 1.10                        |
| Granted   | 2,422,309        | 2.87                           |
| Vested  | (993,888)        | 1.04                           |
| Forfeited   | (542,410)        | 2.25                           |
| Unvested options at December 31, 2014                   | 2,702,577        | \$ 2.33                        |

The Company granted 2,422,309 and 603,139 options to employees and non-employees during the years ended December 31, 2014 and 2013, respectively, with a weighted-average grant date fair value of \$2.87 and \$0.95, respectively. The total intrinsic value of options exercised during 2014 and 2013 was approximately \$996,000 and \$348,000, respectively.

The total fair value of options vested during 2014 and 2013 was approximately \$1,054,000 and \$880,000, respectively. As of December 31, 2014, the Company had future employee stock-based compensation expense of approximately \$3,818,000 related to unvested share awards, which is expected to be recognized over an estimated weighted-average period of 2.9 years.

#### **14. Restricted Stock Units**

In 2013, the Company issued Restricted Stock Units ( RSUs ) to certain employees which vest over three years. By their terms, the RSUs become immediately vested upon the earlier of (i) a change of control and (ii) defined vesting dates, subject to the continuous service with the Company at the applicable vesting event. When vested, the RSUs represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The fair value of each RSU is estimated based upon the closing price of the Company's common stock on the grant date. Share-based compensation expense related to RSUs and awards is recognized over the requisite service period as adjusted for estimated forfeitures.

The following is a summary of the RSU activity for the years ended December 31, 2014 and 2013:

|                             | Number of<br>Restricted<br>Stock Units<br>Outstanding | Weighted<br>Average<br>Grant<br>Date Fair<br>Value |
|-----------------------------|---|--|
| Unvested, December 31, 2012 |   |  |
| Granted                     | 210,000   | \$ 7.19  |
| Vested                      |   |  |
| Unvested, December 31, 2013 | 210,000   | \$ 7.19  |
| Granted                     |   | \$   |
| Vested                      | 70,000  |  |
| Unvested, December 31, 2014 | 140,000   | \$ 7.19  |

As of December 31, 2014 and 2013, the Company recorded approximately \$503,000 and \$121,000, respectively, in compensation expense for the RSUs. As of December 31, 2014, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$0.9 million, which is expected to be recognized over a weighted average period of approximately 1.75 years. The weighted average grant date fair value of the RSUs granted in 2013 was \$7.19. No restricted stock units were granted in 2014.

## 15. Warrants

On March 22, 2013, SafeStitch entered into a stock purchase agreement with approximately 17 investors (the 2013 PIPE Investors ) pursuant to which the 2013 PIPE Investors purchased an aggregate of approximately 2,420,000 shares of common stock at a price of \$1.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of warrants to purchase approximately 1,209,600 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$1.65 per share and five year expiration. Among the 2013 PIPE Investors purchasing shares were related parties who purchased 1.28 million shares and received 640,000 warrants. There were approximately 1.2 million warrants outstanding that were assumed as of the Merger. During the years ended December 31, 2014 and 2013, 10,000 and 54,000, respectively of these warrants were exercised.

On January 17, 2012, TransEnterix Surgical entered into the Original Loan Agreement (the Original Loan Agreement ) with Silicon Valley Bank and Oxford Finance LLC. (collectively, the Lenders ). Pursuant to such agreement, TransEnterix Surgical issued preferred stock warrants to the Lenders on January 17, 2012 and December 21, 2012, respectively, to purchase shares of TransEnterix Surgical preferred stock. The preferred stock warrants expire 10 years from the issue date. The preferred stock warrants were remeasured immediately prior to the Merger. As a result of the remeasurement, the Company recorded approximately \$1.8 million of other expense in the accompanying 2013 consolidated statement of operations and other comprehensive income (loss). As of the Merger, the preferred stock warrants converted to common stock warrants, adjusted based on the Exchange Ratio of 1.1533, and the preferred stock warrant liability was reclassified to additional paid-in capital. These warrants are exercisable for an aggregate of approximately 279,588 shares of common stock, with an exercise price of \$1.45. During the year ended December 31, 2013, 139,794 of these warrants were exercised in a cashless transaction for 112,766 shares of common stock. None of these warrants were exercised during the year ended December 31, 2014.

On September 26, 2014, the Company entered into an amended and restated loan and security agreement (the Amended and Restated Loan Agreement ) with the Lenders. In connection with the Amended and Restated Loan Agreement and the first tranche borrowings, the Company issued 38,325 common stock warrants to the Lenders to purchase shares of the Company's common stock, with an exercise price of \$4.015 per share. Additional common stock warrants will be issued if additional tranche Term Loans are made under the Amended and Restated Loan Agreement. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and will be amortized using the effective interest method from issuance to the maturity of the term loans. None of these warrants were exercised during the year ended December 31, 2014.

|  | Number of Warrants | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Weighted Average Fair Value |
|--|--------------------|---------------------------------|--|-----------------------------|
| Outstanding at December 31, 2012           | 279,588            | \$ 1.45                         | 9.1  | \$ 0.45                     |
| Granted                                    |                    |                                 |  |                             |
| Warrants assumed in merger with SafeStitch | 1,199,600          | 1.65                            | 4.3  | 1.15                        |
| Exercised                                  | (193,794)          | 1.45                            |  | 5.25                        |
| Expired/cancelled                          |                    |                                 |  |                             |
| Outstanding at December 31, 2013           | 1,285,394          | \$ 1.45                         | 4.7  | \$ 1.75                     |
| Granted                                    | 38,325             | 4.02                            | 6.7  | 1.41                        |
| Exercised                                  | (10,000)           | 1.65                            |  |                             |
| Outstanding at December 31, 2014           | 1,313,719          | \$ 1.70                         | 3.9  | \$ 1.75                     |

The aggregate intrinsic value of the common stock warrants in the above table was \$1.6 million and \$8.7 million at December 31, 2014 and 2013, respectively. The aggregate intrinsic value is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the estimated fair market value of the applicable stock as of the respective dates.

## 16. Notes Payable

On January 17, 2012, TransEnterix Surgical entered into a loan and security agreement with Silicon Valley Bank and Oxford Finance LLC. The terms of the Original Loan Agreement provided for two term loans in aggregate of \$10,000,000 comprised of a \$4,000,000 term loan and a \$6,000,000 term loan. In connection with the Merger, the Company assumed and became the borrower under TransEnterix Surgical's Original Loan Agreement, and agreed to amendments to the Original Loan Agreement, dated as of September 3, 2013 and October 31, 2013, respectively. The Original Loan Agreement had a maturity date of January 1, 2016 and a fixed interest rate of 8.75%. As of September 26, 2014, the outstanding principal amount of the Original Loan Agreement was \$5,604,000.

On September 26, 2014, the Company entered into the Amended and Restated Loan Agreement with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders have agreed to make certain term loans (the "Term Loans") in an aggregate principal amount of up to \$25,000,000. The first tranche increased the Company's borrowings at September 26, 2014 from \$5,604,000 to \$10,000,000. Two additional tranches are to be made available as follows. The second tranche of \$5,000,000 will be available at any time prior to one year after the closing date when the Company files a 510(k) application for its SurgiBot System, and completes an offering of its equity securities at or above \$35 million. The third tranche of \$10,000,000, will be made available to the Company at any time prior to two years after the closing date upon recognition of at least \$10,000,000 of trailing six-month revenues from the SurgiBot System and SurgiBot-related products. The Company is entitled to make interest-only payments for 12 months from the closing date, which interest-only period is extended to 18 months if the Company receives 510(k) clearance for its SurgiBot System at any time before October 31, 2015. The maturity date of the Term Loans is April 1, 2018 without the interest-only extension and October 1, 2018 with the interest-only extension.





As of December 31, 2014 future principal payments under the Company's notes payable agreements are as follows:

Years ending December 31,

(In thousands)

|              |                  |
|--------------|------------------|
| 2015         | \$ 610           |
| 2016         | 3,824            |
| 2017         | 4,122            |
| 2018         | 1,444            |
| <b>Total</b> | <b>\$ 10,000</b> |

The Term Loans bear interest at a fixed rate equal to 7.50% per annum, subject to adjustment at funding for subsequent tranches on an increase in LIBOR above a designated rate. The Term Loans will be required to be prepaid if the Term Loans are accelerated following an event of default. In addition, the Company is permitted to prepay the Term Loans in full at any time upon 10 days' written notice to the Lenders. Upon the earliest to occur of the maturity date, acceleration of the term loans, or prepayment of Term Loans, the Company is required to make a final payment equal to 5.45% of the original principal amount of each Term Loan without the interest-only extension or 6.75% with the interest-only extension (the Final Payment Fee). Any prepayment, whether mandatory or voluntary, must include the Final Payment Fee, interest at the default rate (which is the rate otherwise applicable plus 5%) with respect to any amounts past due, and the Lenders' expenses and all other obligations that are due and payable to the Lenders.

In connection with the entry into the Amended and Restated Loan Agreement, the Company became obligated to make a payment equal to the accrued portion of the 3.33% final payment fee due under the Original Loan Agreement plus a facility fee payment of \$75,000. In addition, in connection with the first tranche borrowings, the Company issued warrants to the Lenders to purchase shares of the Company's common stock. Additional warrants will be issued if additional tranche Term Loans are made under the Amended and Restated Loan Agreement. The warrants expire seven years from their respective issue date.

The Amended and Restated Loan Agreement is secured by a security interest in all assets of the Company and its current and future subsidiaries, including a security interest in intellectual property proceeds, but excluding a current security interest in intellectual property. The Amended and Restated Loan Agreement contains customary representations (tested on a continual basis) and covenants that, subject to exceptions, restrict the Company's ability to do the following things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business.

In accordance with ASC 470-50 *Debt Modifications and Extinguishments*, it was determined that the debt refinancing was considered to be a debt modification. Accordingly, the Company recorded approximately \$129,000 of debt discount, consisting of the \$75,000 facility fee and the relative fair value of warrants on the issue date of \$54,000. Additionally, approximately \$30,000 of legal fees were recorded as deferred financing costs. The debt discount and deferred financing costs will be amortized over the life of the new debt agreement using the effective interest method into Interest expense, net.



In conjunction with the Original Loan Agreement, TransEnterix Surgical issued the Lenders warrants to purchase 1,397,939 shares of the TransEnterix Surgical's Series B-1 Convertible Preferred Stock. The warrants were issued on January 17, 2012 and December 12, 2012 with an initial exercise price of \$0.29 per share and expire on January 16, 2022. The warrants were recorded at fair value as a liability on the Company's balance sheet on the date of issuance and are revalued as of each balance sheet date. The warrants converted to common stock warrants on the Merger date, adjusted based on the Exchange Ratio of 1.1533, and the preferred stock warrant liability was reclassified to additional paid-in capital (see Note 15 Warrants).

## 17. Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options and warrants and conversion of preferred stock. In computing diluted net loss per share for the years ended December 31, 2014 and 2013, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants and conversion of preferred stock would be anti-dilutive.

Potential common shares not included in calculating diluted net loss per share are as follows:

|                                  | <b>December 31,</b> |                  |
|----------------------------------|---------------------|------------------|
|                                  | <b>2014</b>         | <b>2013</b>      |
| Stock options                    | 5,423,741           | 3,822,887        |
| Stock warrants                   | 1,313,719           | 1,285,394        |
| Nonvested restricted stock units | 140,000             | 210,000          |
| <b>Total</b>                     | <b>6,877,460</b>    | <b>5,318,281</b> |

## 18. Public Offering of Common Stock

On April 14, 2014, the Company sold 12,500,000 shares of common stock at a public offering price of \$4.00 per share for aggregate gross proceeds of \$50.0 million in an underwritten firm commitment public offering. Certain of the Company's existing stockholders that are affiliated with certain of the Company's directors purchased \$10.0 million of common stock in the public offering. The closing of the public offering occurred on April 21, 2014. The Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of Common Stock to cover over-allotments. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of \$4.00 per share for aggregate additional gross proceeds of \$6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were \$52.4 million, net of issuance costs of \$4.0 million. The common stock was offered and sold pursuant to the Shelf Registration Statement (the April 2014 Shelf Registration Statement), which was declared effective on April 2, 2014. The April 2014 Shelf Registration Statement allowed the Company to raise up to \$100.0 million through the sale of debt securities, common stock, preferred stock, warrants, or any combination thereof.

