

TRANSENERIX INC.  
Form 10-K/A  
April 02, 2014  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-K/A**  
**AMENDMENT NO. 3**

x **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**

**TRANSENERIX, INC.**

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

**Delaware** **11-2962080**  
**(State or other jurisdiction of** **(I.R.S. Employer**  
**incorporation or organization)** **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:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>None</b>	<b>None</b>

**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 .

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 .

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

On June 30, 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 March 28, 2014 was 244,276,923. This number does not reflect the 1-for-5 reverse stock split effected by the Registrant on March 31, 2014.

**Table of Contents****TRANSENERIX, INC.****ANNUAL REPORT ON FORM 10-K/A****EXPLANATORY NOTE**

This Amendment No. 3 to Form 10-K amends our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, originally filed on March 5, 2014 and amended by Amendment No. 1 to the Form 10-K filed on March 14, 2014 and further amended by Amendment No. 2 to the Form 10-K filed on March 31, 2014. We refer to the Annual Report on Form 10-K, the Amendment No. 1 to the Form 10-K and Amendment No. 2 to the Form 10-K as the Original Filing in this Form 10-K/A Amendment No. 3. We are filing this Form 10-K/A Amendment No. 3 to revise the certifications filed as Exhibits 31.1 and 31.2 as required by Exchange Act Rule 13a-14(a) and Item 601(b)(31)(i) of Regulation S-K. Except as described above, no other changes have been made to the Original Filing. The Original Filing continues to speak as of the dates respectively filed.

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 name to TransEnterix, Inc. In this Form 10-K/A Amendment No. 3, 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 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.

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**FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K/A Amendment No. 3 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 those set forth under the heading Risk Factors in the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014.

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**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 name to TransEnterix, Inc. In this Form 10-K/A Amendment No. 3, 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 13, 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 SafeStitch common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one business day prior to the effective date of the Merger). Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, SafeStitch assumed all of TransEnterix Surgical's options and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

All references to share amounts in this Form 10-K/A Amendment No. 3 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

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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 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 Form 10-K/A Amendment No. 3 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





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developed other surgical devices, including the SMART Dilator , to be utilized in treating obesity, GERD and esophageal strictures. SafeStitch also developed and was commercializing 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 patient's abdominal wall.



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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 is continuing to develop the Gastroplasty Device for obesity. 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.

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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.

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### *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 applicators, 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.



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*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

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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



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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 (which was also used in the SMART Dilator and bite blocks products). 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. 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



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jointly by Dr. Filipi, and/or any Creighton employees or agents who work directly with him, and our employees or agents. Notwithstanding the foregoing, Creighton owns all inventions conceived of or reduced to practice under its research and development budget, and all patent applications and patents claiming such inventions, even if conceived of solely by our employees or agents, and such inventions, patent applications and all resulting licensed patent rights are subject to the Creighton Agreement. The Company has seven years after the later of the effective date of the Creighton Agreement or the disclosure and acceptance of a licensed patent and associated know-how (each as defined in the Creighton Agreement) to commence development of the licensed patent or commercially exploit the licensed products developed. We believe the Company's work in developing the Gastroplasty Device has satisfied this requirement; however, if necessary, such seven-year term can be extended by the Company by payment, per licensed patent, of a term extension fee. If the Company fails to develop or commercially exploit a licensed patent and associated know-how within such term, the licensed patent and associated know-how revert back to Creighton. Otherwise, no specific term is established under the Creighton Agreement. Our 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.

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### **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





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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 or that the SurgiBot System is a Class II device. If that were to occur, we would be required to undertake the more complex and costly PMA process or perhaps be considered for a de novo reclassification. However, for either the 510(k), de novo, or the PMA process, the FDA could require us to conduct clinical trials, which would take more time, cost more money and pose certain other risks and uncertainties.

We have participated in discussions with, and intend to continue to engage in discussions with, the FDA regarding the appropriate regulatory pathway for our products, with primary emphasis directed toward confirming the regulatory pathway for the SurgiBot System. While clinical trial data for Class II devices are generally not required, we have received information from 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



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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.



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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 and 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

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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 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.





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**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>.

**PART II**

**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 our Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014. The following discussion contains forward-looking statements. See cautionary note regarding Forward-Looking Statements at the beginning of this Form 10-K/A Amendment No. 3.*

**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<sup>®</sup> Surgical System, (the SPIDER System) a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilizes flexible instruments and articulating channels that are controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System 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.



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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 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 13, 2013, and amended by a First Amendment dated August 30, 2013 (collectively, the Merger Agreement) by and

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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 SafeStitch common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one business day prior to the effective date of the Merger). Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, SafeStitch assumed all of TransEnterix Surgical's options and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

Following the announcement of the Merger on August 14, 2013, the common stock price increased prior to the Merger closing date of September 3, 2013, generating additional goodwill. As of December 31, 2013, the net carrying value of our goodwill and other intangible assets totaled approximately \$96.6 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 August 2013, TransEnterix Surgical issued promissory notes (the Bridge Notes) in the aggregate principal amount of \$2.0 million. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, as amended, 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



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converted into ten (10) 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.





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### **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.

### **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.

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### **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.



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### **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. Once the SEC declares the Shelf Registration Statement effective, it will allow 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.

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**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 August 2013, TransEnterix Surgical issued promissory notes (the Bridge Notes) in the aggregate principal amount of \$2.0 million. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the 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



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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 will 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.

**Table of Contents****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
Long-term debt obligations	\$ 9.7	\$ 4.5	\$ 5.2	
Operating leases	\$ 1.1	\$ 0.5	\$ 0.5	\$ 0.1
Total contractual obligations	\$ 10.8	\$ 5.0	\$ 5.7	\$ 0.1

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

Operating lease amounts include future minimum lease payments under all our non-cancelable operating leases with an initial term in excess of one year. We rent office space under an operating lease which expires in 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 in the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014. 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 the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014. 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.

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

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

Indefinite-lived intangible assets, such as goodwill are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists, 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 our stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies. The expected term of options granted by the Company has been determined based upon the simplified method, because we do not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield is assumed to be zero. We 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.

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### **Recent Accounting Pronouncements**

See Note 2. Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements in Item 8. Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014 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 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.

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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.

