

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

FORM 10-K

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

For the fiscal year ended December 31, 2015

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

TRANSENTERIX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

11-2962080
(I.R.S. Employer
Identification No.)

635 Davis Drive, Suite 300, Morrisville, NC 27560
(Address of principal executive offices) (Zip Code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock \$0.001 par value per share	NYSE MKT

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

None
(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 .

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, 2015, 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 \$156,772,221. The number of shares outstanding of the registrant's common stock, as of February 29, 2016 was 106,576,714.

Documents Incorporated By Reference: Part III of this Annual Report on Form 10-K is incorporated by reference to our Definitive Proxy Statement on Schedule 14A to be filed in respect of our 2016 Annual Meeting of Stockholders.

TRANSENERIX, INC.
ANNUAL REPORT ON FORM 10-K

DECEMBER 31, 2015

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FORWARD-LOOKING STATEMENTS

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

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

- our history of operating losses and uncertainty as to our ability to continue as a going concern;
- our need to obtain additional funding to continue our operations;
- our ability to successfully integrate the ALF-X System into our business;
- our ability to successfully develop, clinically test and commercialize our products;
- the timing and outcome of the regulatory review process for our products;
- our ability to attract and retain key management, marketing and scientific personnel;
- competition from existing and new market entrants;
- our ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights;
- our ability to successfully transition from a research and development company to a company focused on marketing, sales and distribution of our products in development;
- changes in the health care and regulatory environments of the United States, Italy and other countries in which the Company operates;
- our ability to identify and pursue development of additional products; and
- other factors contained in the section entitled “Risk Factors” contained in this Annual Report.

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

PART I

ITEM 1. BUSINESS

Overview

TransEnterix, Inc. (the “Company”) is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical challenges associated with current laparoscopic and robotic options. The Company is focused on the commercialization and further development of the ALF-X® Surgical Robotic System (the “ALF-X System”), a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology, and on the development and commercialization of the SurgiBot™ System (the “SurgiBot System”), a single-port, robotically enhanced laparoscopic surgical platform. The ALF-X System has been granted a CE Mark in Europe for laparoscopic abdominal and pelvic surgery, as well as limited thoracic operations excluding cardiac and vascular surgery, but is not available for sale in the U.S. The SurgiBot System has been submitted for clearance to the U.S. Food and Drug Administration (“FDA”), and is not yet available for sale in any market.

The ALF-X System is a multi-port robotic surgery system which allows multiple robotic arms to control instruments and a camera. The system features advanced technology to enable surgeons with haptic feedback and the ability to move the camera via eye movement. The system replicates laparoscopic motion that is familiar to experienced surgeons, and integrates three-dimensional high definition (“3DHD”) vision technology. The ALF-X System also offers responsible economics to hospitals by offering robotic technology with reusable instruments thereby reducing additional costs per surgery when compared to laparoscopy.

The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for 3DHD vision technology.

Corporate Transactions

On September 18, 2015, the Company entered into a Membership Interest Purchase Agreement, (the “Purchase Agreement”) with SOFAR S.p.A., (“SOFAR”) as seller, Vulcanos S.r.l. (“Vulcanos”), as the acquired company, and TransEnterix International, Inc. (“TransEnterix International”), a direct, wholly owned subsidiary of the Company which was incorporated in September 2015, as buyer. The closing of the transactions occurred on September 21, 2015 (the “Closing Date”) pursuant to which the Company acquired all of the membership interests of Vulcanos from SOFAR (the “ALF-X Acquisition”), and changed the name of Vulcanos to TransEnterix Italia S.r.l (“TransEnterix Italia”). The acquisition included all of the assets, employees and contracts related to the ALF-X System. For a description of the ALF-X Acquisition and related transactions, see the disclosure on page 42 of this Annual Report.

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

As used herein, the terms “Company,” “we” or “us” each refers to both the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, and the addition of TransEnterix International and TransEnterix Italia after giving effect to the ALF-X Acquisition, unless the context otherwise provides. The term “SafeStitch” refers to the historic business of SafeStitch Medical, Inc. prior to the Merger, and the term

“TransEnterix Surgical” refers to the historic business of TransEnterix Surgical, Inc. prior to the Merger. For a description of the Merger and related transactions, see the disclosure on page 44 of this Annual Report.