## 19. Closing of Merger and Financing Transaction

Pursuant to an Agreement and Plan of Merger dated August 13, 2013, as amended by a First Amendment dated August 30, 2013 (collectively, the Merger Agreement), on September 3, 2013, the Company consummated the Merger in which a wholly owned subsidiary of SafeStitch merged with TransEnterix Surgical. Under the terms of the Merger Agreement, TransEnterix Surgical remained as the surviving corporation and as a wholly owned subsidiary of SafeStitch.

Pursuant to the Merger Agreement, each share of TransEnterix Surgical's capital stock issued and outstanding immediately preceding the Merger was converted into the right to receive 1.1533 shares of the Company's common stock, par value \$0.001 per share, other than those shares of TransEnterix Surgical's common stock held by non-accredited investors, which shares were instead converted into the right to receive an amount in cash per share of SafeStitch common stock equal to \$1.08, without interest, which was the volume-weighted average price of a share of common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one business day prior to the effective date of the Merger). Upon the closing of the Merger, and in accordance with the terms of the Merger Agreement, the Company issued an aggregate of 21,109,949 shares of the Company's common stock as Merger consideration and paid \$293,000 to unaccredited investors in lieu of common stock. Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, the Company assumed all of TransEnterix Surgical's options, whether vested or unvested, and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

During July 2013, TransEnterix Surgical issued promissory notes (the Bridge Notes) to related parties consisting of existing investors of TransEnterix Surgical, in the aggregate principal amount of \$2.0 million, as contemplated by the Merger Agreement. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the loan evidenced by the Original Loan Agreement. The Bridge Notes were converted into Series B Preferred Stock of the Company at the effective time of the Merger.

Concurrent with the closing of the Merger, and in accordance with the terms of the Purchase Agreement, the Company consummated a private placement (the Private Placement) transaction in which it issued and sold shares of its Series B Convertible Preferred Stock, par value \$0.01 per share (the Series B Preferred Stock) to provide funding to support the Company's operations following the Merger. The Private Placement was done pursuant to a Securities Purchase Agreement (the Purchase Agreement) with accredited investors (the Investors), the majority of which were considered related parties as existing investors in SafeStitch or TransEnterix Surgical. Under the Purchase Agreement, the Company issued 7,544,704.4 shares of Series B Preferred Stock, each share of which is convertible, subject to certain conditions, into two shares of common stock, for a purchase price of \$4.00 per share of Series B Preferred Stock, which was paid in cash, cancellation of certain Bridge Notes of TransEnterix Surgical or a combination thereof. Pursuant to the Purchase Agreement, the Company issued and sold an additional 25,000 shares of Series B Preferred Stock within the period provided in the Purchase Agreement resulting in gross proceeds to the Company of approximately \$100,000. Each share of Series B Preferred Stock was converted into two shares of our common stock, par value \$0.001 per share, on December 6, 2013.

In connection with the Merger Agreement and the September 2013 private placement, certain of SafeStitch's and TransEnterix Surgical's former stockholders, comprising approximately 93% of our stock on the effective date of the Merger, entered into Lock-up and Voting Agreements, pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company's securities held by them (collectively, Covered Securities) for one year following the September 3, 2013 closing date (the Closing Date). The Lock-up and Voting Agreements provide that such persons may sell, transfer or convey: (i) up to 50% of their respective Covered Securities during the period commencing on the one-year anniversary of the Closing Date and ending on the eighteen-month anniversary of the Closing Date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on the eighteen-month anniversary of the Closing Date and ending on the two-year anniversary of the Closing Date. The restrictions on transfer contained in the Lock-up and Voting

Agreements cease to apply to the Covered Securities following the second anniversary of the Closing Date.

At the closing of the Merger, each outstanding share of capital stock of TransEnterix Surgical was cancelled and extinguished and converted into the right to receive a portion of the Merger consideration in accordance with the Merger Agreement. The Bridge Notes were terminated at the closing of the Merger, and the holders of such Bridge Notes received Merger consideration in accordance with the Merger Agreement.

The Merger effectuated on September 3, 2013 qualified as a tax-free reorganization under Section 368 of the Internal Revenue Code. As a result of the Merger, the utilization of certain tax attributes of the Company may be limited in future periods under the rules prescribed under Section 382 of the Internal Revenue Code.

The Company's assets and liabilities are presented at their preliminary estimated fair values, with the excess of the purchase price over the sum of these fair values presented as goodwill.

The following table summarizes the purchase price (in thousands):

|   |           |
|---|-----------|
| Common shares outstanding at the date of Merger | 12,350    |
| Closing price per share                         | \$ 7.60   |
|   | \$ 93,858 |
| Cash consideration                              | 293       |
| Total purchase price                            | \$ 94,151 |

The purchase price was allocated to the net assets acquired utilizing the methodology prescribed in ASC 805. The Company recorded goodwill of \$93.8 million after recording net assets acquired at fair value as presented in the following table.

The following table summarizes the allocation of the purchase price to the net assets acquired (in thousands):

|  |           |
|--|-----------|
| Cash and cash equivalents              | \$ 597    |
| Accounts receivable                    | 54        |
| Inventory                              | 50        |
| Other current assets                   | 53        |
| Property and equipment                 | 185       |
| Other long-term asset                  | 2         |
| Intangible assets                      | 10        |
| Goodwill                               | 93,842    |
| Total assets acquired                  | \$ 94,793 |
| Accounts payable and other liabilities | 642       |
| Total purchase price                   | \$ 94,151 |

Following the announcement of the Merger, the SafeStitch stock price increased prior to the Merger closing date of September 3, 2013, generating additional goodwill. There may be impairment in the future and the impairment of goodwill will be assessed annually.



The Company allocated \$10,000 of the purchase price to identifiable intangible assets of trade names that met the separability and contractual legal criterion of ASC 805. The trade names will be amortized using the straight-line method over 5 years.

The results of operations of SafeStitch have been included in the Company's consolidated financial statements from the date of the Merger. The following pro forma results of operations assume the acquisition of SafeStitch as of the beginning of 2012. The pro forma results for the year ended December 31, 2013 presented below reflect our historical data and the historical data of the SafeStitch business. The pro forma results of operations presented below may not be indicative of the results the Company would have achieved had the Company completed the Merger on January 1, 2013, or that the Company may achieve in the future.

|                        | Year ended December 31,          |           |
|------------------------|----------------------------------|-----------|
|                        | 2013                             | 2012      |
|                        | (In thousands, except per share) |           |
| Revenues               | \$ 1,456                         | \$ 2,150  |
| Net loss               | (30,420)                         | (22,149)  |
| Earnings per share (1) | \$ (0.85)                        | \$ (0.65) |

(1) Adjusted for 1:5 reverse stock split on March 31, 2014.

## 20. Stockholders' Equity

### TransEnterix Surgical

#### Common and Preferred Stock

On July 12, 2006, TransEnterix Surgical had 11,533,000 shares of common stock authorized. On December 27, 2007, TransEnterix Surgical authorized an additional 2,883,250 shares of common stock for a total of 14,416,250 authorized shares. On October 2, 2009, TransEnterix Surgical authorized an additional 24,219,300 shares of common stock for a total of 38,635,550 authorized shares. On November 30, 2011 TransEnterix Surgical authorized an additional 88,227,450 shares of common stock for a total of 126,863,000 authorized shares. In January 2012 TransEnterix Surgical authorized an additional 3,459,900 shares of common stock for a total of 130,322,900 authorized shares. As of December 31, 2012, 5,391,095 shares of common stock were issued at \$ 0.001 par value per share and were outstanding. Each holder of common stock was entitled to one vote for each share held thereof. In connection with the Merger, the TransEnterix Surgical common stock was converted to common stock of the Company.

On December 27, 2007, TransEnterix Surgical had 6,500,000 shares of preferred stock authorized. On October 2, 2009, TransEnterix Surgical authorized an additional 15,234,402 shares of preferred stock for a total of 21,734,402 authorized shares. On November 30, 2011, TransEnterix Surgical authorized an additional 40,958,843 shares of preferred stock for a total of 62,693,245 authorized shares. In January 2012, TransEnterix Surgical authorized an additional 3,000,000 shares of preferred stock for a total of 65,693,245 shares. In connection with the Merger, the TransEnterix Surgical preferred stock was converted to common stock of the Company.



On December 31, 2007, TransEnterix Surgical completed the issuance of 3,143,749 shares of Series A Redeemable Convertible ( Series A ) Preferred Stock at \$ 3.49 per preferred share. In March 2008, TransEnterix Surgical completed a second closing of Preferred Stock and had 3,373,882 shares of Series A Preferred Stock at \$3.49 per preferred share issued and outstanding as of December 31, 2008. On February 18, 2009, TransEnterix Surgical completed the final closing of Series A Preferred Stock and had 5,734,402 shares of Preferred Stock at \$3.49 per preferred share issued and outstanding as of December 31, 2011. During 2012, 38,141 shares of Series A Preferred Stock were converted to common stock. At December 31, 2012 TransEnterix Surgical had 5,696,261 shares of Series A Preferred Stock at \$3.49 per preferred share issued and outstanding. In connection with the Merger, the TransEnterix Surgical Series A Preferred Stock was converted to common stock of the Company.

On October 6, 2009, TransEnterix Surgical completed the issuance of 11,504,298 shares of Series B Redeemable Convertible ( Series B ) Preferred Stock at \$ 3.49 per preferred share. On November 30, 2011, TransEnterix Surgical completed the closing of Series B-1 Redeemable Convertible ( Series B-1 ) Preferred Stock and had 45,121,691 shares of Preferred Stock at \$0.33 per preferred share issued and outstanding as of December 31, 2011. In January 2012, TransEnterix Surgical completed a second closing of Series B-1 Preferred Stock. During 2012, 49,998 shares of TransEnterix Surgical's Series B Preferred Stock were converted to common stock. TransEnterix Surgical had 45,998,220 shares of Series B-1 Preferred Stock at \$ 0.33 per share issued and outstanding at December 31, 2012. In connection with the Merger, the TransEnterix Surgical Series B-1 Preferred Stock was converted to common stock of the Company.

### **Voting Rights**

The holders of TransEnterix Surgical common stock and preferred stock shall vote together and not as separate classes, except as otherwise provided by law or agreed to contractually. Each holder of preferred stock was entitled to the number of votes equal to the number of shares of common stock, into which the shares of preferred stock held by such holder could be converted immediately after the close of business on the record date fixed for a stockholders meeting or the effective date of a written consent. The holders of shares of preferred stock were entitled to vote on all matters on which the common stock was entitled to vote and act by written consent in the same manner as the common stock.

Holders of preferred stock were entitled to notice of any stockholders meeting in accordance with the bylaws of TransEnterix Surgical. Fractional votes were not, however, permitted and any fractional voting rights were disregarded.

### **Dividends**

In any calendar year, the holders of outstanding shares of preferred stock were entitled to receive dividends, when, as and if declared by the Board of Directors, out of any assets at the time legally available therefore, at the dividends rate specified for such shares of preferred stock payable in preference and priority to any declaration or payment of any distribution on Common stock of TransEnterix Surgical in such calendar year. No distributions were to be made with respect to the common stock until all declared dividends on preferred stock had been paid or set aside for payment to the preferred stock holders. Payments of any dividends to the holders of the Preferred Stock were to be made on a pro rata basis. The right to receive dividends on shares of preferred stock were not to be cumulative, and no right to such dividends were to accrue to holders of preferred stock by reason of the fact that dividends on said shares were not paid or declared in any calendar year. No dividends were declared during the years ended December 31, 2014 and 2013.

