

TRANSETERIX INC.  
Form 10-K  
March 05, 2014

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

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**FORM 10-K**

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ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended **December 31, 2013**

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**

**TRANSETERIX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**11-2962080**

(I.R.S. Employer Identification No.)

**635 Davis Drive, Suite 300, Morrisville, NC 27560**

(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:

**Title of each class**

None

**Name of each exchange on which registered**

None

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

**Common Stock, \$0.001 par value per share**

(Title of class)

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

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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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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, 2013, 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 \$10,671,629.

The number of shares outstanding of the registrant's common stock, as of February 28, 2014 was 244,272,728.

Part III of this Annual Report on Form 10-K is incorporated by reference to our Definitive Proxy Statement on Schedule 14A to be filed in respect of our 2014 Annual Meeting of Stockholders.

**TRANSENERIX, INC.  
ANNUAL REPORT ON FORM 10-K**

**DECEMBER 31, 2013**

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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;
- 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 of Corporate Structure

On September 3, 2013, SafeStitch Medical, Inc., a Delaware corporation (SafeStitch) and TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical) 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 corporate name to TransEnterix, Inc. In this Annual Report, when we refer to the registrant as a combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, we use the terms “TransEnterix,” the “Company,” “we,” “us,” and “ours”. When we refer to the historic business, operations and corporate status of the parent in the Merger we use the term “SafeStitch” and when we refer to the historic business, operations and corporate status of the subsidiary in the Merger, we use the term “TransEnterix Surgical.”

#### Overview of the 2013 Merger Transaction

##### The Merger

On September 3, 2013, pursuant to an Agreement and Plan of Merger dated August 14, 2013, and amended by a First Amendment dated August 30, 2013 (collectively, the Merger Agreement) by and among SafeStitch, Tweety Acquisition Corp., a Delaware corporation (Merger Sub) and TransEnterix Surgical, the Merger was consummated and TransEnterix Surgical became 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 (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 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.

All references to share amounts in this Annual Report on Form 10-K have been retroactively adjusted to reflect the impact of the Exchange Ratio.

##### The Private Placement

On September 3, 2013, 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), pursuant to which the Investors agreed to purchase an aggregate of 7,544,704.4 shares of the Company’s Series B Convertible Preferred Stock, par value \$0.01 per share (the Series B Preferred Stock), each share of which was convertible, subject to certain conditions, into ten (10) shares of common stock (the Conversion Shares and, together with the Series B Preferred Stock, the Private Placement Securities), 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, the Company 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.

On December 6, 2013, the Company filed an Amended and Restated Certificate of Incorporation (the Restated Certificate) to change its corporate name to TransEnterix, Inc. and to increase the authorized shares of common stock from 225,000,000 to 750,000,000. In accordance with the terms of the Certificate of Designation of Series B Convertible Preferred Stock, each outstanding share of Series B Preferred Stock automatically converted into ten shares of the Company's common stock upon the filing of the Restated Certificate. An aggregate of 75,697,094 shares of common stock were issued in the conversion of the Series B Preferred Stock.

## **Accounting Treatment**

The Merger is treated as a reverse acquisition of SafeStitch for financial accounting and reporting purposes. As such, TransEnterix Surgical is treated as the acquirer for accounting and financial reporting purposes while SafeStitch is treated as the acquired entity for accounting and financial reporting purposes. Further, as a result, the assets and liabilities and the historical operations that are reflected in this Annual Report and will be reflected in the Company's future financial statements filed with the SEC will be those of TransEnterix Surgical, and SafeStitch assets, liabilities and results of operations will be consolidated with the assets, liabilities and results of operations of TransEnterix Surgical.

## **Smaller Reporting Company**

Following the consummation of the Merger, for 2013 the Company continues to be a "smaller reporting company," as defined in Regulation S-K promulgated under the Exchange Act.

## **Business Description of the Combined Company**

### **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 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 integrates three-dimensional (3-D) high definition vision technology. The Company has commercialized the SPIDER® 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 is U.S. Food and Drug Administration (FDA) cleared. The Company also manufactures multiple instruments that can be deployed using the SPIDER System currently, and which are being adapted for use with the SurgiBot System.

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 has developed other surgical devices, including the SMART Dilator, to be utilized in treating obesity, GERD and esophageal strictures. SafeStitch also developed a surgical stapler called the AMID Hernia Fixation Device. On a going-forward basis, the Company intends to continue to develop the Gastroplasty Device for the treatment of obesity. The Company has discontinued sales of the AMID Hernia Fixation Device.

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 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**

### *TransEnterix Surgical*

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 minimally 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. 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 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 a 3-D operative space, 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 the number of total laparoscopic procedures performed worldwide. 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, in particular general surgery. Despite recent advances, we believe there remain many limitations created by current robotic assisted surgery systems used in connection with laparoscopic surgeries. Existing robotic systems require a large capital investment. Moreover, existing robotic systems require the surgeon to sit outside the sterile field, therefore removing his or her ability to be patient-side within the sterile field. There are further challenges in maneuvering the patient once a large, multi-arm robotic system is fixed in place. Existing robotic systems also suffer from the challenges associated with having a fulcrum near the incision in a patients' abdominal wall.

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 belly button, along with a laparoscopic camera for visualization. This structure resulted in instrument collision, difficulty in establishing triangulation and working space for the instruments, and often difficulty associated with crossing of instruments. More recent attempts at reduced incision surgery have leveraged robotic technology, but these efforts have diminished the benefits typically offered by robotic surgical systems and are plagued by some of their limitations.

*SafeStitch*

SafeStitch's product portfolio and its products under development prior to the Merger were primarily designed to address three market opportunities: obesity, GERD, and hernia repair. The Company intends to continue to develop the Gastroplasty Device for obesity in the future. We believe the Gastroplasty Device could represent an alternative for patients eligible for the common bariatric surgery procedures currently performed for obesity—gastric bypass, gastric sleeve and gastric banding procedures. Bariatric surgery has become more prevalent, an estimated 350,000 to 400,000 bariatric surgical procedures are performed annually worldwide. Bariatric surgery is usually recommended for those people with a body mass index (BMI) of 35 or higher. Gastric bypass combines the creation of a small stomach pouch to restrict food intake and the construction of a duodenal bypass, thereby decreasing the body's ability to absorb nutrients from food. In the gastric sleeve procedure, the stomach volume is significantly reduced, which accelerates the flow of food through the stomach. For gastric banding procedures, a small inflatable/deflatable band (which allows adjustment to the size of the opening between the pouch and the stomach) is placed around the upper part of the stomach, creating a small pouch, so that the patient feels full sooner.

*Combined Company*

Following the Merger, the Company's development efforts have been focused on the SurgiBot System. Although the Company currently continues to sell its SPIDER System pursuant to existing purchase orders and supply agreements entered into in the ordinary course, the Company is in the process of winding down such sales efforts to allow the Company to focus on the SurgiBot System. The Company also continues to pursue development of the Gastroplasty Device.

## **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.

### *SurgiBot System*

The SurgiBot System is currently in development and is designed as a reduced 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 of four 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;
- **The Positioning Arm:** a reusable arm that supports and repositions the SurgiBot Base at the operating table; and
- **The 3-D Vision System:** a three dimensional scope and vision system for laparoscopic surgical visualization that can be viewed by all operating room personnel, not just the surgeon.

Key design features of the SurgiBot System are:

- **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;
- **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;
- **Internal Triangulation:** The SurgiBot System utilizes a deployment mechanism to achieve triangulation of multiple instruments inside the body as contrasted with other 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; and
- **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.

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 significant 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.

We currently estimate that we will make the applicable filings for the SurgiBot System with the FDA and other regulatory bodies in the fourth quarter of 2014.

#### *SPIDER® Surgical System*

The SPIDER Surgical System has a unique design that accommodates a range of flexible instruments (manufactured by the Company) through articulating instrument delivery tubes, and working channels that also allow for the use of rigid instruments. True right and true left instrumentation and triangulation is achieved through a single site. Unlike early single port techniques, the SPIDER System eliminates awkward crossed arms movement, allowing a single surgeon to operate the device instinctively with true right and left instrument manipulation. Its flexible instruments and intra-abdominal triangulation capability are technologies not available in any other commercially available surgical system.

Key features of the SPIDER System are:

- Triangulation achieved via single site access through the belly button;

- True left and true right instrumentation for surgeons;

- Flexible, articulating instruments;

- A single-operator platform; and

- An open platform with multiple working channels.

The SPIDER System is commercially available in a limited release in select markets worldwide. As of December 31, 2013, we have sold over 3,000 FDA-cleared, CE Marked SPIDER Systems. In the years ended December 31, 2013 and 2012, TransEnterix Surgical had one customer who accounted for 37% and 21%, respectively, of the revenue from TransEnterix Surgical's products, including the SPIDER System. That customer, Al Danah Medical Co. W.L.L., was a distributor of such products pursuant to a pre-release distribution agreement with TransEnterix Surgical dated June 10, 2012. Although this customer was the most significant purchaser of TransEnterix Surgical's commercialized products during 2012 and 2013, the Company does not believe it is dependent on such customer, as the Company is focused on developing the SurgiBot System, and has reduced its sales and marketing efforts with respect to the other TransEnterix Surgical products, including the SPIDER 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 appliers, and suction and irrigation instruments. Such instruments are currently being sold in limited volumes in connection with the SPIDER System described below, and are currently being adapted for use with the SurgiBot System. We expect to launch one such

instrument in 2014, which we are calling our flexible energy device. This product has received 510(k) clearance from the FDA, and 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.

### *SafeStitch Product Overview*

With respect to the SafeStitch products and products in development, the Company has focused its efforts since the Merger on the development of the Gastroplasty Device, and has stopped the commercialization or development of the other SafeStitch products. The product descriptions below reflect activities in 2013 prior to the consummation of the Merger.

*Intraluminal Gastroplasty Device (Gastroplasty Device).* The Gastroplasty Device consists of a set of instruments designed to perform incision-less, endoscopic surgery by introduction through the mouth and esophagus. Bariatric and GERD operations are generally performed through an external abdominal incision, and often laparoscopically. Traditional surgery has the potential for significant complications and often requires an in-patient hospital stay, which is expensive.