**Table of Contents****PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Directors and Executive Officers**

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

The following table sets forth names, ages and positions with the Company for all directors and executive officers of the Company as of March 10, 2014:

	Age	Position	Director Since (1)
<b>Directors</b>			
Dennis J. Dougherty	66	Director	2013
Phillip Frost, M.D.	77	Director	2013
Jane H. Hsiao, Ph.D., MBA	66	Director	2005
Aftab R. Kherani, M.D.	40	Director	2013
Paul A. LaViolette	56	Director, Chairman of the Board	2013
David B. Milne	51	Director	2013
Richard C. Pfenniger, Jr.	58	Director	2005
Todd M. Pope	48	Chief Executive Officer, President, Director	2013
William N. Starling	60	Director	2013
<b>Other Executive Officers</b>			
Richard M. Mueller	41	Chief Operating Officer	
Joseph P. Slattery	49	Chief Financial Officer	

- (1) Dennis Dougherty, Aftab Kherani, Paul LaViolette, David Milne and William Starling were members of the Board of Directors of TransEnterix Surgical prior to the Merger. TransEnterix Surgical is now a wholly owned subsidiary of the Company. Mr. Dougherty served as a director of TransEnterix Surgical from September 2010 until September 3, 2013. Dr. Kherani served as a director of TransEnterix Surgical from December 2012 until September 3, 2013. Mr. LaViolette served as a director and Chairman of the Board of TransEnterix Surgical from July 2011 until September 3, 2013. Mr. Milne served as a director of TransEnterix Surgical from December 2007 until September 3, 2013. Mr. Starling served as a director of TransEnterix Surgical from its founding in July 2006

until September 3, 2013. Under the Merger Agreement, at the time of the Merger on September 3, 2013, each of Messrs. Dougherty, LaViolette, Milne and Starling and Dr. Kherani became members of the Board of Directors of the Company and resigned as members of the Board of TransEnterix Surgical.

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**Table of Contents****Directors**

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

***Dennis J. Dougherty***. Mr. Dougherty founded and has been the Managing General Partner of Intersouth Partners since 1985. Mr. Dougherty holds primary responsibility for Intersouth's life science portfolio, which includes companies in biopharmaceuticals, medical technology and agribusiness, working with companies from founding through public offering. Mr. Dougherty has served on the boards of directors of more than 40 companies, most of which were privately held. Mr. Dougherty is a founder of the North Carolina Council for Entrepreneurial Development and was a member of the Steering Committee for the Kauffman Fellows Program. He has served on the Board of Directors of the National Venture Capital Association and is on the Board of Trustees of Oklahoma City University. Mr. Dougherty was also an office managing partner for Touche Ross and Co. (now Deloitte & Touche). He holds a B.S. in Business from Oklahoma City University and completed postgraduate studies in accounting and finance at Duke University. The Board believes that Mr. Dougherty's deep experience in venture investment since his founding of Intersouth Partners, active work with biopharmaceuticals and medical technology companies, commitment to active participation with many entrepreneurial and start-up organizations, and his board service on many publicly held and privately owned companies position him to provide valuable insight and make substantial contributions to our Board.

***Phillip Frost, M.D.*** Dr. Frost currently serves as the CEO and Chairman of OPKO Health, Inc. (OPKO), a specialty healthcare company. Dr. Frost was named the Chairman of the Board of Teva Pharmaceutical Industries, Limited (Teva), in March 2010 and had previously been Vice Chairman since January 2006 when Teva acquired IVAX Corporation (IVAX). Dr. Frost had served as Chairman of the Board of Directors and Chief Executive Officer of IVAX since 1987 until its acquisition by Teva. He was Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach, Florida from 1972 to 1990. Dr. Frost was Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 until the acquisition of Key Pharmaceuticals by Schering Plough Corporation in 1986. Dr. Frost was named Chairman of the Board of Ladenburg Thalmann Financial Services Inc., an investment banking, asset management, and securities brokerage firm providing services through its principal operating subsidiary, Ladenburg Thalmann & Co. Inc., in July 2006 and has been a director of Ladenburg Thalmann from 2001 until 2002 and again since 2004. He serves as a member of the Board of Trustees of the University of Miami and as a Trustee of each of the Miami Jewish Home for the Aged, and the Mount Sinai Medical Center. Dr. Frost is also a director of Castle Brands, a developer and marketer of premium brand spirits, and a director of BioZone Pharmaceutical, Inc., a developer, manufacturer, and marketer of over-the-counter drugs. Dr. Frost previously served as a director for PROLOR Biotech, Inc. (Prolor), Continucare Corporation, Northrop Grumman Corp., Ideation Acquisition Corp., and Protalix Bio Therapeutics, Inc., and as Governor and Co-Vice-Chairman of the American Stock Exchange. Dr. Frost received his B.A. from the University of Pennsylvania and his M.D. from Albert Einstein College of Medicine. The Board believes that Dr. Frost's qualifications, attributes and skills for service on our Board include his medical background, his pertinent experience in the pharmaceutical and healthcare companies, financial expertise, knowledge of the regulatory process for obtaining product clearances and approval, industry knowledge, managerial experience and public company board service.



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

**Aftab R. Kherani, M.D.** Since September 2008, Dr. Kherani has served as a Principal of Aisling Capital. Previously, Dr. Kherani was an Engagement Manager at McKinsey & Company, where he was a member of the Pharmaceutical, Medical Product and Private Equity practices. Prior to McKinsey, Dr. Kherani was a Chief Resident in Surgery at Duke University Medical Center, where he completed his residency in general surgery. He completed a two-year post-doctoral research fellowship at Columbia University, College of Physicians & Surgeons from 2001 to 2003. Dr. Kherani currently serves as a board observer at T2 Biosystems, Inc., a privately-held company. Dr. Kherani received his M.D. from Duke, and his B.S. in Biology and A.B. in Economics from Duke. The Board believes that Dr. Kherani's qualifications, skills and attributes including his experience as a general surgeon, coupled with his strong investment background and healthcare consulting experience, position him to provide unique insights and be a valuable contributor to our Board.