## Liquidation

In the event of a liquidation, dissolution, or winding up of TransEnterix Surgical, either voluntary or involuntary, the holders of Series B-1 Preferred Stock and Series B Preferred Stock were entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of TransEnterix Surgical to the holders of Series A Preferred Stock and the holders of common stock by reason of their ownership of such stock, an amount per share for each share of preferred stock held by them equal to the sum of the liquidation preference for the Series B-1 Preferred Stock and the Series B Preferred Stock, respectively and (ii) all declared and unpaid dividends on such shares of preferred stock. If upon liquidation, the assets of TransEnterix Surgical were insufficient to permit the payments to such stock holders, then the entire assets of TransEnterix Surgical legally available for distributions were to be distributed with equal priority and pro rata among the holders of Series B-1 Preferred Stock and the Series B Preferred Stock in proportion to the full amounts to which they would otherwise be entitled.

After payment or setting aside for payment to the holders of Series B-1 Preferred Stock and Series B Preferred Stock, the holders of Series A Preferred Stock were entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of TransEnterix Surgical to the holders of common stock by reason of their ownership of such stock, an amount per share for each share of preferred stock held by them equal to the sum of the liquidation preference for the Series A Preferred Stock and (ii) all declared and unpaid dividends on such shares of preferred stock. If upon liquidation, the assets of TransEnterix Surgical are insufficient to permit the payments to such stock holders, then the assets of TransEnterix Surgical legally available for distributions to the holders of Series A Preferred Stock after payment of the full amount payable to the holders of Series B-1 Preferred Stock and Series B Preferred Stock were to be distributed with equal priority and pro rata among the holders of Series A Preferred Stock in proportion to the full amounts to which they would otherwise be entitled.

After the payment or setting aside for payment to the holders of preferred stock of the full amounts to holders of Preferred Series B-1, Preferred Series B, and Preferred Series A Stock, the remaining assets of TransEnterix Surgical legally available for distribution were to be distributed pro rata to the holders of the Series B-1 Preferred Stock, Series B Preferred Stock, and common stock of TransEnterix Surgical in proportion to the number of shares of common stock held by them, with the share of Series B-1 Preferred Stock and Series B Preferred Stock being treated for this purpose as if they had been converted to shares of common stock at the then applicable Conversion Rate, as defined in TransEnterix Surgical's Articles of Incorporation.

## Conversion

Each share of Preferred Stock was convertible, at the option of the holder, at any time after the date of issuance at the office of TransEnterix Surgical or any transfer agent for the preferred stock, into that number of fully paid nonassessable shares of common stock determined by dividing the original issue price for the relevant series of preferred stock by the conversion price for such shares in said series. The conversion price for the Preferred Stock Series A and B shall mean \$3.49, and Series B-1 shall mean \$0.33, and was subject to adjustment from time to time for recapitalizations. In connection with the Merger, the TransEnterix Surgical Series A, Series B and Series B-1 Preferred Stock was converted to common stock of the Company.

## Redemption

At the written request of any holder of preferred stock delivered to TransEnterix Surgical on or after the fifth anniversary of the date of the filing of the amended and restated Certificate of Incorporation (November 30, 2016), TransEnterix Surgical shall redeem up to 25% of the shares of preferred stock then held by such holder within 20 days after receiving such notification and up to another 25% of the shares of preferred stock then held by the holder on each of the first three anniversaries of such initial redemption request. The redemption price was equal to the original issuance price plus all declared but unpaid dividends.



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## Carrying Value

The preferred stock was initially recorded by TransEnterix Surgical at the total proceeds received upon issuance, less the issuance costs. The difference between the total proceeds and the total redemption value at the redemption date is charged first to paid-in capital, if any, and then to the accumulated deficit over the period from issuance until redemption first becomes available. The amount of accretion during each period is determined by using the effective interest rate method. Accretion amounted to approximately \$0 and \$40,000 for the years ended December 31, 2014 and 2013, respectively.

## The Company

In connection with the Merger, the Company entered into a securities purchase agreement with accredited investors pursuant to which the investors agreed to purchase an aggregate of 7,569,704.4 shares of the Company's Series B Convertible Preferred Stock for a purchase price of \$4.00 per share of Series B Preferred Stock, which was paid in cash, cancellation of certain indebtedness of TransEnterix Surgical or a combination thereof. Each share of Series B Preferred Stock was converted into ten shares of our common stock, par value \$0.001 per share, on December 6, 2013 amounting to 75,697,044 shares of common stock.

## **21. Agreement with Creighton University**

On May 26, 2006, SafeStitch entered into an exclusive license and development agreement (the "Creighton Agreement") with Creighton University ("Creighton"), granting the Company a worldwide exclusive (even as to the university) license, with rights to sublicense, to all the Company's product candidates and associated know-how based on Creighton technology, including the exclusive right to manufacture, use and sell the product candidates.

Pursuant to the Creighton Agreement, the Company is obligated to pay Creighton, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from the sale of any product licensed under the Creighton Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. Also pursuant to the Creighton Agreement, the Company agreed to invest, in the aggregate, at least \$2.5 million over 36 months, beginning May 26, 2006, towards development of any licensed product. This \$2.5 million investment obligation excluded the first \$150,000 of costs related to the prosecution of patents, which the Company invested outside of the Creighton Agreement. The Company is further obligated to pay to Creighton an amount equal to 20% of certain of the Company's research and development expenditures as reimbursement for the use of Creighton's facilities. Failure to comply with the payment obligations above will result in all rights in the licensed patents and know-how reverting back to Creighton. As of December 31, 2013, the Company had satisfied the \$2.5 million investment obligation and the facility reimbursement obligation described above.

Pursuant to the Creighton Agreement, SafeStitch is entitled to exercise its own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion and other commercial exploitation of any licensed products, provided that, if the Company has not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the Creighton Agreement or the date such technology is disclosed to and accepted by SafeStitch, then the licensed patent and associated know-how shall revert back to the university, with no rights retained by the Company, and the university will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless the Company purchases one or more one-year extensions. The Company is in compliance with these requirements.

**22. Commitments and Contingencies**

On November 2, 2009, TransEnterix Surgical entered into an operating lease for its corporate offices for a period of five years commencing in April 2010. On June 12, 2014, the Company entered into a lease amendment extending the term of the lease for a period of 3 years and 2 months commencing on May 1, 2015 and expiring on June 30, 2018, with an option to renew for an additional three years. On October 25, 2013, the Company entered into an operating lease for its warehouse for a period of four years and four months commencing in January 2014, with an option to renew for an additional six years. Rent expense was approximately \$424,000 and \$360,000 for the years ended December 31, 2014 and 2013, respectively. The Company's approximate future minimum payments for its operating lease obligations that have initial or remaining noncancelable terms in excess of one year are as follow:

Years ending December 31,

(In thousands)

|      |        |
|------|--------|
| 2015 | \$ 452 |
| 2016 | 592    |
| 2017 | 609    |
| 2018 | 373    |

|              |                 |
|--------------|-----------------|
| <b>Total</b> | <b>\$ 2,026</b> |
|--------------|-----------------|

In 2013, TransEnterix Surgical leased a manufacturing facility under a one-year lease from a third party. Rent expense under this lease was \$55,000 for the years ended December 31, 2013. SafeStitch leases various office space on a month to month basis. Rent expense under these leases was \$89,000 and \$55,000 for the years ended December 31, 2014 and 2013, respectively, including \$89,000 and \$48,000 to a company controlled by a shareholder for the years ended December 31, 2014 and 2013, respectively.

The Company is obligated to pay royalties to Creighton on the sales of products licensed from Creighton pursuant to an exclusive license and development agreement (see Note 21). The Company is also obligated under an agreement with Dr. Parviz Amid to pay a 1.5% royalty for the first three years and then a 4% royalty on the following seven years to Dr. Amid on the net sales of any product developed with Dr. Amid's assistance, including the AMID HFD, for a period of ten years from the first commercial sale of such product. No royalties were incurred during the years ended December 31, 2014 and 2013.

On February 13, 2014, TransEnterix Surgical, Inc., a wholly owned subsidiary of the Company, entered into a Robotic Development and Supply Agreement (the "Robotic Agreement") with Microline Surgical, Inc. ("Microline"). Under the Robotic Agreement, Microline is developing a flexible sealer product for exclusive use by the Company with the SurgiBot System in open, minimally invasive and laparoscopic surgery. Development of the contemplated products under the Robotic Agreement is ongoing. If such products are successfully developed and applicable regulatory approvals obtained, the Company will owe an aggregate of \$1,000,000 to Microline in milestone fees. Actual payment of such milestone fees is substantially uncertain and is dependent on product development activities. If the products are successfully developed and applicable regulatory approvals obtained, the Company is committed to product supply commitments set forth in the Robotic Agreement.

The Company has placed orders with various suppliers for the purchase of certain tooling, supplies and contract engineering and research services. Each of these orders has a duration or expected completion within the next twelve months.



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**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2014. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management's Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

For the year ended December 31, 2014, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, management (with the participation of our principal executive officer and principal financial officer) conducted an evaluation of the effectiveness of our internal control over financial reporting based on the original framework established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that, as of December 31, 2014, our internal control over financial reporting was effective.





### **Changes in Internal Controls Over Financial Reporting**

There were no changes in the Company's internal control over financial reporting during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

None.

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

##### Directors and Executive Officers

Our executive officers are elected by the Board of Directors (the Board), and serve for a term of one year, until their successors have been elected and qualified, or until their earlier resignation or removal by the Board. There are no family relationships among any of the directors and executive officers of the Company. Pursuant to the Agreement and Plan of Merger, dated as of August 13, 2013, by and among SafeStitch, Tweety Acquisition Corp. and TransEnterix Surgical, as amended (Merger Agreement), SafeStitch had the ability to appoint three members of our Board, and TransEnterix Surgical had the ability to appoint six members of our Board. Such appointment rights did not continue beyond the initial rights as set forth in the Merger Agreement. In accordance with our amended and restated certificate of incorporation, as amended, incumbent directors are elected to serve until our next annual meeting and until each director's successor is duly elected and qualified. No director or executive officer has been involved in any legal proceeding during the past ten years that is material to an evaluation of his or her ability or integrity.

The following table sets forth names, ages and positions with the Company for all directors and executive officers of the Company as of January 15, 2015:

|                                | Age | Position   | Director Since |
|--------------------------------|-----|--|----------------|
| <b>Directors</b>               |     |  |                |
| Dennis J. Dougherty            | 66  | Director   | 2013           |
| Jane H. Hsiao, Ph.D., MBA      | 67  | Director   | 2005           |
| William N. Kelley, M.D.        | 75  | Director   | 2015           |
| Aftab R. Kherani, M.D.         | 41  | Director   | 2013           |
| Paul A. LaViolette             | 57  | Director, Chairman of the Board                      | 2013           |
| David B. Milne                 | 52  | Director   | 2013           |
| Richard C. Pfenniger, Jr.      | 59  | Director   | 2005           |
| Todd M. Pope                   | 49  | Chief Executive Officer, President, Director         | 2013           |
| William N. Starling            | 61  | Director   | 2013           |
| <b>Other Executive Officer</b> |     |  |                |
| Joseph P. Slattery             | 49  | Executive Vice President and Chief Financial Officer |                |

##### Directors

The following information summarizes, for each of our directors, his or her principal occupations and other public company directorships for at least the last five years and information regarding the specific experiences, qualifications, attributes and skills of such director:

**Dennis J. Dougherty.** Mr. Dougherty founded and has been the Managing General Partner of Intersouth Partners since 1985. Mr. Dougherty holds primary responsibility for Intersouth's life science portfolio, which includes companies in biopharmaceuticals, medical technology and agribusiness, working with companies from founding

through public offering. Mr. Dougherty has served on the boards of directors of more than 40 companies, most of which were privately held. Mr. Dougherty is a founder of the North Carolina Council for Entrepreneurial Development and was a member of the Steering Committee for the Kauffman Fellows Program. He has served on the Board of Directors of the National Venture Capital Association and the Board of Trustees of Oklahoma City University. Mr. Dougherty was also an office managing partner for Touche Ross and Co. (now Deloitte & Touche). He holds a B.S. in Business from Oklahoma City University and completed postgraduate studies in accounting and finance at Duke University. The Board believes that Mr. Dougherty's deep experience in venture investment since his founding of Intersouth Partners, active work with biopharmaceuticals and medical technology companies, commitment to active participation with many entrepreneurial and start-up organizations, and his board service on many publicly held and privately owned companies position him to provide valuable insight and make substantial contributions to our Board.