The Gastroplasty Device is the most tested of the SafeStitch products under development, and has demonstrated its potential for effectiveness. In animal tests and *ex vivo* human testing, the Gastroplasty Devices have been successful in suturing and excising tissue and reducing stomach size. SafeStitch successfully tested its first investigational devices in five patients in Hungary, and follow up observations were reviewed in September 2012, which was approximately 24 months following the initial procedures. At the 24-month follow-up, it was observed, through endoscopic visualization, that the operative site showed significant scar tissue as intended, with the scar forming a restrictive ring for weight. SafeStitch also observed that the weight loss and esophageal monitoring was satisfactory and as expected. SafeStitch expanded its *in vivo* human testing of this device in Hungary during 2013 and we expect to continue to gather additional data. We are preparing obesity trial protocols for this device in preparation for submitting the final investigational device exemption (IDE) trial plans to the FDA for review.

SafeStitch was developing use of the Gastroplasty Device for the diagnosis and treatment of Barrett's Esophagus, which is caused by GERD, and is a condition in which the lining of the esophagus imitates the stomach mucosa, beginning at the esophageal junction and migrating upward. Barrett's esophageal tissue is pre-cancerous and can result in difficulty in swallowing, malignancy and death. Following the Merger, we ceased such development efforts.

*The AMID HFD Stapler.* SafeStitch developed the AMID HFD stapler in cooperation with Dr. Parviz Amid, a pioneer of and renowned expert in the Lichtenstein Hernia Repair. This stapler uses non-absorbable titanium staples to repair inguinal (groin) or ventral (abdominal) hernias, and for the approximation of tissue, including skin. The staples are used to fix mesh in place, which helps prevent the recurrence of a hernia. Hernias impact approximately 3% of the world's population, and roughly 800,000 inguinal hernias are repaired annually in the United States. Greater than 60% of the inguinal hernia repairs performed in developed countries are performed using the Lichtenstein technique popularized by Dr. Parviz Amid, the inventor of the AMID HFD. During the repair, mesh is affixed to tissues to prevent hernia recurrence. Hernias are also repaired through open incision without affixing mesh, and laparoscopically with mesh reinforcement.

In November 2009, SafeStitch received FDA clearance to market the AMID HFD in the United States as a Class II device, and, in February 2010, SafeStitch received CE Mark approval to market the stapler in the European Union and other countries accepting and requiring CE Mark. After SafeStitch commenced production of the AMID HFD in 2010, it voluntarily suspended sales in order to implement several improvements and a more robust and reliable commercial manufacturing process. Thereafter, SafeStitch submitted a "Special 510(k)" to the FDA that was cleared in February 2012. SafeStitch began commercial sales in the United States during the second quarter of 2012. Additionally, SafeStitch supplemented its Technical File for clearance to market the AMID HFD in the European Union. Following the decision to cease sales of the AMID HFD following the Merger, the Company delisted the AMID HFD Stapler in both the U.S. and European Union.



*SMART Dilator* . Dilators are used when an endoscopy procedure demonstrates the narrowing of the esophagus. Narrowing may be treated by administering GERD medication or by using a dilator to expand the esophagus. Approximately 800,000 dilations are performed in the United States each year. According to peer-reviewed literature, dilation results in a 0.5-1.0% perforation rate. Untreated perforation of the esophagus is fatal, usually within two days. SafeStitch's SMART Dilator product, which was developed to address perforation risk, was expected to be used to treat GERD and GERD-related complications such as Barrett's Esophagus, but following the Merger we have ceased further development.

*Bite Blocks*. A bite block is used to protect the endoscope used in transoral gastrointestinal procedures and is utilized in almost all such procedures. Endoscopies require a bite block to protect the endoscope, the patient's teeth and his or her airway. SafeStitch developed a standard bite block and airway bite block to be used during an endoscopy and intended to prevent a low oxygen level during the procedure due to a restricted airway. The latter problem is commonly encountered in obese patients during upper endoscopy and if uncorrected can lead to brain damage and cardiac arrest or arrhythmia. A number of bite blocks are on the market. The bite blocks developed by SafeStitch are Class I 510(k)-exempt devices that required no preclearance from the FDA. The Company is currently developing the bite blocks in connection with the Gastroplasty Device.

## **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, 2012, TransEnterix Surgical incurred research and development expenses of approximately \$6.3 million, while SafeStitch incurred research and development expenses of \$2.9 million. 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.. 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. As both TransEnterix Surgical and SafeStitch had limited past revenues from sales of products, no customers were 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.

*TransEnterix Surgical:* The Company holds three 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. Two of our United States patents resulted from filings relating to the SPIDER System and will remain in force until 2027 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.

*SafeStitch:* 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 (was also used in the SMART Dilator and bite blocks products under development). 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, we have one issued patent and eight patent applications pending in the United States, including those that are exclusively licensed from Creighton. The issued patent, owned by Creighton, relates to the Gastroplasty Device and will expire in 2026. We are also pursuing several of these applications in other countries, and three such foreign patents have been issued.

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, and Creighton owns all inventions conceived of and reduced to practice solely by Dr. Charles Filipi, 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 university 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 obligations to pay royalties ends when the last valid claim (as defined in the Creighton Agreement) expires.

Dr. Filipi was the Chief Medical Officer of SafeStitch prior to the Merger, and he continues to serve as our Chief Medical Officer following the Merger.

### **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, Covidien, Intuitive Surgical, Johnson & Johnson, Olympus America, Karl Storz and Stryker.

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.

The table below lists our products, sourced from TransEnterix Surgical and SafeStitch, and the significant competitors in these product fields:

#### **Products and Products Under Development**

SPIDER® Surgical System

The SurgiBot System  
Gastroplasty Device

#### **Significant Competitors**

Applied Medical, Olympus America, Johnson & Johnson and Covidien  
Intuitive Surgical  
USGI Medical, Endo Gastric Solutions, Inc.,  
ValenTx, Inc., GI Dynamics, Inc. and Medigus, Ltd.

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 ease of use, flexibility and sensitivity, access to the patient, enhanced safety, effectiveness, efficiency and visualization, 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

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, on average, about 90 days, but it can take substantially longer if the FDA has concerns regarding the application. 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 501(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 might not be 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 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 may be required to support a CE Mark filing. The Company is pursuing regulatory guidance on the requirements related to the clinical evaluation to support a CE Mark.

We believe that our Gastroplasty Device for the treatment of obesity is a Class III device subject to PMA approval by the FDA and that this device will require clinical trials in order to meet the PMA requirements. Prior to initiation of pilot or pivotal clinical studies in support of a PMA application the Company will file a pre-submission application and meet with FDA to gain approval on an agreed upon study plan including study population, study objectives, endpoints, means of measure, and statistical methods.

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 a special 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.





A company that intends to manufacture medical devices is required to register with the FDA before it begins to manufacture the device for commercial distribution. As a result, we and any entity that manufactures products on our behalf will be subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) requirements 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. Further, we are required to comply with various FDA and other agency requirements for labeling and promotion. The FDA's Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. In addition, the FDA prohibits us from promoting a medical device for unapproved indications.

#### Impact of Regulation

The FDA, in the course of enforcing the FDCA, may subject a medical device company such as us to various sanctions for violating FDA regulations or provisions of the FDCA, including requiring recalls, issuing Warning Letters, seeking to impose civil money penalties, seizing devices that the agency believes are non-compliant, seeking to enjoin distribution of a specific type of device or other product, seeking to revoke a clearance or approval, and seeking disgorgement of profits.

Further, the levels of revenues and profitability of medical 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, reimbursement will be available or sufficient to allow us to manufacture sell them competitively and profitably.

#### Health Care Regulation

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 Affordability 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 will change 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 Physician Payments Sunshine Act, which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report certain payments or "transfers of value" provided to physicians and teaching hospitals and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. The Centers for Medicare & Medicaid Services, or CMS, issued its final rule implementing the Physician Payments Sunshine Act in February 2013, and required data collection commenced as of August 1, 2013. Manufacturers must report aggregated data for August through December of 2013 to CMS in the first quarter of 2014 and more detailed information regarding the specific payments and transfers of value in the second quarter of 2014. CMS will release the data on a public website by September 30, 2014. The Company is in the process of complying with its obligations under the Physician Payments Sunshine Act. The failure to report appropriate data 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, 2013, we had 92 employees, including 91 full time employees. The Company considers its relationships with its employees to be good.

**Corporate Information**

*TransEnterix Surgical*

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*

SafeStitch was originally incorporated on August 19, 1988 as NCS Ventures Corp. under the laws of the State of Delaware. Its corporate 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.

*Combined Company*

The Company's principal executive offices are located at 635 Davis Drive, Suite 300, Morrisville, NC 27560.

**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, 2013 was \$28.4 million, and our accumulated deficit as of December 31, 2013 was \$93.3 million.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we prepare for clinical trials of our products and continue to commercialize our cleared or approved products. If our products fail in clinical trials 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. 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. On January 8, 2014, we filed a Registration Statement on Form S-3 to register \$100,000,000 of our securities for sale from time to time. Once such Registration Statement is declared effective by the SEC, we do anticipate proceeding with offerings of our securities in accordance with the shelf registration statement requirements. 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 Private Placement, will not be sufficient to support clinical and pre-clinical 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 associated with the integration of the respective businesses and operations of SafeStitch and TransEnterix Surgical;
- 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 our clinical trials;
- the costs of acquiring, licensing or investing in businesses, products and technologies;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals;
- 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; 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 trials 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 may fail to realize some or all of the anticipated benefits of the business combination of SafeStitch and TransEnterix Surgical, which may adversely affect the value of our common stock.***

The success of the integration of TransEnterix will depend, in part, on our ability to realize the anticipated benefits and cost savings from combining the respective business and operations of SafeStitch and TransEnterix Surgical. To realize these anticipated benefits and cost savings, we must successfully combine the acquired business with our legacy operations and integrate our respective operations, technologies and personnel, which is particularly challenging given the geographic and cultural differences between the personnel and facilities based in Florida and North Carolina and the lack of experience we have in combining businesses. If we are not able to achieve these objectives within the anticipated time frame or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully or at all or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the overall integration of the businesses is a complex, time-consuming and expensive process that, without proper planning and effective and timely implementation, could significantly disrupt our operations. Further, it is possible that the integration process could adversely affect our ability to maintain our research and development operations, result in the loss of key employees and other senior management, or to otherwise achieve the anticipated benefits of the acquisition.