**Paul A. LaViolette.** Mr. LaViolette has served as Chairman of our Board since September 2013. Mr. LaViolette is Managing Partner and Chief Operating Officer at SV Life Sciences Fund IV, L.P. (SVLS), a medical device value fund. He joined SVLS in 2009 and has over 33 years of global medical technology management experience. Prior to joining SVLS, Mr. LaViolette was most recently Chief Operating Officer at Boston Scientific Corporation (BSC), an \$8 billion medical device leader. During his 15 years at BSC, he served as COO, Group President, President-Cardiology and President-International. Mr. LaViolette integrated two dozen acquisitions and led extensive product development, operations and worldwide commercial organizations. Mr. LaViolette previously held marketing and general management positions at CR Bard, and various marketing roles at Kendall (Covidien). He currently serves on the boards of Baxano Surgical, Inc. and Thoratec Corporation, each of which are publicly held. Additionally, Mr. LaViolette serves on the boards of Cardiofocus, Inc., CardioKinetix, Inc., Coridea NC2, Inc., CSA Medical Inc., DC Devices Inc., Direct Flow Medical, Inc. and ValenTx, Inc., each of which are privately-held, as well as the Medical Device Manufacturers Association. Mr. LaViolette received his B.A. in Psychology from Fairfield University and his MBA from Boston College. Mr. LaViolette's broad experience and many attributes qualify him to serve on our Board, and as the Chairman of our Board. Mr. LaViolette's vast medical device operating experience makes him knowledgeable in the areas of product launches, new product development, clinical and regulatory affairs, plant management, quality systems, international sales and marketing, acquisitions and integrations and the analysis of investment opportunities.

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

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

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

**William N. Starling.** William N. Starling is Managing Director of Synergy Life Science Partners, LP, a life science venture capital firm founded in 2006, and Chief Executive Officer and co-founder, in 2001, of Synecor, LLC, an incubator for new life science companies. As CEO of Synecor, Mr. Starling is a cofounder of BaroSense Inc., Bioerodible Vascular Solutions, Inc., InnerPulse, Inc., TransEnterix, Interventional Autonomics Corporation, NeuroTronik Limited, and Aegis Surgical, Limited. Mr. Starling currently serves as President and CEO of Aegis Surgical and Interventional Autonomics Corporation, and as a board member of EBR Systems, Inc. and iRhythm Technologies, all of which are privately-held. He began his career in the medical technology device industry at American Edwards Laboratories and subsequently was part of the founding management team and Director of Marketing for Advanced



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Cardiovascular Systems, Inc.; a cofounder, Vice President and board member of Ventritex, Inc.; and a cofounder and Chairman of the Board of Directors and President/CEO of Cardiac Pathways Corporation. Mr. Starling received his BSBA degree from the University of North Carolina at Chapel Hill and his MBA degree from the University of Southern California. The Board believes that Mr. Starling's experience in working with companies throughout their life cycle from start-up, through IPO to publicly traded, his extensive contributions to the medical device industry and his public company board experience make him a valuable contributor to our Board.

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

**Richard M. Mueller.** Mr. Mueller has served as our Chief Operating Officer since September 3, 2013. Prior to the Merger he served as the Chief Operating Officer of TransEnterix Surgical from January 2013, after serving as its Chief Technology Officer from January 2011 until his appointment as Chief Operating Officer. Mr. Mueller oversees the innovation, development and research of TransEnterix's technologies for minimally invasive surgery. He also directs the realization of new technologies to market through the sourcing and manufacturing process. A biomechanical engineer, who received his B.S. from Case Western Reserve University, Mr. Mueller previously served, from January 2005 until January 2011 as vice president of research and development at NuVasive Inc., a publicly-traded spinal device company. Prior thereto, he was director of research and product development at Theken Spine, a start-up later acquired by Integra Life Sciences. Mr. Mueller has participated in more than 100 medical device launches and has extensive experience in the medical device industry.

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

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

Under section 16(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the Company's directors, executive officers and persons who own more than ten percent (10%) of our common stock are required to file with the Securities and Exchange Commission (the SEC), initial reports of ownership and reports of changes in ownership of the common stock and other equity securities of the Company. To the Company's knowledge, based solely on a review of copies of such reports furnished to the Company during and/or with respect to year ended December 31, 2013, the Company is not aware of any late or delinquent filings required under Section 16(a) of the Exchange Act in respect of the Company's equity securities.

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### **Code of Ethics**

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

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

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

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

### **Communication with the Board**

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

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

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

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

**SUMMARY COMPENSATION TABLE**

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	NonEquity	Nonqualified	All	Total
						Incentive Plan Compensation	Deferred Compensation	Other Compensation	
Todd M. Pope President and Chief Executive Officer (3)	2013	\$ 325,000			\$ 401,694 (4)	\$ 146,250 (5)			\$ 872,944
	2012	\$ 310,000			\$ 186,516 (4)	150,000 (5)			\$ 646,516
Joseph P. Slattery, Executive Vice President, Chief Financial Officer (6)	2013	\$ 69,103	\$ 25,000	\$ 1,430,000					\$ 1,524,103
Richard M. Mueller, Chief Technology Officer and Chief Operating Officer	2013	\$ 300,000				\$ 100,000 (5)			\$ 400,000
	2012	\$ 285,000			\$ 98,957 (7)	\$ 90,000 (5)			\$ 473,957
Jeffrey G. Spragens, former Chief Executive Officer and President (8)	2013				\$ 59,925 (9)				\$ 59,925
	2012				\$ 53,431 (9)				\$ 53,431

- (1) Represented grant of restricted stock units (RSUs) to Mr. Slattery upon his hiring. The RSU award vests in three equal installments on the first three anniversaries of the date of grant. If a change of control event (as defined in his RSU agreement) occurs and Mr. Slattery's employment is terminated involuntarily within twelve months following the change in control, the vesting of his RSUs will accelerate.
- (2) The grant date fair values reported above for stock option awards to all named executive officers except Mr. Spragens were determined by taking into account the number of shares and exercise prices in respect of such stock option awards granted by TransEnterix Surgical, but do not give effect to the exchange ratio in the Merger. As a result of the Merger, the shares underlying the stock option awards are multiplied by the Merger exchange ratio of 1.1533 and the exercise prices of the stock option awards are divided by the exchange ratio, for purposes of calculating the number of shares of our common stock that each option award is now exercisable for and for calculating the corresponding exercise prices, respectively, following the Merger. Unless otherwise indicated, the number of shares underlying stock option awards and the exercise price for such stock options in this Form 10-K/A Amendment No. 3 have been adjusted to reflect the exchange ratio of 1.1533. For all stock options, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions made in the calculation of these amounts are described in Note 13 to the Company's audited financial statements, included in the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014.
- (3) Todd Pope became our President and Chief Executive Officer on September 3, 2013 in connection with the consummation of the Merger; prior thereto he was the president and chief executive officer of TransEnterix

Surgical.