**Jane H. Hsiao, Ph.D., MBA.** Dr. Hsiao served as Chairman of the Board from September 2007 until September 2013. Dr. Hsiao has served since May 2007 as Vice-Chairman and Chief Technical Officer of OPKO. Since October 2008, Dr. Hsiao has served as Chairman of the Board and, since February 2012, Interim CEO of medical device developer, Non-Invasive Monitoring Systems, Inc. (NIMS). Additionally, Dr. Hsiao serves as a director Neovasc, Inc., a company developing and marketing medical specialty vascular devices. Dr. Hsiao previously served as the Vice Chairman-Technical Affairs and Chief Technical Officer of IVAX, from 1995 until IVAX was acquired in January 2006 by Teva. Dr. Hsiao also served as Chairman, CEO and President of IVX Animal Health, IVAX's veterinary products subsidiary, from 1998 until 2006, and as IVAX's Chief Regulatory Officer from 1992 to 1995. Dr. Hsiao previously served on the board of directors of Prolor, Ivax Diagnostics, Inc. and Sorrento Therapeutics, Inc., a development stage biopharmaceutical company. Dr. Hsiao received her B.S. from National Taiwan University and her Ph.D. from the University of Illinois, Chicago. Dr. Hsiao's background in building and growing companies in the pharmaceutical and medical device industry, her strong technical expertise, as well as her senior management experience and extensive board service allow her to play an integral role as a member of our Board. Her broad experience in many biotechnology and life science companies gives her a keen understanding and appreciation of the many regulatory and developmental issues confronting medical device, pharmaceutical and biotechnology companies.

**William N. Kelley, M.D.** has served as a director of the Company since November 2014. He is currently Professor of Medicine at the School of Medicine of the University of Pennsylvania. He is also a director of GenVec, Inc., since June 2002. From 1989 to 2000, Dr. Kelley served as Executive Vice President of the University of Pennsylvania with responsibilities as Chief Executive Officer for the Medical Center, Dean of the School of Medicine, and the Robert G. Dunlop Professor of Medicine and Biochemistry and Biophysics. In the national leadership arena, Dr. Kelley has served as President of the American Society for Clinical Investigation, President of the American College of Rheumatology, Chair of the American Board of Internal Medicine, and Chair of the Residency Review Committee for Internal Medicine. Within the past five years, Dr. Kelley served on the board of directors of Merck & Co. Inc., Beckman Coulter, Inc., Advanced Biosurfaces, Inc. and Polymedix, Inc.

**Aftab R. Kherani, M.D.** Since September 2008, Dr. Kherani has served as an investment professional of Aisling Capital, where he is currently a Partner. Previously, Dr. Kherani was an Engagement Manager at McKinsey & Company, where he was a member of the Pharmaceutical, Medical Product and Private Equity practices. Prior to McKinsey, Dr. Kherani was a Chief Resident in Surgery at Duke University Medical Center, where he completed his residency in general surgery. He completed a two-year post-doctoral research fellowship at Columbia University, College of Physicians & Surgeons from 2001 to 2003. Dr. Kherani currently serves as a board observer at Syros Pharmaceuticals, Inc. and EarLens, Inc., both privately-held companies. Dr. Kherani received his M.D. from Duke, and his B.S. in Biology and A.B. in Economics from Duke. The Board believes that Dr. Kherani's qualifications, skills and attributes including his experience as a general surgeon, coupled with his strong investment background and healthcare consulting experience, position him to provide unique insights and be a valuable contributor to our Board.

**Paul A. LaViolette.** Mr. LaViolette has served as Chairman of our Board since September 2013. Mr. LaViolette is Managing Partner and Chief Operating Officer at SV Life Sciences (SVLS), a medical device value fund. He joined SVLS in 2009 and has over 33 years of global medical technology management experience. Prior to joining SVLS, Mr. LaViolette was most recently Chief Operating Officer at Boston Scientific Corporation (BSC), an \$8 billion medical device leader. During his 15 years at BSC, he served as COO, Group President, President-Cardiology and President-International. Mr. LaViolette integrated two dozen acquisitions and led extensive product development, operations and worldwide commercial organizations. Mr. LaViolette previously held marketing and general management positions at CR Bard, and various marketing roles at Kendall (Covidien). He currently serves on the boards of Thoratec Corporation, which is publicly held. Additionally, Mr. LaViolette serves on the boards of Axon Therapies, Cardiofocus, Inc., CardioKinetix, Inc., Cibiem, Inc., CSA Medical Inc., DC Devices Inc., Direct Flow Medical, Inc., Soffio Medical, Inc., ValenTx, Inc., Ximedica, each of which are privately-held, as well as the Medical Device Manufacturers Association. Mr. LaViolette received his B.A. in Psychology from Fairfield University and his MBA from Boston College. Mr. LaViolette's broad experience and many attributes qualify him to serve on our Board, and as the Chairman of our Board. Mr. LaViolette's vast medical device operating experience makes him knowledgeable in the areas of product launches, new product development, clinical and regulatory affairs, plant management, quality systems, international sales and marketing, acquisitions and integrations and the analysis of investment opportunities.

**David B. Milne.** Mr. Milne is a Managing Partner at SVLS. He joined SVLS in 2005 and has 25 years of experience in the healthcare industry having worked at several leading public and private medical technology companies. From 1999 until joining SVLS in 2005, he held the position of Vice President of Corporate Business Development at BSC and was responsible for over 50 transactions totaling nearly \$2 billion in acquisitions, equity investments and development partnerships. Mr. Milne currently sits on the board of AqueSys, Inc., Altura Medical, Inc., EBR Systems, Inc., Entellus Medical, Inc., ReShape Medical, Inc., and Spinal Kinetics, Inc. Previously Mr. Milne worked at Scimed Life Systems, Becton Dickinson and Parker Laboratories. He holds an MBA in Marketing/Finance from New York University and a BS in Biology from Rutgers University. The Board believes Mr. Milne brings his managerial, leadership and operational experience, particularly his acquisition, equity investment, licensing and collaboration experience to provide insights and substantial contributions to our Board.

**Richard C. Pfenniger, Jr.** Mr. Pfenniger served as the Interim CEO of Vein Clinics of America, Inc., a privately held company, from May 2014 through February 2015 and as the Interim CEO of IntegraMed America, Inc., a privately held company (IntegraMed), from January 2013 through June 2013. Previously, Mr. Pfenniger served as Chief Executive Officer and President of Continucare Corporation, a provider of physician services, from October 2003 until December 2011, and the Chairman of Continucare's board of directors from September 2002 until December 2011. Additionally, Mr. Pfenniger served as CEO and Vice Chairman of Whitman Education Group, Inc., a post-secondary education provider, from 1997 until 2003. From 1994 to 1997, Mr. Pfenniger served as Chief Operating Officer of IVAX Corporation, and from 1989 to 1994 he served as Senior Vice President-Legal Affairs and General Counsel of IVAX Corporation. Prior to that, Mr. Pfenniger was engaged in the private practice of law, and earlier in his career, Mr. Pfenniger worked as a C.P.A. with Price Waterhouse & Co. Mr. Pfenniger is a director of GP Strategies, Inc., a corporate education and training company, OPKO Health, Inc., and IntegraMed. Mr. Pfenniger received his B.B.A. from Florida Atlantic University and his J.D. from the University of Florida. As a result of Mr. Pfenniger's multi-faceted experience as a chief executive officer, chief operating officer and general counsel, he is able to provide valuable business, leadership and management advice to the Board in many critical areas. In addition, Mr. Pfenniger's knowledge of the healthcare business has given him insight into many aspects of our business. Mr. Pfenniger also brings financial expertise to the Board, including through his service as Chairman of our Audit Committee.

**Todd M. Pope.** Mr. Pope became our President and Chief Executive Officer on September 3, 2013 in connection with the consummation of the Merger. Prior to the Merger, he was the president and chief executive officer of TransEnterix Surgical from September 2008. Mr. Pope has spent more than 20 years working in key leadership positions within the medical device industry. Prior to joining TransEnterix Surgical, Mr. Pope served as worldwide president of Cordis, a multi-billion-dollar division within Johnson & Johnson's medical device business. Mr. Pope previously held a number of leadership positions within Johnson & Johnson and Boston Scientific Corporation. Mr. Pope received his bachelor's degree from University of North Carolina at Chapel Hill, and currently serves on the University's Kenan-Flagler Board of Visitors, and Educational Foundation Executive Board. The Board believes that Mr. Pope's more than 20 years leadership experience in the medical device industry, at both privately held and multi-national companies, and his knowledge of the industry, coupled with his deep understanding of our technologies, product candidates, market and history make him an essential contributor to our Board.

**William N. Starling.** William N. Starling is Managing Director of Synergy Life Science Partners, LP, a life science venture capital firm founded in 2006, and Chief Executive Officer and co-founder, in 2000, of Synecor, LLC, an incubator/accelerator for new medical device companies. As CEO of Synecor, Mr. Starling is a cofounder of BaroSense Inc., Bioerodible Vascular Solutions, Inc., InnerPulse, Inc., TransEnterix, Interventional Autonomics Corporation, NeuroTronik Limited, Aegis Surgical, Limited, and Artius Limited. Mr. Starling currently serves as President and CEO of Aegis Surgical and Atrius Limited, and as a board member of EBR Systems, Inc., iRhythm Technologies, and Novacor, Inc., all of which are privately-held. He began his career in the medical technology device industry at American Edwards Laboratories and subsequently was part of the founding management team and Director of Marketing for Advanced Cardiovascular Systems, Inc.; a cofounder, Vice President and board member of Ventritex, Inc.; and a cofounder and Chairman of the Board of Directors and President/CEO of Cardiac Pathways Corporation. Mr. Starling received his BSBA degree from the University of North Carolina at Chapel Hill and his MBA degree from the University of Southern California. The Board believes that Mr. Starling's experience in working with companies throughout their life cycle from start-up, through IPO to publicly traded, his extensive contributions to the medical device industry and his public company board experience make him a valuable contributor to our Board.

#### **Executive Officers (Non-Board Members)**

**Joseph P. Slattery.** Mr. Slattery has served as our Executive Vice President and Chief Financial Officer since October 2013. Previously, Mr. Slattery served as Executive Vice President and Chief Financial Officer of Baxano Surgical, Inc., a minimally invasive spine company, from April 2010 until September 2013. Mr. Slattery served as a member of the Baxano Surgical board of directors from November 2007 until April 2010 and resigned in connection with his appointment as an officer. From October 2006 through August 2007, Mr. Slattery served as Chief Financial Officer and Senior Vice President of Finance and Information Systems of Digene Corporation, a molecular diagnostics company that was acquired by Qiagen, N.V. in August 2007. Prior to being appointed Chief Financial Officer, he served as Senior Vice President, Finance and Information Systems, beginning in September 2002. Previously, he served as Vice President, Finance, from July 1999 to September 2002 and as Controller from February 1996 to July 2000. Mr. Slattery served on the board of directors of Micromet, Inc., a publicly-held biopharmaceutical company, which was acquired by Amgen in March 2012, and currently serves on the board of directors of CVRx, Inc., a privately-held medical device company, and Exosome Diagnostics, a privately-held molecular diagnostics company. Mr. Slattery received a B.S. degree in Accountancy from Bentley University and is a Certified Public Accountant.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Under section 16(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the Company's directors, executive officers and persons who own more than ten percent (10%) of our common stock are required to file with the Securities and Exchange Commission (the SEC) initial reports of ownership and reports of changes in ownership of the common stock and other equity securities of the Company. To the Company's knowledge, based solely on a review of copies of such reports furnished to the Company during and/or with respect to year ended December 31, 2014, the Company is not aware of any late or delinquent filings required under Section 16(a) of the Exchange Act in respect of the Company's equity securities.

### **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and other persons performing similar functions. A copy of our Code of Business Conduct and Ethics is available on our website at [www.transenterix.com](http://www.transenterix.com). We intend to post amendments to, or waivers from a provision of, our Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer or persons performing similar functions on our website.