Risks in integrating the SafeStitch and TransEnterix Surgical operations in order to realize the anticipated benefits of the acquisition include, among other factors:

- failure to effectively coordinate research and development efforts and capabilities effectively;
- failure to adequately communicate our product capabilities and expected product roadmap;
- failure to compete effectively against companies already serving the broader market opportunities expected to be available to us and our potential expanded product offerings;
- coordinating research and development activities to enhance the introduction of new devices and platforms acquired in the acquisition;





failure to successfully integrate and harmonize financial reporting and information technology systems of the two companies;

· integrating a senior management team as well as members from both companies into our Board of Directors;

· retaining and integrating key employees from TransEnterix Surgical and SafeStitch;

· managing effectively the diversion of management's attention from business matters to integration issues;

retaining TransEnterix Surgical's relationships with partners and integrating partnering efforts so that new partners acquired can easily do business with us; and

· transitioning all facilities to a common information technology environment.

In addition, the actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration plan may not be realized. Actual cost synergies, if achieved at all, may be lower than we expect and may take longer to achieve than anticipated. If we are not able to adequately address these challenges, we may be unable to successfully integrate the operations of SafeStitch and TransEnterix Surgical, or to realize the anticipated benefits of the integration. The anticipated benefits and synergies assume a successful integration and are based on projections, which are inherently uncertain, and other assumptions. Even if integration is successful, anticipated benefits and synergies may not be achieved. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock.

***We have incurred significant costs related to the Merger and expect to incur additional costs as integration plans continue. If we are unable to offset the costs of the acquisition through realization of efficiencies, our financial condition, liquidity and results of operations will suffer.***

We have incurred, and expect to continue to incur, various non-recurring costs associated with combining the operations of TransEnterix Surgical and SafeStitch, including, but not limited to, legal, accounting and financial advisory fees. The substantial majority of non-recurring expenses have been composed of these costs and expenses related to the execution of the acquisition, facilities and systems consolidation costs and employment-related costs. We have also incurred fees and costs related to formulating and implementing integration plans. Additional unanticipated costs may be incurred in the integration of the businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, should allow us to offset incremental acquisition and acquisition-related costs over time, this net benefit may not be achieved in the near term, or at all.

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

In connection with the Merger we became a party to, and jointly and severally liable for, \$9.4 million of outstanding debt of TransEnterix Surgical, and the associated obligations owed by TransEnterix Surgical under a Loan and Security Agreement, dated January 17, 2012, among TransEnterix Surgical, Silicon Valley Bank (SVB) and Oxford Finance LLC (Oxford) (the SVB-Oxford LSA). The Second and Third Amendment to the SVB-Oxford LSA, dated as of September 3, 2013 and October 31, 2013, respectively, amend the SVB-Oxford LSA among the lenders and the Company (as so amended, the Amended Loan Agreement). The Amended Loan Agreement evidences a term loan, which will mature on January 1, 2016 (the Term Loan). 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 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 Loan Agreement when due, this could result in a default under the Amended 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 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.

***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 intraluminal 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, some of our products are still in early stages of development and are prone to the risks of failure inherent in medical device product development. In particular, any of our products in clinical trials may fail to show desired efficacy and safety traits despite early promising results. 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.

***Our product research and development activities may not result in commercially viable products.***

Some of our products are still in early stages of development and are prone to the risks of failure inherent in medical device product development. For any Class III devices, we will likely be required to undertake significant clinical trials to demonstrate to the FDA that our devices are safe and effective for their intended uses. We may also be required to undertake clinical trials by non-U.S. regulatory agencies. Clinical trials are expensive and uncertain processes that may take years to complete. Failure can occur at any point in the process, and early positive results do not ensure that the entire clinical trial will be successful.

***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 our current and planned clinical trials 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 or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our Class III products are safe and effective for their intended uses. Generally, clinical data is not required to support a 510(k) application, but if applicable for our Class II products, we may require clinical data to demonstrate that the devices are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under Section 510(k).



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 or, for a Class III device, may grant approval contingent on the performance of costly post-marketing clinical trials. 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 our products, and we cannot give any assurance that our products will receive regulatory clearance or that any of our products 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 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, Covidien, Intuitive Surgical, Johnson & Johnson, Olympus, Stryker, USGI Medical, Endo Gastric Solutions, Inc., ValenTx, Inc., GI Dynamics, Inc., Medigus, Ltd., 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;
- our ability to protect 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 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 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.

Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities or the IRB for any given site. 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.

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.

***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 have already received FDA clearance for the SPIDER System, we continue in discussions with the FDA regarding the appropriate regulatory pathway for our SurgiBot System and our Gastroplasty Device. 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.

***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. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which are publicly available. 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.

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.

***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 Affordability 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 will change 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. This excise tax will likely increase our expenses in the future.



Further, the 2010 Health Care Reform Legislation includes the Physician Payments Sunshine Act, which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report certain payments or "transfers of value" provided to physicians and teaching hospitals and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. The Centers for Medicare & Medicaid Services, or CMS, issued its final rule implementing the Physician Payments Sunshine Act in February 2013, and required data collection commenced as of August 1, 2013. Manufacturers must report aggregated data for August through December of 2013 to CMS in the first quarter of 2014 and more detailed information regarding the specific payments and transfers of value in the second quarter of 2014. CMS will release the data on a public website by September 30, 2014. The Company is in the process of complying with its obligations under the Physician Payments Sunshine Act. The failure to report appropriate data 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 AMID HFD stapler and SPIDER System and have not made any sales of the SurgiBot System or the Gastroplasty Device. 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, for products such as the Gastroplasty Device, availability of coverage and reimbursement from government and other third-party payors can also impact the acceptance of our product offerings.



***If our products fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.***

There is significant uncertainty related to the third-party coverage and reimbursement of newly cleared or approved medical devices. Normally, surgical devices are not directly covered; instead, the procedure using the device is subject to a coverage determination by the insurer. The commercial success of our existing and future products in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our existing and future products. These payors may conclude that our products are not as safe or effective as existing devices or that procedures using our devices are not as safe or effective as the existing procedures using other devices. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our products for coverage and adequate reimbursement. The failure to obtain coverage and adequate reimbursement for our existing and future products or health care cost containment initiatives that limit or restrict reimbursement for our existing and future products may reduce any future product revenue.

***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, Richard M. Mueller 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.

***We have not sought an advisory stockholder vote to approve the compensation of our named executive officers.***

Rule 14a-21 under the Exchange Act requires us to provide a separate stockholder advisory vote in our proxy statements to approve the compensation of our named executive officers, not less frequently than once every three years (say-on-pay vote), and, at least once every six years, to provide a separate stockholder advisory vote on the frequency with which we will submit advisory say-on-pay votes to our stockholders (say-on-frequency vote). In 2013, the year in which Rule 14a-21 became applicable to smaller reporting companies, we did not submit to our stockholders a say-on-pay vote to approve an advisory resolution regarding our compensation program for our named executive officers, or a say-on-frequency vote. Consequently, the Board of Directors has not considered the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers. At our 2014 annual meeting, we will be asking our stockholders to vote on a proposal to approve an advisory resolution regarding our compensation program for our named executive officers, and presenting a separate say-on-frequency vote. Following such annual meeting, the Board will consider the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers, and will report on the results of the say-on-pay vote and the say-on-frequency vote as required by applicable SEC rules.

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

In 2013 we operated manufacturing facilities for production of the SPIDER System and maintained manufacturing facilities for the AMID HFD product. In the future, we may choose to use a third-party manufacturer for our other products. In addition, certain of our SPIDER System product component parts 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 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 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, including a limited number of direct sales representatives. 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. 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.

***For our Gastroplasty Device, we rely on our license with Creighton, and any loss of our rights under such license agreement, or failure to properly maintain or enforce the patent applications underlying such license agreement, could materially adversely affect our business prospects for the Gastroplasty Device.***

A significant number of the patents and patent applications in our patent portfolio related to the Gastroplasty Device are not owned by us, but are licensed from Creighton University. Presently, we rely on such licensed technology for our Gastroplasty Device and relied on it in developing the SMART Dilator and bite blocks products and may license additional technology from other third parties in the future. The Creighton Agreement gives us rights for the commercial exploitation of the patents resulting from the patent applications, subject to certain provisions of the license agreement. Failure to comply with these provisions could result in the loss of our rights under the Creighton agreement. Our inability to rely on these patent applications which are the basis of certain aspects of our technology would have an adverse effect on our business.

Further, our success will depend in part on the ability of us, Creighton and other third-party licensors to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights. We, Creighton or other third-party licensors may not successfully prosecute the patent applications which are licensed to us, may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than necessary to obtain an acceptable outcome from any such litigation. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and results of operations.

***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 two issued patents and we have filed over 30 patent applications in the United States and abroad. To our knowledge, none of the technology we have licensed has been patented in the U.S. 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, including Creighton.

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, 2013, the net carrying value of our goodwill and other intangible assets totaled approximately \$93.8 million. 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 market capitalization 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 of Series B Preferred Stock 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.

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, 2013, the market price of our common stock fluctuated from a high of \$1.78 per share to a low of \$0.21 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.

Moreover we may effect a reverse split of our common stock in connection with our plans to apply to list the common stock for trading on the NYSE MKT. While there will not be any change in a stockholder's economic interest in the Company as a result of such a reverse stock split, stockholders may not view such a reverse stock split in a favorable manner. If such a reverse stock split is not viewed favorably by stockholders, this could result in increased volatility in the price and trading volume of our common stock, which could also cause a decline in the value of our common stock.

***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 OTCBB. 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 immediately following the consummation of the Merger and the Private Placement, approximately 65% 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.

***Because our common stock may be a "penny stock," it may be more difficult for investors to sell shares of our common stock, and the market price of our common stock may be adversely affected.***

Our common stock may be a "penny stock" if, among other things, the stock price is below \$5.00 per share, it is not listed on a national securities exchange or approved for quotation on the Nasdaq Stock Market or any other national stock exchange or it has not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This risk-disclosure document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor

in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their shares of our common stock. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stocks and the market price of our common stock may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to resell their shares of our common stock publicly at times and prices that they feel are appropriate.