- (4) Mr. Pope was granted the following stock option awards in 2013 and 2012:
- (a) stock options to purchase 1,729,950 shares of our common stock granted on August 26, 2013 at an exercise price of \$0.40 per share; one-fourth of the shares underlying this stock option award vest on the first anniversary of the Merger and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months; and
  - (b) stock options to purchase 4,646,319 shares of our common stock granted on April 12, 2012 at an exercise price \$0.07 per share; one-fourth of the shares underlying this stock option award vested on February 2, 2013, and 1/48<sup>th</sup> of the shares underlying the full award vest each month thereafter for 36 months.

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The incremental fair value of stock options to purchase 658,457 shares granted to Mr. Pope on March 15, 2008, repriced as of June 21, 2012, and of stock options to purchase 864,974 shares granted to Mr. Pope on December 14, 2009, repriced as of June 21, 2012, were \$4,702 and \$17,590, respectively.

- (5) Represents bonuses paid under a TransEnterix Surgical incentive bonus plan. Mr. Pope and Mr. Mueller were eligible for awards under such plan during 2012 and 2013. The awards are based at target on a percent of base salary (50% for Mr. Pope and 40% for Mr. Mueller). Corporate performance goals were established by the Compensation Committee for each year and individual performance goals established for each of Mr. Pope and Mr. Mueller at the beginning of the plan year. For 2013, the corporate goals focused on successful consummation of a corporate finance transaction and achievement of product development milestones. The Compensation Committee reviews the self-evaluations by the applicable named executive officers at the end of each plan year, considers the CEO recommendations for all named executive officers other than the CEO, and determines the achievement of each performance goal in determining the actual bonus for each plan year. The bonus amounts for 2012 represent the bonus earned for and paid in 2012. In addition, during 2012, Mr. Pope was paid his 2011 incentive bonus of \$116,250, and Mr. Mueller was paid his 2011 incentive bonus of \$78,203. In the Current Report on Form 8-K filed on September 6, 2013, the amounts paid for both the 2011 and 2012 bonuses for Mr. Pope and Mr. Mueller were reported as bonus for 2012.
- (6) Mr. Slattery became our Executive Vice President and Chief Financial Officer on October 2, 2013.
- (7) Mr. Mueller was granted stock options on April 12, 2012 to purchase 2,465,126 shares of common stock at an exercise price of \$0.07 per share; one-fourth of the shares underlying this award vested on February 2, 2013, and 1/48th of the shares underlying the full award vest each month thereafter for 36 months. The incremental fair value of stock options to purchase 532,602 shares granted to Mr. Mueller on February 9, 2011, repriced as of June 21, 2012, was \$7,574.44.
- (8) Mr. Spragens was SafeStitch's President and Chief Executive Officer until September 2, 2013. During 2012 and 2013, Mr. Spragens did not receive a salary for serving as SafeStitch's President and Chief Executive Officer.
- (9) Mr. Spragens was granted stock options in February 2012 and April 2013 to purchase 100,000 and 150,000 shares of common stock at an exercise price of \$0.65 and \$0.45 per share, respectively. Each stock option was to vest in four equal installments on the first four anniversaries of the date of grant. At the time of the Merger, the unvested stock options accelerated and the exercise period for Mr. Spragens' vested stock options was extended for one year following the closing date of the Merger.

**Agreements with Named Executive Officers**

*Todd M. Pope.* In connection with the Merger, TransEnterix assumed the offer letter from TransEnterix Surgical to Todd Pope dated June 9, 2008, which constituted an employment agreement with Mr. Pope. The employment agreement provides Mr. Pope with a base salary of \$25,000 per month. Mr. Pope is eligible for a cash bonus of up to 50% of his base salary each year if milestones mutually agreed upon by Mr. Pope and the Company are met. The employment agreement gives the Board of Directors the discretion to increase Mr. Pope's base salary and bonus. The employment agreement further provides that if Mr. Pope's employment is terminated by TransEnterix without cause (as defined in the agreement) or if Mr. Pope experiences a constructive termination (as defined in the employment agreement) at the time of or within twelve (12) months following the close of a change of control (as defined in the employment agreement), Mr. Pope will receive, subject to signing a release of claims in favor of TransEnterix: (1) twelve months of Mr. Pope's regular base salary; (2) target bonus for the year in which the change of control occurs; (3) full acceleration and vesting of Mr. Pope's outstanding stock





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option granted following his start date in 2008 to purchase up to five percent of TransEnterix Surgical's fully diluted capitalization following a Series A preferred financing (the Option) upon the date of termination; and (4) up to six months of reimbursement for premiums paid for COBRA coverage. The Option is fully vested as of the date of this Form 10-K/A Amendment No. 3.

The employment agreement with Mr. Pope also provides that if Mr. Pope's employment is terminated by TransEnterix without cause or if Mr. Pope experiences a constructive termination at any other time, Mr. Pope will receive, subject to signing a release of claims in favor of TransEnterix: (1) six months of Mr. Pope's regular base salary; (2) target bonus for the year in which the involuntary termination occurs; (3) full acceleration and vesting of the Option; and (4) up to six months of reimbursement for premiums paid for COBRA coverage. The Option is fully vested as of the date of this Form 10-K/A Amendment No. 3.

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

Under the employment agreement, Mr. Slattery will also be entitled to a stock option grant exercisable for 2.5 million shares of the Company's common stock (the Fundraising Option Grant) following the successful closing of a Company fundraising in which at least \$20.0 million in proceeds is raised for the Company and where at least 50% of the funds raised come from non-insiders (the Fundraising). The exercise price of Fundraising Option Grant shall be the fair market value of the Company's common stock on the date of grant and such options will vest, if at all, 25% on the one (1) year anniversary of Mr. Slattery's start date and thereafter will vest in thirty-six (36) equal monthly installments. Mr. Slattery will be prohibited from exercising any stock options for a period of six (6) months following the date of grant. In the event the Company is acquired or there is a change of control transaction prior to the Fundraising such that the Fundraising Option Grant is not able to be awarded and earned, Mr. Slattery shall be entitled to a grant of 1,000,000 RSUs (Secondary RSU Grant) which will vest, if at all, one-third (1/3) each year beginning one (1) year from the date of grant.