### **Board Nominations by Security Holders**

The Board will consider candidates recommended by our stockholders pursuant to written applications submitted to our Corporate Secretary, TransEnterix, Inc., 635 Davis Drive, Suite 300, Morrisville, North Carolina 27560.

There have been no changes to the procedures by which security holders may recommend nominees to our Board.

### **Communication with the Board**

Interested parties who want to communicate with the independent or non-management directors as a group, with the Board as a whole, any Board committee or any individual Board members should address their communications to the Board, the Board members or the Board committee, as the case may be, and send them to c/o Corporate Secretary, TransEnterix, Inc., 635 Davis Drive, Suite 300, Morrisville, North Carolina 27560, or call the Corporate Secretary at (305) 575-4602. The Corporate Secretary will forward all such communications directly to such Board members. Any such communications may be made on an anonymous and confidential basis.

There have been no changes to the procedures by which interested parties may communicate with the Board.



**ITEM 11. EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table lists the summary compensation of our named executive officers for the prior two fiscal years:

**SUMMARY COMPENSATION TABLE**

| Name and Principal Position               | Year | Salary     | Bonus     | Stock Awards<br>(1) | Option Awards<br>(2) | Non-Equity Incentive Plan Compensation<br>(3) | Nonqualified Deferred Compensation<br>(4) | Other Compensation<br>(5) | Total        |
|---|------|------------|-----------|---------------------|----------------------|---|---|---------------------------|--------------|
| Todd M. Pope                              |      |            |           |                     |                      |   |   |                           |              |
| President and Chief Executive Officer (3) | 2014 | \$ 400,000 |           |                     | \$ 367,802(4)        | \$ 90,000                                     |   |                           | \$ 857,802   |
|   | 2013 | \$ 325,000 |           |                     | \$ 401,694(4)        | \$ 146,250(5)                                 |   |                           | \$ 872,944   |
| Joseph P. Slattery,                       |      |            |           |                     |                      |   |   |                           |              |
| Executive Vice President,                 | 2014 | \$ 282,808 | \$        | \$                  | \$ 1,118,718(7)      | \$ 51,300                                     |   |                           | \$ 1,452,826 |
| Chief Financial Officer (6)               | 2013 | \$ 69,103  | \$ 25,000 | \$ 1,430,000        | \$                   | \$  |   |                           | \$ 1,524,103 |
| Richard M. Mueller,                       |      |            |           |                     |                      |   |   |                           |              |
| Chief Technology Officer and              | 2014 | \$ 269,063 |           |                     |                      | \$  | \$ 70,167(10)                             |                           | \$ 339,230   |
| Chief Operating Officer (8)               | 2013 | \$ 300,000 |           |                     |                      | \$ 100,000(9)                                 | \$  |                           | \$ 400,000   |

- (1) Represented grant of restricted stock units ( RSUs ) to Mr. Slattery upon his hiring. The RSU award vests in three equal installments on the first three anniversaries of the date of grant. If a change of control event (as defined in his RSU agreement) occurs and Mr. Slattery's employment is terminated involuntarily within twelve months following the change in control, the vesting of his RSUs will accelerate.
- (2) The grant date fair values reported above for stock option awards to all named executive officers were determined by taking into account the number of shares and exercise prices in respect of such stock option awards granted by TransEnterix Surgical, but do not give effect to the Merger Exchange Ratio. As a result of the Merger, the shares underlying the stock option awards are multiplied by the Merger exchange ratio of 1.1533 and the exercise prices of the stock option awards are divided by the exchange ratio, for purposes of calculating the number of shares of our common stock that each option award is now exercisable for and for calculating the corresponding exercise prices, respectively, following the Merger. Unless otherwise indicated, the number of shares underlying stock option awards and the exercise price for such stock options in this Annual Report have been adjusted to reflect the exchange ratio of 1.1533. For all stock options, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions made in the calculation of these amounts are described in Note 13 to the Company's audited financial statements, included in this Annual Report.
- (3) Todd Pope became our President and Chief Executive Officer on September 3, 2013 in connection with the consummation of the Merger; prior thereto he was the president and chief executive officer of TransEnterix Surgical.
- (4) Mr. Pope was granted the following stock option awards in 2014 and 2013:
- stock options to purchase 345,990 shares of our common stock granted on August 26, 2013 at an exercise price of \$2.00 per share, one-fourth of the shares underlying this stock option award vested on the first anniversary of the date of grant and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months;
  - stock option to purchase 80,000 shares of our common stock granted on February 13, 2014 at an exercise price of \$8.00 per share, with vesting based on pre-defined corporate performance goals established on the

date of grant;

- (c) stock options to purchase 48,000 shares of our common stock granted on February 13, 2014 at an exercise price of \$8.00 per share, one-fourth of the shares underlying this stock option award vest on the first anniversary of the date of grant and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months; and
  - (c) stock options to purchase 82,600 shares of our common stock granted May 27, 2014 at an exercise price of \$3.94 per share, one-fourth of the shares underlying this stock option award vest on the first anniversary of the date of grant and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months.
- (5) Represents bonuses paid under a TransEnterix incentive bonus plan for 2014 and a TransEnterix Surgical incentive bonus plan for 2013. The awards were based at target of 50% base salary. Corporate performance goals were established by the Compensation Committee for each year and individual performance goals established for Mr. Pope at the beginning of the plan year. For 2014, 100% of Mr. Pope's incentive bonus was based on achievement of pre-established corporate goals focused on the development of the Company's SurgiBot System, achieving designated regulatory-based goals, and successful consummation of a corporate finance transaction. For 2013, the corporate goals focused on successful consummation of a corporate finance transaction and achievement of product development milestones. The Compensation Committee reviews the self-evaluations by the applicable named executive officers at the end of each plan year, considers the CEO recommendations for all named executive officers other than the CEO, and determines the achievement of each performance goal in determining the actual bonus for each plan year.
- (6) Mr. Slattery became our Executive Vice President and Chief Financial Officer on October 2, 2013.
- (7) Mr. Slattery was granted the following stock option awards in 2014:
- (a) stock options to purchase 40,000 shares of our common stock granted February 13, 2014 at an exercise price of \$8.00 per share, with vesting based on pre-defined corporate performance goals established on the date of grant;
  - (b) stock options to purchase 500,000 shares of our common stock granted April 21, 2014 at an exercise price of \$4.02 per share, one-fourth of the shares underlying this stock option award vested on October 2, 2014, and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months; and
  - (c) stock options to purchase 25,900 shares of our common stock granted May 27, 2014 at an exercise price of \$3.94 per share, one-fourth of the shares underlying this stock option award vest on the first anniversary of the date of grant and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months.
- (8) Mr. Mueller resigned on November 7, 2014.
- (9) Represents a bonus paid under a TransEnterix Surgical incentive bonus plan for 2013. The award for Mr. Mueller was based at target of 40% base salary. Corporate performance goals were established by the Compensation Committee for each year and individual performance goals established for Mr. Mueller at the beginning of the plan year. For 2013, the corporate goals focused on successful consummation of a corporate finance transaction and achievement of product development milestones. The Compensation Committee reviews the self-evaluations by the applicable named executive officers at the end of each plan year, considers the CEO recommendations for all named executive officers other than the CEO, and determines the achievement of each performance goal in determining the actual bonus for each plan year.
- (10) Consists of \$45,937 in severance and \$24,230 of accrued paid time off at the time of his departure.

**Agreements with Named Executive Officers**

*Todd M. Pope.* On February 3, 2015, the Company, entered into a new employment agreement (the Employment Agreement) with Todd M. Pope regarding Mr. Pope's continued employment with the Company as its President and Chief Executive Officer. The initial employment period under the Employment Agreement commenced on September 3, 2013 and continues until December 31, 2015. The term of the Employment Agreement then will automatically renew for successive one-year terms, unless terminated in accordance with the terms of the Employment Agreement. Under the Employment Agreement Mr. Pope is paid an annual base salary of \$400,000, subject to increase in accordance with the Employment Agreement; is eligible to receive annually, or otherwise, an incentive compensation award opportunity, payable in cash, as determined by the Compensation Committee or the Board of Directors (the Board), and long term incentive equity compensation. During the term, Mr. Pope's target annual cash incentive compensation opportunity will be no less than 50% of his base salary for the portion of the employment period falling within a given fiscal year, and performance goals shall be based on both Company performance metrics and personal performance metrics, as established and approved by the Compensation Committee or the Board annually. The equity-based compensation will be awarded under the Company's Amended and Restated 2007 Equity Incentive Plan or any successor thereto in the discretion of the Compensation Committee or the Board. Mr. Pope is entitled to severance benefits as follows: (i) if the Employment Agreement is terminated without cause or for good reason, or if the Employment Agreement is not extended at the end of the then-current term, Mr. Pope will receive severance and continued health and welfare benefits for twelve months following termination; and (ii) if Mr. Pope's employment is terminated in connection with a Change in Control of the Company (as defined in the Employment Agreement), his severance benefits would be expanded to twenty-four (24) months. The severance payable is the sum of (a) his annual rate of base salary immediately preceding his termination of employment, and (b) his target annual bonus for the fiscal year in which the termination occurs. Such severance benefit can be paid in a lump sum in the Change in Control context, subject to a payment delay required by applicable law. In addition, in the event of termination of his employment in connection with a Change in Control, to the extent not previously accelerated, all of Mr. Pope's unvested outstanding equity awards shall accelerate and vest upon the date of termination. Mr. Pope is subject to non-solicitation and non-competition covenants during the terms of the Employment Agreement and for one (1) year immediately following the termination of his employment.

*Joseph P. Slattery.* In connection with his hiring, we entered into an offer letter, which constituted an employment agreement, with Mr. Slattery. Under the employment agreement, Mr. Slattery will receive a base salary of \$275,000 per year. Mr. Slattery will be eligible for a \$25,000 bonus for the year ending December 31, 2013 and an annual year-end bonus of 40% of his base salary beginning in 2014 and thereafter. Mr. Slattery also received a grant of 1,000,000 RSUs, which vest one-third (1/3) per year on the anniversary of Mr. Slattery's start date with the Company.

Under the employment agreement Mr. Slattery was entitled to a stock option grant exercisable for 500,000 shares of the Company's common stock (the Fundraising Option Grant) following the successful closing of a Company fundraising in which at least \$20.0 million in proceeds was raised for the Company and where at least 50% of the funds raised come from non-insiders (the Fundraising). The Fundraising Option Grant was awarded on April 21, 2014, with an exercise price of \$4.02 per share, with vesting of 25% on the one (1) year anniversary of Mr. Slattery's start date and thereafter vesting in thirty-six (36) equal monthly installments. Mr. Slattery was prohibited from exercising any the Fundraising Option Grant for a period of six (6) months following the date of grant.

The Initial RSU grant and the Fundraising Stock Option Grant will each accelerate in the event of Mr. Slattery's involuntary termination from employment with the Company at the time of or within twelve (12) months following a change of control.

In the event that there is a change of control of the Company affecting his employment, Mr. Slattery shall be entitled to receive a lump sum payment equal to 12 months of his base salary and reimbursement for COBRA premiums for a period of up to 12 months, subject to signing a release of claims in favor of TransEnterix.



*Richard M. Mueller.* In connection with the Merger, TransEnterix assumed the offer letter, dated December 15, 2010 from TransEnterix Surgical to Richard Mueller, which constituted an employment agreement with Mr. Mueller. The employment agreement provides Mr. Mueller with a base salary of \$22,917 per month and provided him with eligibility for a 2011 yearend bonus. The employment agreement gives the Board of Directors the discretion to increase Mr. Mueller's base salary and bonus. The employment agreement further provided for a stock option grant to Mr. Mueller which was made in 2011, and relocation benefits which were paid in 2011.

In connection with Mr. Mueller's resignation on November 7, 2014, Mr. Mueller and the Company entered into a Separation Agreement and General Release (the Separation Agreement). Under the Separation Agreement, the Company will provide Mr. Mueller with cash severance and an extension of the period in which he can exercise vested stock options for six months following his termination date. The Separation Agreement also includes a release of employment claims and sets forth certain confidentiality, non-solicitation and non-competition covenants applicable following termination of employment.