***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 65% of our outstanding voting securities as of immediately following the consummation of the Merger and the Private Placement financing, and continue to hold such beneficial ownership. 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 Agreement and the Private Placement, the Investors and a majority of SafeStitch's and TransEnterix Surgical's former stockholders, including the largest stockholders of each of SafeStitch and TransEnterix Surgical prior to the Merger comprising, in the aggregate, 93% of our common stock on the effective date of the Merger, and members of our Board of Directors, agreed to enter 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 during the period commencing on the one-year anniversary of the Merger closing date and ending on the eighteen-month anniversary of the Merger 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 Merger closing date and ending on the two-year anniversary of the Merger closing date. The restrictions on transfer contained in the Voting Agreements cease to apply to the Covered Securities following the second anniversary of the Merger closing date.

Additionally, pursuant to the Voting Agreements, each Investor party thereto has agreed, for the period commencing on the Merger closing date and ending on the one-year anniversary of the Merger 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 of Directors; 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. Each of these identified events were approved by majority consent of our stockholders prior to the filing of this Annual Report.

The Voting Agreement had the effect of securing the approval, by a majority of our stockholders, of the designated corporate actions, which were approved and effected on December 6, 2013, and limits the ability of our principal stockholders to transfer shares of our common stock for a significant period after the Merger consummation. These limitations may add to the low volume of shares of our common stock that trade on the OTCBB during the time period described.

**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, Durham, 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. 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 lease 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 largest beneficial stockholders and a director, as well as approximately 1,200 square feet of warehouse space in Miami, Florida from Frost Real Estate Holdings, LLC, from which we are in the process of exiting.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



## PART II

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

Since December 9, 2013, our common stock has been 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 in the over-the-counter market as reported on the OTCBB. The bid prices represent inter-dealer transactions, without adjustments for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

	Bid Prices	
	High	Low
2014		
First Quarter (through February 28, 2014)	\$ 2.41	\$ 1.55
2013		
First Quarter	\$ 0.50	\$ 0.255
Second Quarter	0.655	0.35
Third Quarter	1.72	0.3601
Fourth Quarter	1.76	1.29
2012		
First Quarter	\$ 1.01	\$ 0.45
Second Quarter	0.98	0.51
Third Quarter	0.75	0.22
Fourth Quarter	0.51	0.21

As of February 28, 2014, there were approximately 280 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, 2013 and 2012, 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 15,680,775 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 24,700,000 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, 2013:

Plan Category	Number of securities to be issued upon exercise of outstanding options (1)	Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance (2)
Equity compensation plans approved by security holders	3,802,000	\$ 0.81	20,845,500
Equity compensation plans not approved by security holders (3)	16,362,436	\$ 0.13	0
Total	20,164,436		20,845,500

(1) Includes 20,114,436 shares underlying outstanding stock options awarded under the 2007 Plan and 50,000 restricted stock units awarded under the 2007 Plan.

(2) These shares are all available for future awards under the 2007 Plan.

(3) Represents 15,362,436 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger, and a new hire award of 1,000,000 restricted stock units 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 2013 except the 1,000,000 restricted stock units awarded as a new hire grant to the Company's Chief Financial Officer.

#### **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.

## **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 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 integrates three-dimensional (3-D) high definition vision technology. The Company has commercialized the SPIDER® 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 is U.S. Food and Drug Administration (FDA) cleared. The Company also manufactures multiple instruments that can be deployed using the SPIDER System currently, and which are being adapted for use with the SurgiBot System.

The Company has maintained the operations of SafeStitch that are focused on developing its Gastroplasty Device for the treatment of obesity.

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 are designed to; (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 ambulatory surgery centers (ASCs) 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 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 trials, manufacturing, recruiting qualified personnel and raising capital.

Since inception, we have been unprofitable. As of December 31, 2013 we had an accumulated deficit of \$98.3 million.

We expect to continue to invest in research and development and related clinical trials, 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.

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

The Company operates in one business segment.

## **Recent Events**

### **Merger**

On September 3, 2013, SafeStitch Medical, Inc., a Delaware corporation (SafeStitch) and TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical) 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 corporate name to TransEnterix, Inc. As used herein, when we refer to the registrant as a combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, we use the terms “TransEnterix,” the “Company,” “we,” “us,” and “ours”. When we refer to the historic business, operations and corporate status of the parent in the Merger we use the term “SafeStitch” and when we refer to the historic business, operations and corporate status of the subsidiary in the Merger we use the term “TransEnterix Surgical.”

On September 3, 2013, pursuant to an Agreement and Plan of Merger dated August 14, 2013, and amended by a First Amendment dated August 30, 2013 (collectively, the Merger Agreement) by and among SafeStitch, Tweety Acquisition Corp., a Delaware corporation (Merger Sub) and TransEnterix Surgical, the Merger was consummated and TransEnterix Surgical became 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 (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 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, 2013, 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 market capitalization 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, 2013. Based upon the results of our analysis, we determined that no impairment of goodwill existed as of this date.

### **TransEnterix Surgical Bridge Loan**

During July 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 loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, among Silicon Valley Bank and Oxford Finance LLC, and TransEnterix Surgical. The Bridge Notes were converted into Series B Convertible Preferred Stock of the Company at the effective time of the Merger.

### **Private Placement**

On September 3, 2013, 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 for the Company's operations following the Merger. The Private Placement was done pursuant to a Securities Purchase Agreement (the Purchase Agreement) with certain private investors (the Investors), pursuant to which the Investors agreed to purchase an aggregate of 7,544,704.4 shares Series B Preferred Stock, each share of which was convertible, subject to certain conditions, into ten (10) shares of common stock (the Conversion Shares and, together with the Series B Preferred Stock, the Private Placement Securities), 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, the Company issued and sold an additional 25,000 shares of Series B Preferred Stock on September 17, 2013 for cash proceeds of \$100,000. Proceeds from the issuance of the Series B Preferred Stock, net of issuance costs, were \$28.2 million. Each outstanding share of Series B Preferred Stock was automatically converted into ten shares of common stock on December 6, 2013, upon the filing of the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock.

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

In connection with the Merger Agreement and the Private Placement, certain of SafeStitch's and TransEnterix Surgical'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. The events in (i) and (iii) took place during the fourth quarter of 2013, and the reverse stock split was approved by our stockholders in 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, 2013 decreased 33% to \$1.4 million compared to \$2.1 million for the year ended December 31, 2012. The \$0.7 million decrease was primarily due to lower sales volumes as a result of the reduction in our U.S. sales force headcount. 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 will remain on the market, and we will focus on serving existing customers.

### **Cost of Goods Sold**

Cost of goods sold consists of materials, labor and overhead incurred internally to produce our products. 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, 2013 increased 9% to \$4.8 million as compared to \$4.4 million for the year ended December 31, 2012. The \$0.4 million increase was primarily related to an increase in the reserve for obsolete inventory of \$0.7 million for raw material inventory that we do not anticipate utilizing, as we limit sales of our SPIDER System to our existing customers and an increase in other manufacturing and quality costs of \$0.3 million, offset by a decrease of \$0.6 million in cost of finished goods as a result of a decrease in sales during the same

period.

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### **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 grow as we continue to invest in basic research, clinical trials, product development and intellectual property. R&D expenses are expensed as incurred.

R&D expenses for the year ended December 31, 2013 increased 102% to \$12.7 million as compared to \$6.3 million for the year ended December 31, 2012. The \$6.4 million increase resulted primarily from the increase of personnel related expenses of \$2.4 million as we increased the headcount in our research and development and regulatory functions, the increase in supplies and other expenses of \$2.3 million and an increase of \$1.4 million for contract engineering services and consulting related to product development of our SurgiBot System. R&D expenses incurred by SafeStitch from the date of the Merger through December 31, 2013 were also \$0.3 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.

Sales and marketing expenses for the year ended December 31, 2013 decreased 49% to \$1.9 million compared to \$3.7 million for the year ended December 31, 2012. The \$1.8 million decrease was primarily related to lower personnel-related costs of \$1.2 million and travel related expenses of \$0.2 million as we decreased our direct sales and marketing personnel and reduced expenditures for marketing clinical studies, demonstration product and tradeshow and other marketing expenses of \$0.4 million.

### **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, 2013 increased 50% to \$4.2 million compared to \$2.8 million for the year ended December 31, 2012. The \$1.4 million increase was primarily due to increased personnel costs of \$0.4 million, increased stock compensation costs of \$0.5 million, increased legal, accounting and investor relation fees of \$0.4 million, and increased insurance costs of \$0.2 million, offset by decreased consulting expenses of \$0.1 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.

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

Loss on disposal of property and equipment 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, 2013 increased to \$2.8 million compared to \$0.4 million for the year ended December 31, 2012. The \$2.4 million increase was related to the remeasurement of fair value of the preferred stock warrant liability immediately preceding the Merger of \$1.8 million, and an increase in interest expense of \$0.6 million as a result of an additional \$6.0 million in proceeds received by us from the issuance of debt in December 2012.

### **Liquidity and Capital Resources**

#### **Sources of Liquidity**

Since our inception we have incurred significant losses and, as of December 31, 2013, we had an accumulated deficit of \$98.3 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, 2013 and 2012 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 a "universal shelf" Registration Statement on Form S-3 (the Shelf Registration Statement) with the SEC. Depending on our non-affiliated public equity float during the time period prior to consummating a financing transaction, the Shelf Registration Statement allows us to raise up to an additional \$100.0 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof.

At December 31, 2013, we had cash, cash equivalents and short-term investments of approximately \$16.2 million. Our cash and cash equivalents increased by approximately \$1.1 million during the year ended December 31, 2013 primarily as a result of net cash provided by Private Placement transaction of \$28.2 million, proceeds from issuance of bridge notes of \$2.0 million, proceeds from the exercise of options and warrants of \$0.1 million, and cash received in acquisition of a business, net of cash paid of \$0.2 million offset by net cash used in operating activities of \$21.2 million, payments on term debt of \$1.5 million, purchases of property and equipment of \$1.4 million, and purchase of investments, net of sales of \$5.3 million.