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

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

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



Table of ContentsOutstanding Equity Awards at Fiscal Year-End

The following table lists the outstanding equity awards held by TransEnterix's named executive officers at December 31, 2013:

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END****OPTION AWARDS (1)****STOCK AWARDS**

Name	(2) Number of Securities Underlying Unexercised Options Exercisable	(2) Number of Securities Underlying Unexercised Options	Equity Incentive Plan Awards:		Option Expiration Date	Number of Shares or Units of Stock that have not Vested	Market Value of Shares or Units of Stock that have not Vested(4)	Equity Incentive Plan Awards:	Equity Incentive Plan Awards:
			Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options				Number of Shares or Units of Stock that have not Vested	Market Value of Shares or Units of Stock that have not Vested
Todd M. Pope	658,457			0.07	9/15/2018				
	864,974			0.07	12/14/2019				
	2,129,563	2,516,756		0.07	4/12/2022				
		1,729,950		0.40	8/12/2023				
Joseph P. Slattery						1,000,000	1,650,000		
Richard M. Mueller	388,359	144,243		0.07	2/9/2021				
	1,129,850	1,335,276		0.07	4/12/2022				
Jeffrey G. Spragens	5,000			3.10	9/03/2014				
	60,000			0.80	9/03/2014				
	100,000			1.20	9/03/2014				
	100,000			1.12	9/03/2014				
	100,000			0.65	9/03/2014				
	150,000			0.45	9/03/2014				

(1) The number of shares and exercise prices in respect of the option awards granted by TransEnterix Surgical listed above give effect to the exchange ratio of 1.1553 in the Merger.

(2) One-fourth of the shares underlying each option award vests on the first anniversary of the grant date of such option award, and 1/48th of the shares underlying the full award vest each month thereafter for 36 months.

(3)

During May 2012, TransEnterix Surgical provided its employees, including Mr. Pope and Mr. Mueller, with an offer to have their option awards repriced so that the exercise price of their option awards was amended to equal TransEnterix Surgical's then-current fair market value of its common stock, or \$0.08 per share. The option awards listed above that were issued prior to 2012 reflect the adjusted exercise price, which adjusted exercise price became effective as of June 21, 2012, as further adjusted by the exchange ratio.

- (4) Based on the closing price of the Company's common stock on December 31, 2013 of \$1.65 per share.

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**Equity Compensation Plan**

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 of 1.1533, which were exercisable, as of the Merger date, 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 the 2006 Plan that remain outstanding; no future awards are authorized to be made under the 2006 Plan. The 2007 Plan was originally approved by the Board and adopted by the majority of our stockholders on November 13, 2007. It was later amended and restated (and approved by the Board and approved by a majority of our stockholders on October 29, 2013) to increase the number of shares of common stock authorized under the 2007 Plan to 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 Company can issue stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards under the 2007 Plan.

**Agreements with Former Executive Officers**

In connection with the Merger, the Company entered into letter agreements with each of James J. Martin and Charles J. Filipi, M.D., the Chief Financial Officer and Chief Medical Officer, respectively, of SafeStitch prior to the Merger. Our agreement with Mr. Martin provided for him to continue in the role of Chief Financial Officer, a role he held until October 2, 2013, when Mr. Slattery joined the Company. Our agreement with Dr. Filipi continued his role as Chief Medical Officer of the Company following the Merger. Neither of Mr. Martin nor Dr. Filipi were executive officers of the Company after October 2012, as determined by our Board of Directors. The letter agreements provide that if the employee's employment is terminated without cause (as defined in the letter agreements), death or disability, the employee would be entitled to receive (i) in the case of Mr. Martin, an amount equal to six (6) months base salary and reimbursement of COBRA premiums for a six (6) month period, subject to the execution of a release of claims in favor of TransEnterix; and (ii) in the case of Dr. Filipi, an amount equal to twelve (12) months base salary and reimbursement of COBRA premiums for a twelve (12) month period, subject to the execution of a release of claims in favor of TransEnterix. As of December 31, 2013, each of Mr. Martin and Dr. Filipi remained as non-executive employees of the Company.

**Table of Contents****Director Compensation**

The following table lists the compensation paid during 2013 to the non-employee directors of the Company as of and after the effective date of the Merger:

**DIRECTOR COMPENSATION (1)**

Name	Fees Earned or Paid in		Option Awards (\$)	Nonqualified Non-Equity Deferred Compensation		All Other Compensation	Total(\$)
	Cash	Stock Awards		Earnings	Compensation		
Dennis J. Dougherty							
Phillip Frost, M.D.(2)							
Jane H. Hsiao, Ph.D., MBA(3)			80,220				80,220
Aftab R. Kherani, M.D.							
Paul A. LaViolette							
David B. Milne							
Richard C. Pfenniger, Jr.(3)			10,028				10,028
William N. Starling							

- (1) Prior to the effective date of the Merger, the Board of Directors of SafeStitch consisted of the following individuals, in addition to Jane H. Hsiao and Richard C. Pfenniger: Jeffrey G. Spragens, Charles J. Filipi, M.D., Chao C. Chen, Ph.D., Steven D. Rubin and Kevin T. Wayne, D.B.A. On April 23, 2013, in addition to amounts shown for Dr. Hsiao and Mr. Pfenniger, the non-employee directors of SafeStitch received the following stock option grants from SafeStitch as compensation: Dr. Chen, 20,000 options (value of \$8,022); Mr. Rubin, 35,000 options (value of \$14,039); and Mr. Wayne 20,000 options (value of \$8,022). The exercise price for each option was \$0.45 (fair market value on the date of grant) and the options vested in full on the first anniversary of the date of grant. The vesting of each of the non-employee director options, other than those held by Dr. Hsiao, was accelerated in connection with the closing of the Merger. For all stock options in the table and the footnotes, the option values reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions made in the calculation of these amounts are described in Note 13 to the Company's audited financial statements, included in the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014.
- (2) On April 23, 2013, Dr. Frost received a stock option to acquire 100,000 shares of common stock from SafeStitch as compensation for serving as a consultant to SafeStitch prior to the Merger. The option value was \$40,110, the exercise price was \$0.45 per share and the options will vest on the first anniversary of the date of grant.
- (3) The stock option award to Dr. Hsiao vests on April 23, 2014. The vesting of the stock option award to Mr. Pfenniger was accelerated in full upon the consummation of the Merger.