**Outstanding Equity Awards at Fiscal Year-End**

The following table lists the outstanding equity awards held by TransEnterix's named executive officers at December 31, 2014:

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

| Name               | OPTION AWARDS (1)  |  |  |                              | STOCK AWARDS                 |  |   |  |   |   |
|--------------------|--|--|--|------------------------------|------------------------------|--|---|--|---|---|
|                    | (2)<br>Number<br>of<br>Securities<br>Underlying<br>Unexercised<br>Options<br>Exercisable | (2)<br>Number<br>of<br>Securities<br>Underlying<br>Unexercised<br>Options<br>Not Exercisable | Equity<br>Incentive<br>Plan<br>Awards:<br>Number<br>of<br>Securities<br>Underlying<br>Unexercised<br>Options | Exercise<br>Price<br>(\$)(3) | Option<br>Expiration<br>Date | Number<br>of<br>Shares<br>or<br>Units of<br>Stock<br>that<br>have<br>not<br>Vested | Market<br>Value of<br>Shares<br>or<br>Units of<br>Stock<br>that<br>have<br>not<br>Vested(4) | Equity<br>Incentive<br>Plan<br>Awards:<br>Equity Market<br>Incentive or<br>Plan Payout<br>Awards: Value<br>Number of | Unearned,<br>Shares,<br>Units<br>or<br>Other<br>Rights<br>that<br>have<br>not<br>Vested | Unearned,<br>Shares,<br>Units<br>or<br>other<br>Rights<br>that<br>have<br>not<br>Vested |
|                    |  |  |  |                              |                              |  |   |  |   |   |
|                    |  |  |  |                              |                              |  |   |  |   |   |
| Todd M. Pope       | 81,691   |  |  | 0.35                         | 9/15/2018                    |  |   |  |   |   |
|                    | 172,995  |  |  | 0.35                         | 12/14/2019                   |  |   |  |   |   |
|                    | 658,232  | 271,031  |  | 0.35                         | 4/12/2022                    |  |   |  |   |   |
|                    | 108,126  | 237,864  |  | 2.00                         | 8/12/2023                    |  |   |  |   |   |
|                    |  | 128,000  |  | 8.00                         | 2/13/2024                    |  |   |  |   |   |
|                    |  | 82,600   |  | 3.94                         | 5/27/2024                    |  |   |  |   |   |
| Joseph P. Slattery |  | 40,000   |  | 8.00                         | 2/13/2024                    | 133,334  | 388,002   |  |   |   |
|                    | 145,833  | 354,167  |  | 4.02                         | 4/21/2024                    |  |   |  |   |   |
|                    |  | 25,900   |  | 3.94                         | 5/27/2024                    |  |   |  |   |   |
| Richard M. Mueller | 99,863   |  |  | 0.35                         | 2/9/2021                     |  |   |  |   |   |
|                    | 335,960  |  |  | 0.35                         | 4/12/2022                    |  |   |  |   |   |

- (1) The number of shares and exercise prices in respect of the option awards granted by TransEnterix Surgical listed above give effect to the Merger Exchange Ratio of 1.1553.
- (2) One-fourth of the shares underlying each option award vests on the first anniversary of the grant date of such option award, and 1/48th of the shares underlying the full award vest each month thereafter for 36 months.

- (3) During May 2012, TransEnterix Surgical provided its employees, including Mr. Pope and Mr. Mueller, with an offer to have their option awards repriced so that the exercise price of their option awards was amended to equal TransEnterix Surgical's then-current fair market value of its common stock, or \$0.35 per share. The option awards listed above that were issued prior to 2012 reflect the adjusted exercise price, which adjusted exercise price became effective as of June 21, 2012, as further adjusted by the exchange ratio.
- (4) Based on the closing price of the Company's common stock on December 31, 2014 of \$2.91 per share.



**Equity Compensation Plan**

The Company currently has one equity compensation plan under which it makes awards, the TransEnterix, Inc. Amended and Restated 2007 Incentive Compensation Plan (the 2007 Plan). In connection with the Merger, SafeStitch assumed all of TransEnterix Surgical's options that were issued and outstanding immediately prior to the Merger at the exchange ratio of 1.1533, which were exercisable, as of the Merger date, for approximately 3,136,165 shares of common stock. Such options were granted under the TransEnterix, Inc. 2006 Stock Plan (the 2006 Plan) which was assumed by the Company in the Merger. The 2006 Plan is maintained solely for the purpose of the stock options granted under the 2006 Plan that remain outstanding; no future awards are authorized to be made under the 2006 Plan. The 2007 Plan was originally approved by the Board and adopted by the majority of our stockholders on November 13, 2007. It was later amended and restated (and approved by the Board and approved by a majority of our stockholders on October 29, 2013) to increase the number of shares of common stock authorized under the 2007 Plan to 4,940,000 shares, and to make other changes. The 2007 Plan is used for plan-based awards for officers, other employees, consultants, advisors and non-employee directors. The Company can issue stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards under the 2007 Plan.

**Director Compensation**

The following table lists the compensation paid to the non-employee directors of the Company for the year ended December 31, 2014:

**DIRECTOR COMPENSATION**

| Name                      | Fees<br>Earned<br>or<br>Paid<br>in |              | Option<br>Awards | Non-Equity Nonqualified<br>Incentive Plan    Deferred Compensation    All Other |          |              | Total(\$) |
|---------------------------|------------------------------------|--------------|------------------|---|----------|--------------|-----------|
|                           | Cash                               | Stock Awards |                  | Compensation  | Earnings | Compensation |           |
| Dennis J. Dougherty       |                                    |              | (1)              | 14,739  |          |              | 14,739    |
| Jane H. Hsiao, Ph.D., MBA |                                    |              |                  | 18,424  |          |              | 18,424    |
| Aftab R. Kherani, M.D.    |                                    |              |                  | 14,739  |          |              | 14,739    |
| Paul A. LaViolette        |                                    |              |                  | 22,109  |          |              | 22,109    |
| David B. Milne            |                                    |              |                  | 14,739  |          |              | 14,739    |
| Richard C. Pfenniger, Jr. |                                    |              |                  | 18,424  |          |              | 18,424    |
| William N. Starling       |                                    |              |                  | 18,424  |          |              | 18,424    |

- (1) For all stock options in the table and the footnotes, the option values reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions made in the calculation of these amounts are described in Note 13 to the Company's audited financial statements, included in this Annual Report.

**Director Compensation Arrangements**

On May 28, 2014, the Board approved a plan of compensation for its non-employee directors. Under the compensation plan, each new non-employee director shall receive a stock option grant to purchase 30,000 shares of common stock, vesting in equal installments on the first three anniversaries of the date of grant. In addition, each non-employee member of the Board shall receive an annual stock option grant to purchase 20,000 shares of common

stock; the Chair of the Board shall receive an annual stock option grant to purchase 30,000 shares of common stock; and the Chair of each of the Audit, Compensation and Corporate Governance and Nominating Committee shall receive an annual stock option grant to purchase 25,000 shares of common stock. The annual stock option grants shall vest quarterly over one year. The term of each stock option is ten years and all such stock options are awarded under, and subject to the provisions of, the Company's Amended and Restated 2007 Stock Incentive Plan.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

### Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information concerning the beneficial ownership of Common Stock by: (i) each person known by us to be the beneficial owner of more than 5% of our outstanding Common Stock currently; (ii) each of our current directors; (iii) each of our named executive officers; and (iv) all of our current executive officers and directors as a group. Ownership information is set forth as of January 15, 2015. Unless otherwise noted, each of the following disclaims any beneficial ownership of the shares, except to the extent of his, her or its pecuniary interest, if any, in such shares. Unless otherwise indicated, the mailing address of each individual is c/o TransEnterix, Inc., 635 Davis Drive, Suite 300, Morrisville, NC 27560.

| Name and Address of Beneficial Owner                              | As of January 15, 2015               |   |
|---|--------------------------------------|---|
|   | Number of Shares of Common Stock (1) | Percentage of Outstanding Common Shares (2) |
| Paul LaViolette (3)   | 7,574,358                            | 12.0%                                       |
| David Milne (4)   | 7,561,692                            | 12.0%                                       |
| William N. Starling (5)   | 5,881,938                            | 9.3%  |
| Jane H. Hsiao, Ph.D., MBA (6)                                     | 4,953,980                            | 7.8%  |
| William N. Kelley   | 0                                    | *   |
| Dennis J. Dougherty (7)   | 3,953,981                            | 6.3%  |
| Todd M. Pope (8)  | 1,113,748                            | 1.7%  |
| Richard C. Pfenniger, Jr. (9)                                     | 90,150                               | *   |
| Joseph P. Slaterry (10)   | 260,749                              | *   |
| Aftab R. Kherani, M.D. (11)                                       | 15,000                               |   |
| Richard M. Mueller (12)   | 435,823                              | *   |
| All Executive Officers and Directors as a group (11 persons) (13) | 31,841,419                           | 48.5%                                       |
| Frost Gamma Investments Trust (14)                                | 4,308,469                            | 6.8%  |
| Aisling Capital III, L.P. (15)                                    | 8,335,819                            | 13.2%                                       |
| SV Life Sciences Fund (16)  | 7,546,692                            | 11.9%                                       |
| Synergy Life Science Partners, L.P. (17)                          | 5,711,091                            | 8.4%  |
| StepStone Funds (18)  | 3,480,512                            | 5.5%  |
| Intersouth Partners VII, L.P. (19)                                | 3,938,981                            | 6.2%  |
| BlackRock, Inc. (20)  | 4,046,042                            | 6.4%  |

\* Less than 1%.

- (1) A person is deemed to be the beneficial owner of shares of Common Stock underlying options and warrants held by that person that are exercisable as of January 15, 2015 or that will become exercisable within 60 days thereafter.
- (2) Based on 63,182,806 shares of Common Stock outstanding as of January 15, 2015. Each beneficial owner's percentage ownership is determined assuming that options and warrants that are held by such person (but not those held by any other person) and that are exercisable as of January 15, 2015, or that will become exercisable

within 60 days thereafter, have been exercised into Common Stock. The additional shares resulting from such exercise are included in both the numerator and denominator for such beneficial owner for purposes of their calculation.