#### **Cash Flows**

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

Net cash used in operating activities was \$21.2 million during the year ended December 31, 2013. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation and amortization, stock-based compensation, remeasurement of fair value of preferred stock warrant liability, impairment loss on property and equipment, plus the net change in operating assets and liabilities for the year ended December 31, 2013, which consisted primarily of increases in accounts payable and accrued expenses and a decrease in inventory and accounts receivable.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$6.5 million during the year ended December 31, 2013. This amount reflected the net cash paid for the purchases of property and equipment of \$1.4 million and purchase of investments, net of sales of \$5.3 million, offset by cash received in the acquisition, net of cash paid of \$0.2 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the year ended December 31, 2013 was \$28.8 million, which reflected the \$28.2 million net proceeds from the issuance of preferred stock under the Securities Purchase Agreement, proceeds from issuance of bridge notes of \$2.0 million, and proceeds from the issuance of stock options and warrants of \$0.1 million, offset by the payment on debt of \$1.5 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, 2014. 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 July 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 loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, among Silicon Valley Bank and Oxford Finance LLC, and TransEnterix Surgical. The Bridge Notes were converted into Series B Convertible Preferred Stock of the Company at the effective time of the Merger.

On September 3, 2013, the Company consummated the Private Placement transaction in which it issued and sold shares of its Series B Preferred Stock to finance the operations of the Company following the Merger. The Private Placement was done pursuant to the Purchase Agreement with the Investors signatory thereto, 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 ten (10) 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, the Company issued and sold an additional 25,000 shares of Series B Preferred Stock on September 17, 2013 for cash proceeds of \$100,000. Proceeds from the issuance of the Series B Preferred Stock, net of issuance costs, were \$28.2 million.

In connection with the Merger, the Company assumed and became the borrower under TransEnterix Surgical's outstanding credit facility pursuant to the terms of the Loan and Security Agreement, dated as of January 17, 2012, (the SVB-Oxford LSA), among the Company, Silicon Valley Bank, and Oxford Finance, LLC, as lenders (the Lenders). The Second and Third Amendment to the SVB-Oxford LSA, dated as of September 3, 2013 and October 31, 2013, respectively, amend the SVB-Oxford LSA among the Lenders and the Company (as so amended, the Amended Loan Agreement). The Amended Loan Agreement evidences a term loan, which will mature on January 1, 2016 (the Term Loan).

The Term Loan bears interest at a fixed rate equal to 8.75%. Commencing August 2013, the Amended Loan Agreement provides for the amortization of principal (in the form of level monthly payments of principal and interest). The Term Loan will be required to be prepaid if the Term Loan is accelerated following an event of default. In addition, the Company is permitted to prepay the Term Loan 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 Loan, or prepayment of the Term Loan, the Company is required to make a final payment equal to the original principal amount of the Term Loan multiplied by 3.33% (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.

The Amended Loan Agreement is secured by a security interest in substantially all assets of the Company and any future subsidiaries, other than intellectual property. The Amended Loan Agreement contains customary representations (tested on a continual basis) 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; fail to appoint a chief executive officer, chief financial officer or chief technology officer upon vacancy; undergo a change in control; add or change business locations; and engage in businesses that are not related to the Company's existing business

Under the Shelf Registration Statement, we have the ability to issue debt securities, common stock, preferred stock, or warrants, or any combination thereof. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. In addition, any debt securities we issue could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Furthermore, any preferred equity securities we issue could have rights senior to those associated with our common stock. Depending on our non-affiliated public equity float during the time period prior to consummating another financing transaction, the Shelf Registration Statement will allow us to raise up to an additional \$100.0 million of securities. The timing and terms of any additional financing transactions, whether pursuant to the Shelf Registration Statement or otherwise, have not yet been determined. Any additional financing may not be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

### **Contractual Obligations and Commercial Commitments**

The following table summarizes our contractual obligations as of December 31, 2013 (in millions):

	Total	Payments due by period		
		Less than 1 year	1 to 3 years	3 to 5 years
Operating leases	\$ 1.1	\$ 0.5	\$ 0.5	\$ 0.1



Total contractual obligations	\$ 1.1	\$ 0.5	\$ 0.5	\$ 0.1
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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 2015, 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, 2013, 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 elsewhere in 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, 2013 and 2012, which are attached as Item 8 of this Annual Report on Form 10-K. 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 evaluates 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, using a fair value based test.

### **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 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 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 estimate 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. Raw materials consist of purchased material as well as sub-assemblies for which some labor has been applied. 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” 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. as of December 31, 2013 and 2012 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, 2013. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2013, 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 accumulated a deficit of \$98.3 million, including a net loss of \$28.4 million for the year ended December 31, 2013, and has not generated significant revenue or positive cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ BDO USA, LLP

Raleigh, North Carolina  
March 5, 2014

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

	December 31, 2013	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	\$ 10,014	\$ 8,896
Short-term investments	6,191	907
Accounts receivable, net	188	536
Interest receivable	68	16
Inventory, net	701	1,382
Other current assets	593	235
Total Current Assets	17,755	11,972
Restricted cash	375	375
Property and equipment, net	1,864	1,767
Intellectual property, net	2,741	3,241
Trade names, net	10	-
Goodwill	93,842	-
Other long term assets	127	205
Total Assets	\$ 116,714	\$ 17,560
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current Liabilities		
Accounts payable	\$ 1,804	\$ 521
Accrued expenses	1,406	538
Note payable - current portion	3,879	1,519
Total Current Liabilities	7,089	2,578
Long Term Liabilities		
Preferred stock warrant liability	-	109
Note payable - less current portion	4,602	8,481
Total Liabilities	11,691	11,168
Commitments and Contingencies		
Redeemable Convertible Preferred Stock		
Series A Redeemable Convertible Preferred Stock, \$0.001 par value, 5,734,402		
shares authorized; and 5,696,261 shares issued and outstanding at December 31, 2012	-	19,885
Series B Redeemable Convertible Preferred Stock, \$0.001 par value, 11,504,298	-	40,016
shares authorized; and 11,489,972 shares issued and outstanding at		

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December 31, 2012		
Series B-1 Redeemable Convertible Preferred Stock, \$0.001 par value, 48,454,545 shares authorized; and 45,998,220 shares issued and outstanding at December 31, 2012	-	15,104
Stockholders' Equity (Deficit)		
Common stock \$0.001 par value, 750,000,000 and 130,322,900 shares authorized at December 31, 2013 and December 31, 2012, respectively; 244,207,733 and 5,391,095 shares issued and outstanding at December 31, 2013 and December 31, 2012, respectively	244	5
Additional paid-in capital	203,043	1,288
Accumulated deficit	(98,264)	(69,906)
Total Stockholders' Equity (Deficit)	105,023	(68,613)
Total Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)	\$ 116,714	\$ 17,560

*See accompanying notes to consolidated financial statements.*



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

	Years ended December 31, 2013	2012
Sales	\$ 1,431	\$ 2,115
Operating Expenses		
Cost of goods sold	4,810	4,420
Research and development	12,700	6,283
Sales and marketing	1,943	3,723
General and administrative	4,221	2,763
Loss on disposal of property and equipment	450	-
Merger expenses	2,911	-
Total Operating Expenses	27,035	17,189
Operating Loss	(25,604)	(15,074)
Other (Expense) Income		
Remeasurement of fair value of preferred stock warrant liability	(1,800)	-
Interest expense, net	(954)	(351)
Total Other (Expense) Income, net	(2,754)	(351)
Net Loss	\$ (28,358)	\$ (15,425)
Other comprehensive income (loss)	-	-
Comprehensive loss	\$ (28,358)	\$ (15,425)
Net loss per share - basic and diluted	\$ (0.45)	\$ (2.86)
Weighted average common shares outstanding - basic and diluted	63,655	5,391

*See accompanying notes to consolidated financial statements.*

**TransEnterix, Inc.**  
**Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit)**  
(in thousands)

	Preferred Stock		Series B Shares	Amount	Series B-1		Preferred Stock		Common Shares
	Series A Shares	Amount			Shares	Amount	Series B Shares	Amount	
Balance, December 31, 2011	5,734	\$ 19,972	11,504	\$ 40,020	45,121	\$ 14,822	-	-	5,282
Proceeds from Issuance of Series B-1 Preferred Stock net of issuance costs of \$21	-	-	-	-	877	268	-	-	-
Accretion of issuance costs	-	46	-	46	-	14	-	-	-
Stock based compensation	-	-	-	-	-	-	-	-	-
Exercise of stock options	-	-	-	-	-	-	-	-	48
Conversion of preferred stock to common stock	(38)	(133)	(14)	(50)	-	-	-	-	61
Net loss	-	-	-	-	-	-	-	-	-
Balance, December 31, 2012	5,696	\$ 19,885	11,490	\$ 40,016	45,998	\$ 15,104	-	-	5,391
Accretion of issuance costs	-	-	-	31	-	9	-	-	-
Stock-based compensation	-	-	-	-	-	-	-	-	-
Exercise of stock options	-	-	-	-	-	-	-	-	341
Exercise of warrants	-	-	-	-	-	-	-	-	833
Reverse acquisition recapitalization adjustment	(5,696)	(19,885)	(11,490)	(40,047)	(45,998)	(15,113)	-	-	162,217
Redemption of TransEnterix Surgical shares for cash to	-	-	-	-	-	-	-	-	(271)

non-accredited investors									
Conversion of preferred stock warrants to common stock warrants	-	-	-	-	-	-	-	-	-
Issuance of preferred stock	-	-	-	-	-	-	7,570	30,197	-
Conversion of preferred stock to common stock	-	-	-	-	-	-	(7,570)	(30,197)	75,697
Net loss	-	-	-	-	-	-	-	-	-
Balance, December 31, 2013	-	\$ -	-	\$ -	-	\$ -	-	\$ -	244,208

*See accompanying notes to consolidated financial statements. See Note 18 for information on the Reverse Merger and the applicable conversion ratio applied to historical common stock amounts.*