**Director Compensation Arrangements**

The Company historically has not had a compensation package for members of its Board of Directors for their service as directors, other than the annual stock option awards made by SafeStitch to its non-employee directors prior to the Merger. In 2014, the Company anticipates establishing a compensation package for its directors.





**Table of Contents****ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.****Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information concerning the beneficial ownership of Common Stock by: (i) each person known by us to be the beneficial owner of more than 5% of our outstanding Common Stock currently; (ii) each of our current directors; (iii) each of our current named executive officers; and (iv) all of our current executive officers and directors as a group. Ownership information is set forth as of February 12, 2014. Unless otherwise noted, each of the following disclaims any beneficial ownership of the shares, except to the extent of his, her or its pecuniary interest, if any, in such shares. Unless otherwise indicated, the mailing address of each individual is c/o TransEnterix, Inc., 635 Davis Drive, Suite 300, Morrisville, NC 27560.

Name and Address of Beneficial Owner	As of February 12, 2014	
	Number of Shares of Common Stock (1)	Percentage of Outstanding Common Shares (2)
Paul LaViolette (3)	34,002,689	13.9%
David Milne (4)	33,983,464	13.9%
William N. Starling (5)	28,165,414	11.5%
Jane H. Hsiao, Ph.D., MBA (6)(21)	24,476,151	9.9%
Phillip Frost, M.D. (7)(13)(21)	21,802,346	8.9%
Dennis J. Dougherty (8)	17,615,990	7.2%
Todd M. Pope (9)	4,040,187	1.7%
Richard M. Mueller (10)	1,756,923	*
Richard C. Pfenniger, Jr. (11)	357,000	*
Joseph P. Slattery	250,000	*
Aftab R. Kherani, M.D.	0	*
Jeffrey G. Spragens (12)	4,394,118	1.8%
All Executive Officers and Directors as a group (11 persons) (13)	132,466,700	52.2%
Frost Gamma Investments Trust (14)	21,542,346	8.8%
Aisling Capital III, L.P. (15)	36,490,260	14.9%
SV Life Sciences Fund (16)	33,983,464	13.9%
Synergy Life Science Partners, L.P. (17)	27,448,207	10.4%
StepStone Funds (18)	17,402,565	7.1%
Intersouth Partners VII, L.P. (19)	17,615,990	7.2%
Quaker Bioventures II, L.P (20)	12,582,848	5.2%

\* Less than 1%.

(1) A person is deemed to be the beneficial owner of shares of Common Stock underlying options and warrants held by that person that are exercisable as of February 12, 2014 or that will become exercisable within 60 days thereafter.

(2)

Based on 244,272,728 shares of Common Stock outstanding as of February 12, 2014. Each beneficial owner's percentage ownership is determined assuming that options and warrants that are held by such person (but not those held by any other person) and that are exercisable as of February 12, 2014 or that will become exercisable within 60 days thereafter have been exercised into Common Stock. The additional shares resulting from such exercise are included in both the numerator and denominator for such beneficial owner for purposes of their calculation.

- (3) Includes 33,045,287 shares held by SV Life Sciences Fund IV, L.P. and 938,177 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. Paul LaViolette is a partner of SVLSF IV, LLC, a control person of both SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. Also includes options to purchase 19,225 shares of Common Stock.
- (4) Includes 33,045,287 shares held by SV Life Sciences Fund IV, L.P. and 938,177 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. David Milne is a managing partner of SVLSF IV, LLC, a control person of both SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P.
- (5) Includes 25,487,597 shares of Common Stock held by Synergy Life Science Partners, L.P., and 1,960,610 shares of Common Stock held by Synecor, L.L.C. William N. Starling is a managing director of Synergy Life Science Partners, L.P. and the chief executive officer of Synecor, L.L.C. Also includes options to purchase 18,020 shares of Common Stock.
- (6) Includes options to purchase 375,000 shares of Common Stock, and warrants to acquire 2,000,000 shares of Common Stock. Dr. Hsiao's Common Stock holdings also include beneficial ownership of shares held by Hsu Gamma Investments, L.P. (Hsu Gamma), which holds 6,288,470 shares of Common Stock. Dr. Hsiao is the general partner of Hsu Gamma.
- (7) Includes options to purchase 260,000 shares of Common Stock and beneficial ownership of shares held by Frost Gamma Investments Trust (see note 13).