- (3) Includes 7,338,352 shares held by SV Life Sciences Fund IV, L.P. and 208,340 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. Paul LaViolette is a partner of SVLSF IV, LLC, a control person of both SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. Also includes options to purchase 27,666 shares of Common Stock.
- (4) Includes 7,338,35 shares held by SV Life Sciences Fund IV, L.P. and 208,340 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. David Milne is a managing partner of SVLSF IV, LLC, a control person of both SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. Also includes options to purchase 15,000 shares of Common Stock.
- (5) Includes 5,318,969 shares of Common Stock held by Synergy Life Science Partners, L.P., and 392,122 shares of Common Stock held by Synecor, L.L.C. William N. Starling is a managing director of Synergy Life Science Partners, L.P. and the chief executive officer of Synecor, L.L.C. Also includes 4,613 shares held by Mark Starling, Trustee of the William N. Starling, Jr. and Dana Gregory Starling 1990 Irrevocable Trust and 135,223 shares held by W. Starling and D. Starling, Trustees of the Starling Family Trust, UDT August 15, 1990. Further includes options to purchase 31,011 shares of Common Stock.
- (6) Includes options to purchase 133,750 shares of Common Stock, and warrants to acquire 400,000 shares of Common Stock. Dr. Hsiao's Common Stock holdings also include beneficial ownership of shares held by Hsu Gamma Investments, L.P. (Hsu Gamma), which holds 1,257,694 shares of Common Stock. Dr. Hsiao is the general partner of Hsu Gamma. Dr. Hsiao's address is 4400 Biscayne Blvd, Miami, FL 33137.
- (7) Consists of 3,938,981 shares of Common Stock held by Intersouth Partners VII, L.P. Dennis Dougherty is a principal of a control person of Intersouth Partners VII, L.P. Also includes options to purchase 15,000 shares of Common Stock.
- (8) Consists of options to purchase 1,113,748 shares of Common Stock.
- (9) Includes 48,000 shares of common stock directly held by Mr. Pfenniger and options to purchase 42,150 shares of Common Stock.
- (10) Includes 83,666 shares of common stock directly held and jointly owned by Mr. Slattery and his spouse and options to purchase 177,083 shares of Common Stock.
- (11) Consists of options to purchase 15,000 shares of Common Stock.
- (12) Consists of options to purchase 435,823 shares of Common Stock.
- (13) Includes options to purchase 2,006,231 shares of Common Stock and warrants to purchase 400,000 shares of Common Stock.
- (14) Frost Gamma Investments Trust holds 4,108,469 shares of Common Stock and warrants to purchase 200,000 shares of Common Stock. Dr. Phillip Frost, a former director, is the trustee, and Frost Gamma Limited Partnership is the sole and exclusive beneficiary, of Frost Gamma Investments Trust. Dr. Frost is one of two limited partners of Frost Gamma Limited Partnership. The general partner of Frost Gamma Limited Partnership is Frost Gamma Inc. and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is also the sole shareholder of Frost-Nevada Corporation.
- (15) The address of Aisling Capital III, LP is 888 Seventh Avenue, 30th Floor, New York, NY 10106. Based on information made available to the Company and on the Schedule 13D filings made by Aisling Capital III, LP, Steve Elms, Dennis Purcell and Andrew Schiff share voting and investment control over the shares of Common Stock held by Aisling Capital III, LP.
- (16) Consists of 7,338,352 shares held by SV Life Sciences Fund IV, L.P. and 208,340 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. The address of each of SV Life Sciences Fund IV, L.P., SV Life Sciences Fund IV Strategic Partners, L.P. and SVLSF IV, LLC, their control person, is One Boston Place Suite 3900, 201 Washington Street, Boston, MA 02108. Based on information made available to the Company and on the Schedule 13G filings made by SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P., David Milne shares voting and investment control over the shares of Common Stock owned by such entities.

- (17) Consists of 5,318,969 shares of Common Stock held by Synergy Life Science Partners, L.P., and 392,122 shares of Common Stock held by Synecor, L.L.C. The address of each of Synergy Life Science Fund and Synecor, L.L.C. is 3284 Alpine Road, Portola Valley, CA 94028. Based on information made available to the Company and on the Schedule 13D filings made by these entities, William N. Starling, Richard S. Stack and Mudit K. Jain share voting and investment control over the shares of Common Stock held by such entities.
- (18) The address of the StepStone Funds is 4350 La Jolla Village Drive, Suite 800, San Diego, CA 92122. Based on information made available to the Company and on the Schedule 13G filings made by the StepStone Funds with the SEC with respect to the Company's shares, the StepStone Funds consist of StepStone Pioneer Capital Buyout Fund II, L.P., StepStone Pioneer Capital II, L.P., and StepStone-SYN Investments, L.L.L.P.; no individuals are identified as having or sharing voting or investment control over the shares of Common Stock owned by the StepStone Funds.
- (19) The address of Intersouth Partners VII, L.P. is 102 City Hall Plaza, Suite 200, Durham, NC 27701. Based on information made available to the Company and on the Schedule 13G filings made by Intersouth Partners VII, L.P., Dennis J. Dougherty and Mitch Mumma share voting and investment power over the shares of Common Stock held by such entity.
- (20) The address of BlackRock, Inc. is 55 East 52nd Street, New York, New York 10022. Based on the Schedule 13G filed by this entity on February 2, 2015, no individuals are identified as having or sharing voting or investment control over the shares of Common Stock held by such entity.

The Company is not aware of any arrangements with any of the foregoing stockholders or any other stockholder of the Company which may result in a change in control of the Company.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information below provides certain disclosures regarding related person transactions and director independence matters related to the combined Company following the Merger.

#### **Certain Relationships and Related Transactions**

SafeStitch entered into a five-year lease for office space in Miami, Florida with a company controlled by Dr. Frost, a principal stockholder and former director who left the Board in June 2014. The current rental payments under the Miami office lease, which commenced January 1, 2008, and expired on December 31, 2012, are approximately \$12,000 per month. The Company terminated the month-to-month lease on August 15, 2014. The Company recorded approximately \$89,000 of rent expense related to the Miami lease for the year ended December 31, 2014.

Dr. Hsiao, Dr. Frost and former director Steven Rubin are each significant stockholders and/or directors of Non-Invasive Monitoring Systems, Inc. ( "NIMS" ), a publicly traded medical device company, Tiger X Medical, Inc. ( "Tiger X" ), a publicly traded medical device company, and Tiger Media, Inc. ( "Tiger Media" ), a publicly traded company operating primarily in China. Director Richard Pfenniger is also a shareholder of NIMS. Since December 2009, TransEnterix's Chief Legal Officer has served under a Board-approved cost sharing arrangement as Corporate Counsel of Tiger Media and as the Chief Legal Officer of each of NIMS and Tiger X. The Company recorded reductions to SG&A costs and expenses for the years ended December 31, 2014 and 2013 of \$5,000 and \$31,000, respectively, to account for the sharing of accounting costs under this arrangement. The Company recorded \$120,000 and \$158,000 of reductions to SG&A costs and expenses for the year ended December 31, 2014 and 2013, respectively, to account for the sharing of legal costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X and Tiger Media were approximately \$24,000 and \$14,000 as of December 31, 2014 and 2013, respectively.



On November 20, 2012, SafeStitch entered into a Promissory Note in the principal amount of \$300,000.00 with Hsu Gamma Investments, L.P. (the "Hsu Gamma Note"), an entity controlled by Dr. Hsiao. The interest rate payable by SafeStitch on the Hsu Gamma Note was 10% per annum, payable on the maturity date of June 30, 2013. In March 2013, the Hsu Gamma Note was paid off in its entirety, plus approximately \$10,000 in accrued interest.

On December 26, 2012, SafeStitch entered into a Promissory Note in the principal amount of \$300,000.00 with Frost Gamma (the "Frost Gamma Note"). The interest rate payable by SafeStitch on the Frost Gamma Note was 10% per annum, payable on the maturity date of June 30, 2013. In March 2013, the Frost Gamma Note was paid off in its entirety, plus approximately \$8,000 in accrued interest.

On February 22, 2013 SafeStitch entered into a promissory note in the principal amount of \$200,000.00 with Dr. Hsiao (the "Hsiao Note"). The interest payable by SafeStitch on the Hsiao Note was 10% per annum, payable on the maturity date of June 30, 2013. In March 2013, the Hsiao Note was paid off in its entirety, plus approximately \$2,000 in accrued interest.

On March 22, 2013, SafeStitch entered into a stock purchase agreement (the "2013 Purchase Agreement") with approximately 17 investors ("2013 PIPE Investors") pursuant to which the 2013 PIPE Investors agreed to purchase an aggregate of approximately 12,100,000 shares of common stock at a price of \$0.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of warrants to purchase approximately 6,050,000 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$0.33 per share and five year expiration. Among the investors purchasing shares were Frost Gamma and Dr. Jane Hsiao. Frost Gamma purchased 2.0 million shares and received 1.0 million warrants, and Dr. Hsiao purchased 4.0 million shares and received 2.0 million warrants.

On August 5, 2013, TransEnterix Surgical entered into a Note and Warrant Purchase Agreement with investment funds affiliated with Messrs. Dougherty, Kherani, LaViolette, Milne and Starling, each a director of TransEnterix Surgical, for the purchase and sale of subordinated convertible notes, together with other investors, in an aggregate amount of approximately \$2,000,000. Each subordinated convertible promissory note was converted into shares of our Series B Preferred Stock upon the Closing Date of the Private Placement.

On August 13, 2013, TransEnterix Surgical entered into the Purchase Agreement, pursuant to which investment funds affiliated with Messrs. Dougherty, Kherani, LaViolette, Milne and Starling, entities affiliated with Drs. Frost and Hsiao, and Dr. Hsiao, in her individual capacity, agreed to purchase, together with other investors, an aggregate of 7,544,704.4 shares of the Company's Series B Preferred Stock, each share of which would initially be convertible, subject to certain conditions, into two shares of Common Stock, for a purchase price of \$4.00 per share of Series B Preferred Stock payable in cash, cancellation of certain indebtedness of TransEnterix Surgical or a combination thereof. In connection with the investment, such investors received registration rights entitling them, under certain circumstances, to require the Company to register their respective shares of common stock received by them in the Merger and upon conversion of the Series B Preferred Stock. The transaction under the Purchase Agreement closed on September 3, 2013 in conjunction with the closing of the Merger. As permitted under the terms of the Purchase Agreement, the Company issued and sold an additional 25,000 shares of the Series B Preferred Stock on September 17, 2013 to Mr. Slattery and his spouse.

TransEnterix Surgical was spun off from Synecor, LLC in 2006 when it was separately incorporated. Various research and development services and administrative services were purchased from Synecor, LLC and its wholly owned subsidiary Synchrony Labs LLC and totaled approximately \$66,000 and \$90,000 for the years ended December 31, 2014 and 2013, respectively. All transactions between Synecor, LLC and TransEnterix Surgical were arms'-length transactions in which fair value was paid for the services provided. Director William Starling is affiliated with Synecor, LLC. The Audit Committee approved all transactions between the Company and Synecor, LLC or Synchrony Labs LLC.





### **Review and Approval of Transactions with Related Persons**

The Audit Committee of our Board reviews and approves all transactions that are required to be reported under Item 404(a) of Regulation S-K, including each transaction described above. In order to approve a related person transaction, the Audit Committee requires that (i) such transactions be fair and reasonable to us at the time it is authorized by the Audit Committee and (ii) such transaction must be authorized, approved or ratified by the affirmative vote of a majority of the members of the Audit Committee who have no interest, either directly or indirectly, in any such related person transaction. While TransEnterix did not have any written policies with respect to review and approval of any such transactions with related persons, TransEnterix believes the processes its Audit Committee has followed ensure the appropriateness of its entry into such transactions with related persons and that such transactions were entered into on terms on an equivalent basis to arms -length transactions.

### **Director Independence**

#### **Board of Directors**

The Board, in the exercise of its reasonable business judgment, has determined that each of our current directors qualify as independent directors pursuant to the applicable NYSE MKT and SEC rules and regulations, except Mr. Pope, who is currently employed as our President and Chief Executive Officer.

#### **Audit Committee**

The current members of the Company's Audit Committee are Mr. Pfenniger, Mr. Dougherty and Dr. Kherani. Mr. Pfenniger serves as the Chair of the Audit Committee. Due to each member's extensive experience in serving operating companies in both managerial and director capacities, the Board determined that each member has the requisite knowledge of financial statements and general understanding of financial and reporting matters to allow each such member to serve on the Audit Committee.

The Board, in the exercise of its reasonable business judgment and utilizing the general standards it applies for determining the independence of directors, has determined that each of the Audit Committee members qualifies as independent pursuant to NYSE MKT Rule 803.

Finally, the Board has determined that Mr. Pfenniger is an audit committee financial expert as defined in Item 407(d)(5)(ii) of Regulation S-K. The Board made this determination based on Mr. Pfenniger's extensive career and background serving as an accountant and auditor as well as his serving various operating companies in both managerial and director capacities.

#### **Compensation Committee**

The current members of the Company's Compensation Committee are Mr. Starling (Chair), Mr. LaViolette, Dr. Kherani and Dr. Hsiao. Due to each member's extensive experience in serving operating companies in both managerial and director capacities, the Board determined that each member has the requisite knowledge and skills to allow each such member to serve on the Compensation Committee.

The Board, in the exercise of its reasonable business judgment and utilizing the general standards it applies for determining the independence of directors, has determined that each of the Compensation Committee members qualifies as independent pursuant to NYSE MKT Rule 803.