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

	Years ended December 31, 2013	2012
Operating Activities		
Net loss	\$ (28,358)	\$ (15,425)
Adjustments to reconcile net loss to net cash and cash equivalents used in		
operating activities:		
Depreciation and amortization	1,483	1,713
Amortization of debt issuance costs	103	39
Remeasurement of fair value of preferred stock warrant liability	1,800	(19)
Accretion/amortization of bond discount/premium	52	144
Stock-based compensation	941	343
Loss on disposal of property and equipment	31	48
Impairment loss on property and equipment	450	-
Changes in operating assets and liabilities:		
Accounts receivable	402	(226)
Interest receivable	(52)	(16)
Inventory	731	(143)
Other current and long term assets	(328)	(108)
Restricted cash	-	125
Accounts payable	641	(139)
Accrued expenses	868	(484)
Net cash and cash equivalents used in operating activities	(21,236)	(14,148)
Investing Activities		
Purchase of investments	(6,240)	(8,150)
Proceeds from sale and maturities of investments	904	7,098
Cash received in acquisition of a business, net of cash paid	246	-
Purchase of property and equipment	(1,377)	(184)
Proceeds from sale of property and equipment	-	49
Net cash and cash equivalents used in investing activities	(6,467)	(1,187)
Financing Activities		
Proceeds from issuance of debt	1,998	10,000
Payment of debt	(1,519)	-
Proceeds from issuance of preferred stock, net of issuance costs	28,199	268
Debt issuance costs	-	(44)
Proceeds from exercise of stock options and warrants	143	3
Net cash and cash equivalents provided by financing activities	28,821	10,227
Net increase (decrease) in cash and cash equivalents	1,118	(5,108)
Cash and Cash Equivalents, beginning of year	8,896	14,004
Cash and Cash Equivalents, end of year	\$ 10,014	\$ 8,896

## Supplemental Disclosure for Cash Flow Information

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Interest paid	\$ 824	\$ 306
Supplemental Schedule of Noncash Investing and Financing Activities		
Issuance of preferred stock warrants and debt issuance costs	\$ -	\$ 128
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.*

**TransEnterix, Inc.**

**Notes to Financial Statements**

**1. Organization and Capitalization**

TransEnterix, Inc., formerly known as SafeStitch Medical, Inc., a Delaware corporation (“SafeStitch”) was originally incorporated in August 1988 as NCS Ventures Corp., after which NCS Ventures Corp. name was changed to Cellular Technical Services Company, Inc. On September 4, 2007, Cellular Technical Services Company, Inc. acquired SafeStitch LLC, and, in January 2008, changed its name to SafeStitch Medical, Inc. On September 3, 2013, SafeStitch and TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (“TransEnterix Surgical”) 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 corporate 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 business of SafeStitch Medical, Inc. prior to the Merger, and the term “TransEnterix Surgical” refers to the business of TransEnterix Surgical, Inc. prior to the Merger.

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 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 105,549,746 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.

In connection with the Merger, the Company entered into a securities purchase agreement with certain private 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 7,569,704.4 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 (the “Private Placement”). Each share of Series B Preferred Stock was automatically converted upon authorization of additional common shares into ten shares of our common stock, par value \$0.001 per share, on December 6, 2013.

The Company is a medical device company that is focused on the development and commercialization of a robotic assisted surgical system called the SurgiBot System (“the SurgiBot System”). The SurgiBot System utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, at the patient’s bedside. The flexible nature of the SurgiBot System allows 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 integrates three-dimensional, (“3-D”), high definition vision technology. The Company has also commercialized the SPIDER® 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 controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The product is U.S. Food and Drug Administration cleared. The Company sells its products through a direct sales force and international distributors.

Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity and GERD.

The Company operates in one business segment.

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## **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 \$98.3 million, including a net loss of \$28.4 million for the year ended December 31, 2013, 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, cease operations and/or seek bankruptcy protection.

### ***Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Isis Tele-Communications, Inc., which has no current operations, 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, SafeStitch and TransEnterix Surgical, 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.

### ***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 \$375,000 as of December 31, 2013 and 2012.

The Company's investments consist of corporate bonds and are 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 and other income. 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 and other income.

### ***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, 2013 and 2012, 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, 2013 and 2012.

### ***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 61% of the Company's net accounts receivable at December 31, 2013. The Company had two customers who constituted 42% and 13%, respectively, of the Company's net accounts receivable at December 31, 2012. The Company had one customer who accounted for 37% and 21% of revenues in 2013 and 2012, respectively.

### ***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. Raw materials consist of purchased material as well as sub-assemblies for which some labor has been applied. The Company records 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.

### ***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, 2013 or 2012.

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, 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.

### ***Impact of Recently Issued Accounting Standards***

In July 2013, the Financial Accounting Standards Board issued ASU No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," which updated the guidance in ASC Topic 740, Income Taxes. The amendments in ASU 2013-11 provide guidance for the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The guidance requires an unrecognized tax benefit to be presented as a decrease in a deferred tax asset where a net operating loss, a similar tax loss, or a tax credit carryforward exists and certain criteria are met. This guidance is effective January 1, 2014. The Company does not expect adoption of this guidance to have a material impact on its consolidated results of operations and financial condition.

Effective January 1, 2013, the Company adopted the amended guidance in ASC Topic 220, Comprehensive Income. The amended guidance requires entities to disclose additional information about reclassification adjustments, including (1) changes in accumulated other comprehensive income by component and (2) significant items reclassified out of accumulated other comprehensive income by presenting the amount reclassified and the individual income statement line items affected. The adoption of ASU No. 2013-02 did not have a material impact on the Company’s consolidated financial position or results of operations.

### ***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***

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Property and equipment consists primarily of molds, 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:

Molds	3 years
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 on the accompanying balance sheet. 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 upon the date of the Merger, the preferred stock warrant liability was reclassified into additional paid-in capital.

Significant assumptions used in the valuation of the preferred stock warrants liability December 31, 2012 were as follows:

Exercise price	\$ 0.29	
Risk-free interest rate	1.78	%
Expected volatility	160	%
Expected life (years)	9	
Expected dividend yield	0	%

***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 employee stock options. Compensation expense for stock-based compensation was \$941,245 and \$343,137 for the years ended December 31, 2013 and 2012, 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 net loss is equal to its net loss for all periods presented.

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

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

	December 31 2013 (In thousands)	2012
Cash	\$ 930	\$ 729
Money market	9,084	8,167
Total cash and cash equivalents	\$ 10,014	\$ 8,896
Corporate bonds	\$ 6,191	\$ 907
Total short-term investments	\$ 6,191	\$ 907
Total restricted cash	\$ 375	\$ 375
Total	\$ 16,580	\$ 10,178



#### 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.

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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 and liabilities measured at fair value on a recurring basis as of December 31, 2013 and 2012, 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, 2013 (In thousands)			Total December 31, 2013
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (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

Description	December 31, 2012 (In thousands)			Total December 31, 2012
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets measured at fair value				
Cash and Cash Equivalents	\$ 8,896	\$ -	\$ -	\$ 8,896
Restricted Cash	375	-	-	375
Short term investments	-	907	-	907
Total Assets measured at fair value	\$ 9,271	\$ 907	\$ -	\$ 10,178
Liabilities measured at fair value				
Preferred Stock Warrant Liability	\$ -	\$ -	\$ (109)	\$ (109)
Total Liabilities measured at fair value	\$ -	\$ -	\$ (109)	\$ (109)



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

	December 31, 2013 (In thousands)	2012
Fair value at beginning of year	\$ 109	\$ -
Issuances	-	128
Change in fair value recorded in other income (expense)	1,800	(19)
Reclassification to additional paid-in capital upon the merger	(1,909)	-
Fair value at end of year	\$ -	\$ 109

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
December 31, 2013				
Corporate bonds	\$ 6,191	\$ -	\$ -	\$ 6,191
December 31, 2012				
Corporate bonds	\$ 907	\$ -	\$ -	\$ 907

None of the securities have contractual maturities of more than one year and therefore do not have continuous unrealized losses greater than 12 months. Gross realized gains were \$0 and \$177 for the years ended December 31, 2013 and 2012, respectively.

## 6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	December 31, 2013 (In thousands)	December 31, 2012
Gross accounts receivable	\$ 220	\$ 586
Allowance for uncollectible accounts	(32)	(50)
Total accounts receivable, net	\$ 188	\$ 536

**7. Inventories**

The following table presents the components of inventories:

	December 31, 2013 (In thousands)	December 31, 2012
Finished goods	\$ 896	\$ 708
Raw materials	-	784
Reserve for excess and obsolete inventory	(195)	(110)
Total inventories	\$ 701	\$ 1,382

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.

**8. Property and Equipment**

Property and equipment consisted of the following:

	December 31, 2013 (In thousands)	December 31, 2012
Machinery and manufacturing equipment	\$ 2,453	\$ 2,722
Molds	-	1,228
Computer equipment	1,327	1,081
Furniture	287	286
Leasehold improvements	1,249	673
Total property and equipment	5,316	5,990
Accumulated depreciation and amortization	(3,452)	(4,223)
Property and equipment, net	\$ 1,864	\$ 1,767

Depreciation expense was \$982,616 and \$1,212,819, for the years ended December 31, 2013 and 2012, respectively.

During the year ended December 31, 2013, an impairment charge of \$449,853 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,	December 31,
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	2013 (In thousands)	2012
Patents	\$ 5,000	\$ 5,000
Accumulated amortization	(2,259)	(1,759)
Intellectual property, net	\$ 2,741	\$ 3,241

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Amortization expense was \$500,004 for the years ended December 31, 2013 and 2012. At December 31, 2013, the estimated amortization expense for each of the five succeeding years is approximately \$500,000 per year. 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 in the amount of \$109,133 and \$43,853 during the years ended December 31, 2011 and 2012, respectively. 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 \$65,318 and \$28,285 for the years ended December 31, 2013 and 2012, respectively.

In January 2012, TransEnterix Surgical recorded \$63,030 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 resulting in \$15,921 and \$10,539 of interest expense for the years ended December 31, 2013 and 2012, respectively.

In December 2012, TransEnterix Surgical recorded \$65,455 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 resulting in \$21,601 and \$592 of interest expense for the year ended December 31, 2013 and 2012, respectively.