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- (8) Consists of 17,615,990 shares of Common Stock held by Intersouth Partners VII, L.P. Dennis Dougherty is a principal of a control person of Intersouth Partners VII, L.P.
- (9) Consists of options to purchase 4,040,187 shares of Common Stock.
- (10) Consists of options to purchase 1,756,923 shares of Common Stock.
- (11) Includes options to purchase 117,000 shares of Common Stock.
- (12) Includes 562,818 shares owned by the Joy Fowler Spragens Family Trust (the Spragens Trust), and 571,015 shares owned by RSLs Investments LLC (RSLs). The Spragens Trust is an irrevocable trust established by Joy Fowler Spragens, the spouse of Mr. Spragens, for the benefit of her descendants and relatives who are unrelated to Mr. Spragens. Although Mr. Spragens is the manager of RSLs, RSLs is 100% owned by his adult children. Accordingly, Mr. Spragens disclaims any beneficial ownership of the shares held by the Spragens Trust and RSLs. Also includes options to purchase 515,000 shares of common stock and warrants to purchase 200,000 shares of common stock.
- (13) Includes options to purchase 6,586,355 shares of Common Stock and warrants to purchase 3,000,000 shares of Common Stock. Does not include shares owned by Mr. Spragens, as he was not an executive officer or director as of February 12, 2014.
- (14) Frost Gamma Investments Trust holds 20,542,346 shares of Common Stock and warrants to purchase 1,000,000 shares of Common Stock. Dr. Phillip Frost is the trustee, and Frost Gamma Limited Partnership is the sole and exclusive beneficiary, of Frost Gamma Investments Trust. Dr. Frost is one of two limited partners of Frost Gamma Limited Partnership. The general partner of Frost Gamma Limited Partnership is Frost Gamma Inc. and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is also the sole shareholder of Frost-Nevada Corporation.
- (15) The address of Aisling Capital III, LP is 888 Seventh Avenue, 30th Floor, New York, NY 10106. Based on information made available to the Company and on the Schedule 13D filings made by Aisling Capital III, LP, Steve Elms, Dennis Purcell and Andrew Schiff share voting and investment control over the shares of Common Stock held by Aisling Capital III, LP.
- (16) Consists of 33,045,287 shares held by SV Life Sciences Fund IV, L.P. and 938,177 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. The address of each of SV Life Sciences Fund IV, L.P., SV Life Sciences Fund IV Strategic Partners, L.P. and SVLSF IV, LLC, their control person, is One Boston Place Suite 3900, 201 Washington Street, Boston, MA 02108. David Milne, as managing partner of SV Life Sciences Fund IV, L.P., is deemed to have voting and investment control over the shares of Common Stock owned by such entity.
- (17) Consists of 25,487,597 shares of Common Stock held by Synergy Life Science Partners, L.P., and 1,960,610 shares of Common Stock held by Synecor, L.L.C. The address of each of Synergy Life Science Fund and Synecor, L.L.C. is 3284 Alpine Road, Portola Valley, CA 94028. Based on information made available to the Company and on the Schedule 13D filings made by these entities, William N. Starling, Richard S. Stack and Mudit K. Jain share voting and investment control over the shares of Common Stock held by such entities.
- (18) The address of the StepStone Funds is 4350 La Jolla Village Drive, Suite 800, San Diego, CA 92122. Based on information made available to the Company and on the Schedule 13G filings made by the StepStone Funds with the SEC with respect to the Company's shares, the StepStone Funds consist of StepStone Pioneer Capital Buyout Fund II, L.P., StepStone Pioneer Capital II, L.P., and StepStone-SYN Investments, L.L.L.P.; no individuals are identified as having or sharing voting or investment control over the shares of Common Stock owned by the StepStone Funds.
- (19) The address of Intersouth Partners VII, L.P. is 102 City Hall Plaza, Suite 200, Durham, NC 27701. Based on information made available to the Company and on the Schedule 13G filings made by Intersouth Partners VII, L.P., Dennis J. Dougherty and Mitch Mumma share voting and investment power over the shares of Common Stock held by such entity.
- (20) The address of Quaker Bioventures II, L.P. is 2929 Arch Street, Philadelphia, PA 19104. Based on the Schedule 13G filed by this entity on February 13, 2014, no individuals are identified as having or sharing voting or

investment control over the shares of Common Stock held by such entity.

(21) The address of this stockholder is 4400 Biscayne Blvd, Miami, FL 33137.

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

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

Reference is made to Item 5 of the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014, for the table showing the securities authorized for issuance under the Company's equity compensation plan.

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

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

**Certain Relationships and Related Transactions**

SafeStitch was a party to a Note and Security Agreement, dated September 4, 2007 (the Credit Facility), with The Frost Group, LLC (the Frost Group), and Jeffrey G. Spragens, a former executive officer, under which SafeStitch had access to a line of credit with available borrowings of up to \$4.0 million, consisting of \$3.9 million from The Frost Group and \$100,000 from Mr. Spragens. Members of the Frost Group, LLC include Jane Hsiao, Ph.D., a director, Steven D. Rubin, a former director, and Frost Gamma Investments Trust (Frost Gamma), a trust controlled by Dr. Phillip Frost, a director. SafeStitch was obligated to pay interest on outstanding borrowings under the Credit Facility at a 10% annual rate, and granted a security interest in favor of The Frost Group and Mr. Spragens in all of our real and personal property, whether now existing or subsequently acquired, in order to secure prompt, full and complete payment of the amounts due under Credit Facility. All amounts due under the Credit Facility, including interest, totaling \$315,000 were paid in March 2013. The Credit Facility expired on June 30, 2013 and was not renewed.

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.

Dr. Hsiao, Dr. Frost and former director Steven Rubin are each significant stockholders and/or directors of Non-Invasive Monitoring Systems, Inc. (NIMS), Aero Pharmaceuticals, Inc. (Aero), Tiger X Medical, Inc., formerly known as Cardo Medical, Inc. (Tiger X) and Tiger Media, Inc. (Tiger Media). Director Richard Pfenniger is also a shareholder of NIMS. During 2013 prior to the Merger, Mr. Martin served as the Chief Financial Officer and supervised the accounting staffs of NIMS and, until its dissolution, Aero, under a Board-approved cost sharing arrangement whereby the total salaries of the accounting staffs of the three companies are shared. Aero has not participated in the cost sharing arrangement since June 30, 2011 and was dissolved in December 2011. Since December 2009, SafeStitch's Chief Legal Officer has served under a similar Board-approved cost sharing arrangement as Corporate Counsel of Tiger Media and as the Chief Legal Officer of each of NIMS and Tiger X. SafeStitch recorded reductions to SG&A costs and expenses for the years ended December 31, 2013 and 2012 of \$31,000 and \$60,000, respectively, to account for the sharing of accounting costs under this arrangement. SafeStitch recorded \$158,000 and \$145,000 of reductions to SG&A costs and expenses for the year ended December 31, 2013 and 2012, respectively, to account for the sharing of legal costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X and TigerMedia were approximately \$14,000 and \$59,000 as of December 31, 2013 and 2012, respectively.

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

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

entirety, plus approximately \$8,000 in accrued interest.

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

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On March 22, 2013, SafeStitch entered into a stock purchase agreement (2013 Purchase Agreement) with approximately 17 investors (2013 PIPE Investors) pursuant to which the 2013 PIPE Investors agreed to purchase an aggregate of approximately 12,100,000 shares of common stock at a price of \$0.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of warrants to purchase approximately 6,050,000 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$0.33 per share and five year expiration. Among the investors purchasing shares were Frost Gamma, Dr. Jane Hsiao and Jeffrey Spragens. Frost Gamma purchased 2.0 million shares and received 1.0 million warrants, Dr. Hsiao purchased 4.0 million shares and received 2.0 million warrants and Mr. Spragens purchased 400,000 shares and received 200,000 warrants.