#### Nominating Committee

The current members of the Company's Nominating Committee are Dr. Hsaio, Chair, Mr. LaViolette and Mr. Milne. Due to each member's extensive experience in serving operating companies in both managerial and director capacities, the Board determined that each member has the requisite knowledge and skills to allow each such member to serve on the Nominating Committee, and qualifies as independent pursuant to NYSE MKT 803.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

#### **Audit Fees**

BDO USA, LLP (BDO) has served as the independent registered public accounting firm of the Company since 2012. The following table sets forth the fees billed to the Company by BDO for its audits of the Company's consolidated annual financial statements and other services for the years ended December 31, 2014 and 2013.

|                        | <b>2014</b>       | <b>2013</b>       |
|------------------------|-------------------|-------------------|
| Audit Fees(1)          | \$ 280,725        | \$ 155,790        |
| Audit-Related Fees (2) |                   | \$ 27,517         |
| Tax Fees               |                   |                   |
| All Other Fees         |                   |                   |
| <b>Total Fees</b>      | <b>\$ 280,725</b> | <b>\$ 183,307</b> |

(1) Fees adjusted to include additional fees billed related to the 2013 audit.

(2) Relates to financial statement services and due diligence services conducted in connection with the Merger and the filing of the Current Report on Form 8-K filed September 6, 2013.

#### **Pre-Approval Policies and Procedures**

Our Audit Committee has a policy in place that requires its review and pre-approval of all audit and permissible non-audit services provided by our independent auditors. The services requiring pre-approval by the audit committee may include audit services, audit-related services, tax services and other services. The pre-approval requirement is waived with respect to the provision of non-audit services if (i) the aggregate amount of all such non-audit services provided to us constitutes not more than 5% of the total amount of revenues paid by us to our independent auditors during the fiscal year in which such non-audit services were provided, (ii) such services were not recognized at the time of the engagement to be non-audit services, and (iii) such services are promptly brought to the attention of the Audit Committee or by one or more of its members to whom authority to grant such approvals has been delegated by the Audit Committee. Subsequent to the Merger, audit-related services, tax services and all other services provided by BDO were pre-approved by the Audit Committee. Prior to the Merger during 2013 and in 2012, EisnerAmper, LLP served as the independent registered public accounting firm for SafeStitch, and all audit-related services, tax services and all other services provided by EisnerAmper LLP to SafeStitch were pre-approved by the Audit Committee. The Audit Committee has considered and determined that the provision of all non-audit services set forth in the table above is compatible with maintaining BDO's independence.



## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) The following consolidated financial statements are filed as a part of this Annual Report:

|  |      |
|--|------|
| Consolidated Financial Statements  | Page |
| Reports of Independent Registered Public Accounting Firm   | 51   |
| Consolidated Balance Sheets as of December 31, 2014 and 2013   | 53   |
| Consolidated Statements of Operations and Comprehensive Loss for each of the years in the two-year period ended December 31, 2014                  | 54   |
| Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit) for each of the years in the two-year period ended December 31, 2014 | 55   |
| Consolidated Statements of Cash Flows for each of the years in the two-year period ended December 31, 2014   | 56   |

(2) Consolidated Financial Statement Schedules: The information required by this item is included in the consolidated financial statements contained in Item 8 of this Annual Report.

(3) Exhibits: The following exhibits are filed as part of, or incorporated by reference into, this Annual Report.

| Exhibit<br>No. | Description   |
|----------------|---|
| 2.1 !          | Agreement and Plan of Merger, dated as of August 13, 2013, by and among SafeStitch Medical, Inc., Tweety Acquisition Corp. and TransEnterix, Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).                     |
| 2.1(a) !       | First Amendment to Agreement and Plan of Merger, dated as of August 30, 2013, by and among SafeStitch Medical, Inc., Tweety Acquisition Corp and TransEnterix, Inc. (filed as Exhibit 2.2 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein). |
| 3.1            | Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).  |
| 3.1.1          | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on April 1, 2014 and incorporated herein by reference).  |
| 3.2            | Amended and Restated Bylaws of TransEnterix, Inc. (filed as Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).  |
| 4.1            | Certificate of Designation of Series A Preferred Stock (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein).   |
| 4.2            | Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).  |



| Exhibit No. | Description   |
|-------------|---|
| 4.3         | Specimen Certificate for Common Stock of TransEnterix, Inc. (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-3, File No. 333-193235, filed with the SEC on January 8, 2014 and incorporated by reference herein).   |
| 4.4         | Form of Common Stock Warrant (filed as Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein).  |
| 4.5         | Form of Common Stock Warrant (filed as Exhibit A to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on March 26, 2013 and incorporated herein by reference)   |
| 10.1        | Securities Purchase Agreement, dated as of August 13, 2013, by and among SafeStitch Medical, Inc. and the Investor parties thereto (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).   |
| 10.2        | Form of Lock-up and Voting Agreement (filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).   |
| 10.3        | Exclusive License and Development Agreement, dated as of May 26, 2006, by and between Creighton University and SafeStitch LLC (filed as Exhibit 10.5 to our Annual Report on Form 10-KSB, as amended, filed with the SEC on March 26, 2008 and incorporated by reference herein).   |
| 10.4        | Patent Assignment, dated as of June 26, 2009, by and between TransEnterix Surgical, Inc. and Synecor, LLC (filed as Exhibit 10.3 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).  |
| 10.5        | Patent Acquisition and License Termination Agreement, dated as of June 26, 2009, by and among TransEnterix Surgical, Inc., Synecor, LLC and Barosense, Inc. (filed as Exhibit 10.4 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).  |
| 10.6 ++     | Robotic Development and Supply Agreement, dated as of February 13, 2014, by and between TransEnterix, Inc. and Microline Surgical, Inc. (filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2014, and incorporated by reference herein)  |
| 10.7        | Amended and Restated Loan and Security Agreement dated as of September 26, 2014, by and among the Registrant, TransEnterix Surgical, Inc. and SafeStitch, LLC, as Borrowers, and Oxford Finance LLC and Silicon Valley Bank, as Lenders and associated notes and warrants issued by TransEnterix to Oxford Finance LLC and Silicon Valley Bank and (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on September 30, 2014, and incorporated by reference herein). |
| 10.8        | Amended and Restated Pre-Release Distribution Agreement, dated as of June 15, 2012, between TransEnterix Surgical, Inc. and Al-Danah Medical Co. W.L.L. (filed as Exhibit 10.9 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).  |
| 10.9        | Registration Rights Agreement, dated as of September 3, 2013, by and among the Company and the investors party thereto (filed as Exhibit 10.10 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).  |
| 10.10 +     | Employment Agreement, dated as of February 3, 2015, by and between the Registrant and Todd M. Pope (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on February 6, 2015, and incorporated by reference herein).   |
| 10.11 +     | Offer letter, dated as of December 15, 2010, by and between the Registrant and Richard M. Mueller (filed as Exhibit 10.7 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013   |

and incorporated by reference herein).

- 10.11.1 + Separation Agreement and General Release, effective as of November 7, 2014, between the Registrant and Richard M. Mueller (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on November 7, 2014, and incorporated by reference herein).



| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 10.12 +            | Offer letter, dated September 12, 2013, by and between the Registrant and Joseph P. Slattery (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on September 23, 2013 and incorporated by reference herein).   |
| 10.13 +            | Offer letter, dated as of August 30, 2013, by and between SafeStitch Medical, Inc. and Charles J. Filipi, M.D. (filed as Exhibit 10.11 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).   |
| 10.14 +            | Amended and Restated TransEnterix, Inc. 2007 Incentive Compensation Plan (the 2007 Plan) (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 333-193234, filed with the SEC on January 8, 2014 and incorporated by reference herein).   |
| 10.15 +            | Form of Employee Stock Option Agreement pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).   |
| 10.16 +            | Form of Employee Stock Option Agreement (performance stock options) pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).   |
| 10.17 +            | Form of Non-Employee Stock Option Agreement pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).   |
| 10.18 +            | Form of Restricted Stock Unit Agreement pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).   |
| 10.19 +            | Restricted Stock Unit Agreement, dated as of October 2, 2013, by and between the Company and Joseph P. Slattery (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).   |
| 10.20              | Promissory Note of SafeStitch Medical, Inc. in favor of Hsu Gamma Investments, L.P (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on November 27, 2012 and incorporated by reference herein).   |
| 10.21              | Promissory Note of SafeStitch Medical, Inc. in favor of Frost Gamma Investments Trust (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on January 2, 2013 and incorporated by reference herein).  |
| 10.22              | Promissory Note of SafeStitch Medical, Inc. in favor of Jane Hsiao (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on February 28, 2013 and incorporated by reference herein).   |
| 10.23              | Form of Stock Purchase Agreement and Common Stock Warrant dated March 22, 2013 (filed as Exhibit 10.1 to our Current Report on Form 8-K filed on March 26, 2013 and incorporated by reference herein).   |
| 10.24              | Lease Agreement, dated as of December 11, 2009, by and between TransEnterix Surgical, Inc. and GRE Keystone Technology Park Three LLC (filed as Exhibit 10.25 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014 and incorporated herein by reference). |
| 10.24.1            | Lease Modification Agreement No. 1, dated as of May 4, 2010, by and between TransEnterix Surgical, Inc. and GRE Keystone Technology Park Three LLC (filed as Exhibit 10.25.1 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March                                  |

31, 2014 and incorporated herein by reference).

- 14.1 Code of Ethics Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to the Registrant's website see Item 1. BUSINESS Available Information. )
- 21.1 \* Subsidiaries of the Registrant.

| Exhibit No. | Description   |
|-------------|---|
| 23.1 *      | Consent of BDO USA, LLP.  |
| 31.1 *      | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).                      |
| 31.2 *      | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).                      |
| 32.1 *      | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 *      | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS *   | XBRL Instance Document.   |
| 101.SCH *   | XBRL Taxonomy Extension Schema Document.  |
| 101.CAL *   | XBRL Taxonomy Extension Calculation Linkbase Document.  |
| 101.LAB *   | XBRL Taxonomy Extension Label Linkbase Document.  |
| 101.PRE *   | XBRL Taxonomy Extension Presentation Linkbase Document.   |
| 101.DEF *   | XBRL Taxonomy Extension Definition Linkbase Document.   |

! The schedules and exhibits to the Agreement and Plan of Merger have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any such schedules and exhibits to the U.S. Securities and Exchange Commission upon request.

+ A management contract, compensatory plan or arrangement required to be separately identified.

++ Confidential treatment has been granted for certain portions of the agreement pursuant to a confidential treatment request filed with the Commission on August 6, 2014. Such provisions have been filed separately with the Commission.

\* Filed herewith.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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: February 20, 2015

**TransEnterix, Inc.**

By: /s/ Todd M. Pope  
 Todd M. Pope  
 President, Chief Executive Officer

and a Director

(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| <b>Signature</b>                                 | <b>Title(s)</b>   | <b>Date</b>          |
|--|---|----------------------|
| /s/ Todd M. Pope<br>Todd M. Pope                 | President, Chief Executive Officer and a Director<br>(principal executive officer)  | February 20,<br>2015 |
| /s/ Joseph P. Slattery<br>Joseph P. Slattery     | Executive Vice President and Chief Financial<br>Officer (principal financial officer and principal<br>accounting officer) | February 20,<br>2015 |
| /s/ Paul A. LaViolette<br>Paul A. LaViolette     | Chairman of the Board and a Director  | February 20,<br>2015 |
| /s/ Dennis J. Dougherty<br>Dennis J. Dougherty   | Director  | February 20,<br>2015 |
| /s/ Jane H. Hsaio<br>Jane H. Hsaio, Ph.D.        | Director  | February 20,<br>2015 |
| /s/ William N. Kelley<br>William N. Kelley, M.D. | Director  | February 20,<br>2015 |
| /s/ Aftab R. Kherani<br>Aftab R. Kherani         | Director  | February 20,<br>2015 |

|                               |          |                   |
|-------------------------------|----------|-------------------|
| /s/ David B. Milne            | Director | February 20, 2015 |
| David B. Milne                |          |                   |
| /s/ Richard C. Pfenniger, Jr. | Director | February 20, 2015 |
| Richard C. Pfenniger, Jr.     |          |                   |
| /s/ William N. Starling, Jr.  | Director | February 20, 2015 |
| William N. Starling, Jr.      |          |                   |