Total amortization expense related to issuance of warrants was \$37,522 and \$39,416 for the years ended December 31, 2013 and 2012, respectively. Total accumulated amortization for the warrant issuance costs was \$76,938 and \$39,416 at December 31, 2013 and 2012, 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, 2013 or December 31, 2012. 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):

	2013	2012
Current deferred tax assets:		
Inventory reserves	\$ 71	\$ 41
Accrued expenses	331	77
Deferred Rent	14	30
Allowance for uncollectible accounts receivable	12	18
Valuation allowance	(428)	(166)
Net current deferred tax asset		
Noncurrent deferred tax assets:		
Stock-based compensation	1,170	186

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Contribution carryforward	2	
Research credit carryforward	2,307	874
Fixed assets	235	141
Capitalized start up costs	4,676	2,180
Net operating loss carryforwards	38,286	22,820
	46,676	26,201
Valuation allowance	(46,672)	(26,201)
Net noncurrent deferred tax asset	4	
Noncurrent deferred tax liability		
Purchase accounting intangibles	(4)	
Net deferred tax asset (liability)	\$	\$

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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, 2013 and 2012, 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 \$20.7 million from the prior year. At December 31, 2013, the Company had federal and state net operating loss tax carryforwards of approximately \$104.7 million and \$75.6 million, respectively. These net operating loss carryforwards expire in various amounts starting in 2027 and 2022, respectively. At December 31, 2013, the Company had federal research credit carryforwards in the amount of \$2.3 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.

On July 23, 2013, North Carolina enacted House Bill 998, which reduced the corporate income tax rate from 6.9% in 2013 to 6% in 2014 and to 5% in 2015. As a result of the new enacted tax rate, the Company adjusted its deferred tax assets in 2013 by applying the lower rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately \$0.4 million.

The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2013 and 2012, the Company has not recorded any amounts associated with unrecognized tax benefits.

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2013, the Company had no accrued interest 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 2010, although carryforward attributes that were generated prior to 2010 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:

	2013		2012			
	Amount	Percent of Pretax Earnings	Amount	Percent of Pretax Earnings		
United States federal tax statutory rate	\$ (9,642)	34.0 %	\$ (5,245)	34.0 %		
State taxes (net of deferred benefit)	(662)	2.3 %	(469)	3.0 %		
Non-deductible expenses	1,556	(5.5) %		0.0 %		
Change in valuation allowance	20,733	(73.1) %	5,101	(33.1) %		
Adjustment for valuation allowance recorded as part of purchase accounting	(11,785)	41.6 %		0.0 %		
Other, net	(200)	0.7 %	613	(3.9) %		

Provision for income taxes	\$	0.0	%	\$	0.0	%
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## 12. Related-Party Transactions

At December 31, 2012, Synecor, LLC owned 37% of the common stock of TransEnterix Surgical. In addition, at December 31, 2012, Synecor, LLC and its shareholders and officers collectively owned approximately 85% of the common stock of TransEnterix Surgical, as well as 17% of the preferred stock of TransEnterix Surgical. At December 31, 2013, Synecor, LLC and its shareholders and officers collectively owned approximately 12% of the Company's common stock. Various research and development services were purchased from Synecor LLC and its wholly owned subsidiary Synchrony Labs LLC and totaled approximately \$90,000 and \$108,000 for the years ended December 31, 2013 and 2012, respectively.

The Company's directors Dr. Hsiao and Dr. Frost 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") (formerly known as Cardo Medical, Inc.), a publicly-traded medical device company, and TigerMedia, Inc. ("TigerMedia") (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 TigerMedia and as the Chief Legal Officer of each of NIMS and Tiger X. Additionally, the Company's former Chief Financial Officer, also serves as the Chief Financial Officer and supervises the accounting staff of NIMS under a Board-approved cost sharing arrangement whereby the total 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, 2013 of \$55,000, 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 \$14,000 as of December 31, 2013 and are included in other receivable related party.

SafeStitch entered into a five-year lease for office space in Miami, Florida with a company controlled by Dr. Frost. 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 and are currently on a month-to-month basis. The Company recorded \$48,000 of rent expense related to the Miami lease for the year ended December 31, 2013.

## 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 5,000,000 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 5,000,000 shares of common stock to 24,700,000 shares of common stock, (b) increase the per-person award limitations for options or stock appreciation rights from 1,000,000 to 2,500,000 shares and for restricted stock, deferred stock, performance shares and/or other stock-based awards from 500,000 to 1,000,000 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 and, within any 12 month period. 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 400,000 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 5,550,264. In 2011, the 2006 Plan was amended to increase the total options pool to 16,890,945. 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, 2013 and 2012, the Company recognized \$941,245 and \$343,137, respectively, of stock-based compensation expense.

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:

Year ended December 31,	2013	2012
Expected dividend yield	0%	0%
Expected volatility	62%-63%	55% - 67%
Risk-free interest rate	1.64% - 1.98%	0.4% - 3.7%
Expected life (in years)	5.7 6.1	2.9 - 10.0

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 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 during the year ended December 31, 2012, and also for options granted prior to the Merger in fiscal 2013.

The following table summarizes the Company's stock option activity, including grants to non-employees, for the years ended December 31, 2013 and 2012:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Options outstanding at December 31, 2011	4,164,090	\$ 0.48	7.58
Granted	11,769,866	0.07	
Cancelled	(2,962,834)	0.14	
Exercised	(48,356)	0.07	
Options outstanding at December 31, 2012	12,922,766	\$ 0.08	8.70
Options assumed through merger with SafeStitch	3,547,750	0.75	
Granted	3,015,696	0.44	
Cancelled	(30,643)	0.08	
Exercised	(341,133)	0.16	
Options outstanding at December 31, 2013	19,114,436	\$ 0.26	7.95

The following table summarizes information about stock options outstanding at December 31, 2013:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Exercisable at December 31, 2013	10,031,605	\$ 0.30	7.23
Vested or expected to vest at December 31, 2013	18,788,438	\$ 0.26	7.94

The aggregate intrinsic value of stock options outstanding, exercisable, and vested or expected to vest at December 31, 2013 was approximately \$24.8 million, \$12.7 million, and \$24.3 million, respectively. This amount is before applicable income taxes and represents the closing market price of the Company's common stock at December 31, 2013 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 Fair Value
Unvested options at December 31, 2011	1,683,733	\$ 0.33
Granted	11,769,866	0.07
Vested	(3,612,025)	0.14
Forfeited	(1,303,895)	0.23
Unvested options at December 31, 2012	8,537,679	\$ 0.08
Unvested options assumed through merger with SafeStitch	1,116,000	0.49
Granted	3,015,696	0.19
Vested	(3,559,092)	0.25
Forfeited	(27,452)	0.04
Unvested options at December 31, 2013	9,082,831	\$ 0.22

The Company granted 3,015,696 and 11,769,866 options to employees and nonemployees during the years ended December 31, 2013 and 2012, respectively, with a weighted-average grant date fair value of \$0.19 and \$0.07, respectively. The total intrinsic value of options exercised during 2013 and 2012 was approximately \$347,593 and \$0, respectively.

The total fair value of options vested during 2013 and 2012 was \$879,826 and \$263,751, respectively. As of December 31, 2013, the Company had future employee stock-based compensation expense of \$1,790,930 related to unvested share awards, which is expected to be recognized over an estimated weighted-average period of 2.6 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 year ended December 31, 2013:

	Number of Restricted Stock Units Outstanding	Weighted Average Grant Date Fair Value
Unvested, December 31, 2012	-	-
Granted	1,050,000	\$ 1.44
Vested	-	-
Unvested, December 31, 2013	1,050,000	\$ 1.44



As of December 31, 2013, the Company recorded \$121,169 in compensation expense for the RSUs. As of December 31, 2013, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$1.4 million, which is expected to be recognized over a weighted average period of approximately 2.8 years. The weighted average grant date fair value of the RSUs granted in 2013 was \$1.44.

## 15. Warrants

On March 22, 2013, SafeStitch entered into a stock purchase agreement (the “2013 Stock Purchase Agreement”) with approximately 17 investors (the “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 PIPE Warrants to purchase approximately 6,048,000 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 2013 PIPE Investors purchasing Shares were related parties who purchased 6.4 million shares and received 3.2 million warrants. There were approximately 6 million warrants outstanding that were assumed as of the Merger. During the year ended December 31, 2013, 270,000 warrants were exercised.

On January 17, 2012, TransEnterix Surgical entered into the SVB-Oxford Loan and Security Agreement with Silicon Valley Bank (“SVB”) and Oxford Finance LLC (“Oxford”). Pursuant to this agreement, TransEnterix Surgical issued preferred stock warrants to SVB and Oxford on January 17, 2012 and December 21, 2012, respectively, to purchase shares of capital stock. The warrants expire 10 years from the issue date. The 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 statements 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 1,397,939 shares of common stock. During the year ended December 31, 2013, 698,967 warrants were exercised in a cashless transaction for 563,834 shares of common stock. The summary of warrant activity for the years ended December 31, 2012 and 2013 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Weighted Average Fair Value
Outstanding at January 1, 2012	-	\$ -	-	\$ -
Granted	1,397,939	0.29	9.1	0.11
Exercised	-	-	-	-
Expired/cancelled	-	-	-	-
Outstanding at December 31, 2012	1,397,939	\$ 0.29	9.1	\$ 0.09
Granted				
Warrants assumed in merger with SafeStitch	5,998,000	0.33	4.3	0.23
Exercised	(968,969)	0.29	-	1.05
Expired/cancelled	-	-	-	-
Outstanding at December 31, 2013	6,426,970	\$ 0.29	4.7	\$ 0.35

The aggregate intrinsic value of the preferred stock warrants in the above table was \$8.7 million and \$0 at December 31, 2013 and 2012, 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 Company’s Series B-1 Preferred Stock as of the respective dates.

## 16. Notes Payable

On January 17, 2012, TransEnterix Surgical entered into a loan and security agreement (the "SVB-Oxford LSA") with Silicon Valley Bank and Oxford Finance, LLC (collectively, "the Lenders"). The terms of the agreement provide 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 outstanding credit facility. The Second and Third Amendment to the SVB-Oxford LSA, dated as of September 3, 2013 and October 31, 2013, respectively, amend the SVB-Oxford LSA among the lenders and the Company (as so amended, the "Amended Loan Agreement"). The Amended Loan Agreement evidences a term loan, which will mature on January 1, 2016 (the "Term Loan"). The following table presents the components of long-term debt:

As of December 31, 2013 future principal payments under the Company's notes payable agreements are as follows:

Years ending December 31, (In thousands)	
2014	\$ 3,879
2015	4,232
2016	370
Total	\$ 8,481

The Term Loan bears interest at a fixed rate equal to 8.75 %.