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

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

TransEnterix Surgical was spun off from Synecor, LLC in 2006 when it was separately incorporated. During the period from 2006 through 2011, TransEnterix Surgical used the services of certain employees of Synecor, LLC to assist with TransEnterix Surgical's intellectual property protection activities. In addition, Synecor, LLC, directly or through its subsidiaries provided administrative services and clinical laboratory services to 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 and administrative 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. All transactions between Synecor, LLC and TransEnterix Surgical were arms-length transactions in which fair value was paid for the services provided.

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

The Audit Committee of our Board reviews and approves all transactions that are required to be reported under Item 404(a) of Regulation S-K, including each transaction described above. In order to

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approve a related party transaction, the Audit Committee requires that (i) such transactions be fair and reasonable to us at the time it is authorized by the Audit Committee and (ii) such transaction must be authorized, approved or ratified by the affirmative vote of a majority of the members of the Audit Committee who have no interest, either directly or indirectly, in any such related party transaction. While TransEnterix did not have any written policies with respect to review and approval of any such transactions with related persons, TransEnterix believes the processes its Audit Committee has followed ensure the appropriateness of its entry into such transactions with related persons and that such transactions were entered into on terms on an equivalent basis to arms -length transactions.

## **Director Independence**

### **Board of Directors**

The Board, in the exercise of its reasonable business judgment, has determined that each of our current directors qualify as independent directors pursuant to Nasdaq Stock Market Rule 5605(a)(2) and the applicable SEC rules and regulations, except Mr. Pope, who is currently employed as our President and Chief Executive Officer, and Dr. Frost.

### **Audit Committee**

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

Additionally, since the Company's stock is quoted on the OTCBB, it is not subject to the Audit Committee member independence requirements set forth in Rule 10A-3 of the Exchange Act. Notwithstanding the foregoing, the Board, in the exercise of its reasonable business judgment and utilizing the general standards it applies for determining the independence of directors, has determined that each of the Audit Committee members qualifies as independent pursuant to NYSE MKT Rule 803.

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

### **Compensation Committee**

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

Additionally, since the Company's stock is quoted on the OTCBB, it is not subject to the Compensation Committee member independence requirements set forth in Rule 10C-1 of the Exchange Act. Notwithstanding the foregoing, the Board, in the exercise of its reasonable business judgment and utilizing the general standards it applies for determining the independence of directors, has determined that each of the Compensation Committee members qualifies as independent pursuant to NYSE MKT Rule 803.





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Nominating Committee

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

**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) (1) The following consolidated financial statements were filed as a part of the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014:

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2013 and 2012

Consolidated Statements of Operations and Comprehensive Loss for each of the years in the two-year period ended December 31, 2013

Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit) for each of the years in the two-year period ended December 31, 2013

Consolidated Statements of Cash Flows for each of the years in the two-year period ended December 31, 2013

(2) Consolidated Financial Statement Schedules: The information required by this item is included in the consolidated financial statements contained in Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the SEC on March 5, 2014.

(3) Exhibits: The following exhibits are filed as part of, or incorporated by reference into, this Form 10-K/A Amendment No. 3.

<b>Exhibit No.</b>	<b>Description</b>
2.1 !	Agreement and Plan of Merger, dated as of August 13, 2013, by and among SafeStitch Medical, Inc., Tweety Acquisition Corp. and TransEnterix, Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).
2.1(a) !	First Amendment to Agreement and Plan of Merger, dated as of August 30, 2013, by and among SafeStitch Medical, Inc., Tweety Acquisition Corp and TransEnterix, Inc. (filed as Exhibit 2.2 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).
3.1	Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on March 31, 2014 and incorporated herein by reference).
3.2	

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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).
- 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).

**Table of Contents****Exhibit**

<b>No.</b>	<b>Description</b>
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 by the First Amendment to the Loan and Security Agreement, dated February 11, 2013 and Second Amendment to the Loan and Security Agreement, dated September 3, 2013, 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).
10.7.1	Third Amendment to the Loan and Security Agreement, dated October 31, 2013, by and among the Registrant, Silicon Valley Bank and Oxford Finance LLC (filed as Exhibit 10.7.1 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014 and incorporated herein by reference).
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 10.8 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014, and incorporated herein by reference).
10.9	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

incorporated by reference herein).

- 10.11 + Offer letter, dated as of December 15, 2010, by and between the Registrant and Richard M. Mueller (filed as Exhibit 10.7 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).

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<b>Exhibit No.</b>	<b>Description</b>
10.12 +	Offer letter, dated September 12, 2013, by and between the Registrant and Joseph P. Slattery (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on September 23, 2013 and incorporated by reference herein).
10.12 +	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 (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
10.16 +	Form of Employee Stock Option Agreement (performance stock options) pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
10.17 +	Form of Non-Employee Stock Option Agreement pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
10.18 +	Form of Restricted Stock Unit Agreement pursuant to the 2007 Plan (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
10.19 +	Restricted Stock Unit Agreement, dated as of October 2, 2013, by and between the Company and Joseph P. Slattery (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
10.20	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).

- 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).



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<b>Exhibit No.</b>	<b>Description</b>
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).
10.25	Lease Agreement, dated as of December 11, 2009, by and between TransEnterix Surgical, Inc. and GRE Keystone Technology Park Three LLC (filed as Exhibit 10.25 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014 and incorporated herein by reference).
10.25.1	Lease Modification Agreement No. 1, dated as of May 4, 2010, by and between TransEnterix Surgical, Inc. and GRE Keystone Technology Park Three LLC (filed as Exhibit 10.25.1 to Amendment No. 2 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 31, 2014 and incorporated herein by reference).
14.1	Code of Ethics Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to the Registrant's website see Item 1. BUSINESS Available Information. )
21.1	Subsidiaries of the Registrant (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
23.1	Consent of BDO USA, LLP (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
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)
101.INS	XBRL Instance Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
101.SCH	XBRL Taxonomy Extension Schema Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).

101.DEF XBRL Taxonomy Extension Definition Linkbase Document (incorporated by reference to the like-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed March 5, 2014).

- ! 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.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K/A Amendment No. 3 to be signed on its behalf by the undersigned thereunto duly authorized.

Date: April 2, 2014

**TransEnterix, Inc.**

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

(principal executive officer)

By: /s/ Joseph P. Slattery  
Joseph P. Slattery  
Executive Vice President and Chief Financial  
Officer

(principal financial officer and principal  
accounting officer)