Commencing August 2013, the Amended Loan Agreement provides for the amortization of principal in the form of level monthly payments of principal and interest. The Term Loan will be required to be prepaid if the Term Loan is accelerated following an event of default. In addition, the Company is permitted to prepay the Term Loan 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 Loan, or prepayment of the Term Loan, the Company is required to make a final payment equal to the original principal amount of the Term Loan multiplied by 3.33 % (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, the Lenders' expenses, and all other obligations that are due and payable to the Lenders.

The Amended Loan Agreement is secured by a security interest in substantially all assets of the Company and any future subsidiaries, other than intellectual property. The Amended Loan Agreement contains customary representations, tested on a continual basis 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; fail to appoint a chief executive officer, chief financial officer, and chief technology officer upon vacancy; undergo a change in control; add or change business locations; and engage in businesses that are not related to the Company's existing business.

In conjunction with the SVB-Oxford LSA, TransEnterix Surgical issued the Lenders warrants to purchase 1,397,939 shares of the Company'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, 2013 and 2012, 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:

	December 31, 2013	2012
Stock options	19,114,436	12,922,766
Stock warrants	6,426,968	1,397,939
Nonvested Restricted stock units	1,050,000	
Total	26,591,404	14,320,705

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## 18. Closing of Merger and Financing Transaction

On September 3, 2013, the Company consummated the Merger in which a wholly owned subsidiary of SafeStitch merged with TransEnterix Surgical, pursuant to the Merger Agreement. Under the terms of the Merger Agreement, TransEnterix Surgical remained as the surviving corporation and as a wholly-owned subsidiary 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 105,549,746 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 Loan and Security Agreement dated as of January 17, 2012, among Oxford, SVB and TransEnterix Surgical. The Bridge Notes were converted into Series B preferred stock at the effective time of the Merger.

Concurrent with the closing of the Merger, and in accordance with the terms of a Securities 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 ten (10) 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. The majority of the Series B Preferred Stock was issued to related parties who were existing stockholders of SafeStitch and TransEnterix Surgical. Pursuant to the Securities Purchase Agreement, the Company issued and sold an additional 25,000 shares of Series B Preferred Stock within the period provided in the Securities Purchase Agreement resulting in gross proceeds to the Company of approximately \$100,000. 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.

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	61,749
Closing price per share	\$ 1.52
	\$ 93,858
Cash consideration	293
Total purchase price	\$ 94,151

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The purchase price was allocated to the net assets acquired utilizing the methodology prescribed in ASC 805. The Company recorded goodwill of \$93.9 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

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	\$ (0.17)	\$ (0.13)



## 19. Stockholders' Equity (Deficit)

### 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.

TransEnterix Surgical recorded the shares of redeemable convertible preferred stock at their fair values at issuance, net of issuance costs. These shares have been presented outside of permanent equity due to the redemption feature. The carrying value of TransEnterix Surgical's redeemable convertible preferred stock was increased by periodic accretion using the effective interest method so that the carrying amount will equal the redemption value at the redemption date.

#### *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, 2013 and 2012.

### ***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.

### *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 \$40,000 and \$106,300 for the years ended December 31, 2013 and 2012, 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.

On December 6, 2013, the Company increased the number of shares of common stock authorized from 225,000,000 to 750,000,000.

As of December 31, 2013, 25,000,000 shares of preferred stock are authorized, no shares are issued and outstanding.

### **20. 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.



## 21. 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, with an option to renew for an additional six 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 \$360,000 for each of the years ended December 31, 2013 and 2012. As of December 31, 2013, the Company's approximate future minimum payments for its operating lease obligations are as follows:

Years ending December 31, (In thousands)	
2014	\$ 498
2015	218
2016	117
2017	121
2018	124
Total	\$ 1,078

TransEnterix Surgical leases its manufacturing facility under a one-year lease from third parties. Rent expense under this lease was \$54,533 and \$51,455 for the years ended December 31, 2013 and 2012, respectively. SafeStitch leases various office space on a month to month basis. Rent expense under these leases was \$55,301 for the year ended December 31, 2013, including \$48,000 to a company controlled by a shareholder.

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 20). 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. Royalties were incurred in the amount of \$1,300 during the year ended December 31, 2012 and no royalties were incurred during the year ended December 31, 2013.

The Company has placed orders with various suppliers for the purchase of certain tooling, inventory and contract engineering and research services. Each of these orders has a duration or expected completion within the next twelve months. The Company currently has no material commitments with terms beyond twelve months.

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

As reported on a Form 8-K, filed September 30, 2013, on September 25, 2013, the Audit Committee of the Board of Directors appointed BDO USA, LLP (BDO) as the Company's principal independent registered public accountant to audit the Company's consolidated financial statements for the fiscal year ended December 31, 2013. This action effectively dismissed EisnerAmper LLP (EisnerAmper) as of September 25, 2013, as the Company's principal independent registered public accountants.

**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, 2013. 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.

In December 2013, our management identified that the Company did not include a shareholder advisory vote on "say-on-pay" or a shareholder advisory vote on "say-on-frequency" as required by Rule 14a-21 in the SafeStitch proxy statement for its 2013 annual meeting of stockholders. SafeStitch was a smaller reporting company at the time and failure to include such advisory votes was inadvertent. Management re-evaluated the effectiveness of the Company's disclosure controls and procedures for the quarters ended June 30, 2013 and September 30, 2013, and concluded that the Company's disclosure controls and procedures were not effective for those quarters in ensuring that all requirements were met in 2013 with respect to the Company's proxy statement. The Company is implementing additional procedures, including securities counsel review of all future SEC filings to ensure that all requirements, including the requirements of Rule 14a-21, are met. Based on such evaluation, and with such changes implemented, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2013, 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, 2013, 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 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that, as of December 31, 2013, 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**

The information required by this Item is incorporated by reference to our Proxy Statement for the 2014 Annual Meeting of Stockholders (the Proxy Statement).

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference to the Proxy Statement.

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

The information required by this Item is incorporated by reference to the Proxy Statement.

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

The information required by this Item is incorporated by reference to the Proxy Statement.

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

The information required by this Item is incorporated by reference to the Proxy Statement.

**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:

<u>Consolidated Financial Statements</u>	Page
Report of Independent Registered Public Accounting Firm	52
Consolidated Balance Sheets as of December 31, 2013 and 2012	53
Consolidated Statements of Operations and Comprehensive Loss for each of the years in the two-year period ended December 31, 2013	54
Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit) for each of the years in the two-year period ended December 31, 2013	55
Consolidated Statements of Cash Flows for each of the years in the two-year period ended December 31, 2013	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  
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).  |
| 3.2     | 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 29, 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	Development and Supply Agreement, dated as of November 4, 2011, by and between TransEnterix Surgical, Inc. and Microline Surgical, Inc. (filed as Exhibit 10.5 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein)
10.7	Loan and Security Agreement dated as of January 17, 2012, by and among the Registrant, Silicon Valley Bank and Oxford Finance LLC, as amended, and associated notes and warrants issued by TransEnterix to Silicon Valley Bank and Oxford Finance LLC (filed as Exhibit 10.8 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 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 +	Offer letter, dated as of June 9, 2008, by and between the Registrant and Todd M. Pope (filed as Exhibit 10.6 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and

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incorporated by reference herein).

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<b>Exhibit No.</b>	<b>Description</b>
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).
10.12 +	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).
10.12 +	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).
10.13 +	Offer letter, dated as of August 30, 2013, by and between SafeStitch Medical, Inc. and James J. Martin (filed as Exhibit 10.12 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.
10.16 + *	Form of Employee Stock Option Agreement (performance stock options) pursuant to the 2007 Plan.
10.17 + *	Form of Non-Employee Stock Option Agreement pursuant to the 2007 Plan.
10.18 + *	Form of Restricted Stock Unit Agreement pursuant to the 2007 Plan.
10.19 + *	Restricted Stock Unit Agreement, dated as of October 2, 2013, by and between the Company and Joseph P. Slattery.
10.20	Note and Security Agreement, dated as of September 4, 2007, by and among the Registrant, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens (filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on September 10, 2007 and incorporated by reference herein).
10.20.1	First Amendment to Note and Security Agreement, dated March 25, 2009, by and among the Registrant, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens (filed as Exhibit 10.8 to our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 27, 2009 and incorporated by reference herein).
10.20.2	Second Amendment to Note and Security Agreement, dated March 29, 2010, by and among the Registrant, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens (filed as Exhibit 10.14 to our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 31, 2010 and incorporated by reference herein).
10.20.3	Third Amendment to Note and Security Agreement, dated March 28, 2011, by and among the Registrant, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens (filed as Exhibit 10.20 to



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our Annual Report on Form 10-K for the year ended December 31, 2010, filed with the SEC on March 30, 2011 and incorporated by reference herein).

<b>Exhibit No.</b>	<b>Description</b>
10.20.4	Fourth Amendment to Note and Security Agreement, dated August 10, 2011, by and among the Registrant, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed with the SEC on August 12, 2011 and incorporated by reference herein).
10.21	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).
10.22	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).
10.23	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).
10.24	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).
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
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

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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.

\* Filed herewith.

**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.

**TransEnterix, Inc.**

Date: March 5, 2014

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 Todd M. Pope	President, Chief Executive Officer and a Director (principal executive officer)	March 5, 2014
/s/ Joseph P. Slattery Joseph P. Slattery	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 5, 2014
/s/ Paul A. LaViolette Paul A. LaViolette	Chairman of the Board and a Director	March 5, 2014
/s/ Dennis J. Dougherty Dennis J. Dougherty	Director	March 5, 2014
/s/ Phillip Frost Phillip Frost, M.D.	Director	March 5, 2014
/s/ Jane H. Hsaio Jane H. Hsaio, Ph.D.	Director	March 5, 2014
/s/ Aftab R. Kherani Aftab R. Kherani	Director	March 5, 2014
/s/ David B. Milne David B. Milne	Director	March 5, 2014
/s/ Richard C. Pfenniger, Jr. Richard C. Pfenniger, Jr.	Director	March 5, 2014
/s/ William N. Starling, Jr. William N. Starling, Jr.	Director	March 5, 2014