The Company operates in one business segment. Please see the disclosure in Note 2 “Summary of Significant Accounting Policies – Segments” in the Notes to our Consolidated Financial Statements in Item 8 of this Annual Report regarding our business operations in the U.S. and elsewhere.

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

Market Overview

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

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

Despite such limitations, traditional laparoscopy remains the prevalent technique in minimally invasive surgery. We believe that robotic devices that replicate laparoscopic motion are more comfortable for surgeons to adopt, thereby increasing the opportunity to enhance traditional surgical methods with robotics. Our ALF-X System and SurgiBot System each mimic laparoscopic surgery.

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 total laparoscopic procedures performed. While initial widespread adoption of robotic-assisted surgery was focused on urologic and gynecologic procedures that were primarily performed in an open fashion prior to robotics, recently developed robotic approaches have been applied to many other clinical applications, particularly in general surgery. Despite recent advances, we believe there remain many limitations associated with current robotic-assisted surgery systems used in connection with laparoscopic surgeries.

Product Overview

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

Current Product Offerings

ALF-X System

The ALF-X System is a multi-port robotic surgery system which allows up to four arms to control robotic instruments and a camera. The system builds on the success of laparoscopy by enhancing the traditional features that surgeons have come to expect from existing products and by addressing some of the limitations associated with robotic surgery systems for laparoscopic procedures. The ALF-X System also offers responsible economics to hospitals by offering robotic technology with reusable instruments with minimal additional costs per surgery when compared to laparoscopy. The ALF-X System has been granted a CE Mark in Europe for use in abdominal and pelvic surgery, but is not available for sale in the U.S.

Key features of the ALF-X System are:

- **Haptic Feedback:** The ALF-X System's haptic feedback feature provides the surgeon with the ability to feel the tactile response of the body during a procedure.
- **Enhanced Vision:** The ALF-X System features 3DHD vision technology and gives the surgeon the ability to move the camera via eye movement so that the camera is centered in the surgeon's field of vision.
- **Laparoscopic Motion:** The ALF-X System utilizes laparoscopic motion that is similar to the motion used during traditional laparoscopic surgeries.
- **View of the Sterile Field:** The ALF-X System offers the user an open view of the operating room and sterile field from the console.
- **Enables Use of Standard Trocars:** The ALF-X System allows for standard laparoscopic trocars to be used and does not require that robotic arms be docked directly to the patient.

Current Products in Development

SurgiBot System Robotic Platform

The SurgiBot System is currently in development and is designed as a single-incision, patient-side robotic-assisted surgery system. The system is intended to bring many of the advantages of robotic assistance to single incision laparoscopic surgery while mitigating many of the drawbacks of existing robotic-assisted surgery systems. On June 1, 2015, the Company submitted its 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. In August 2015, the FDA requested additional information related to the SurgiBot System 501(k) submission. The Company responded to the additional information request in February 2016. The Company anticipates that it will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016, and thereafter intends to launch sales of the SurgiBot System during the second quarter of 2016.

Key features of the SurgiBot System are:

- **Patient Side:** The SurgiBot System is positioned next to the operating table, thereby allowing the surgeon, as operator, to control the system from within the sterile field next to the patient.
- **Precision with Scaling:** The SurgiBot System allows the user to adjust the level of mechanized movement using scaled ratios.
- **Strength:** The SurgiBot System features powered motion driven by motors controlled by the surgeon.
- **Ergonomics:** The SurgiBot System stabilizes multiple instruments and a laparoscope and allows the surgeon to reposition his or her hands in an ergonomic fashion.
- **Internal Triangulation:** The SurgiBot System utilizes a deployment mechanism to achieve triangulation of multiple instruments inside the body as contrasted with other single-port robotic

systems that rely on crossing instruments at the patient's abdominal wall. The SurgiBot System allows for triangulation that can be adjusted in the surgical field during a procedure and be maintained at positions throughout a body cavity.

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

We believe that future advancements in robotic surgery will leverage three growth drivers: (1) build on the success of laparoscopy while addressing limitations; (2) develop innovative technology that addresses trade-offs; and (3) provide a compelling economic value to hospitals. The ALF-X System and the SurgiBot System are designed to meet those needs, and help expand robotic surgery to more diverse markets and a wide range of patients.

Other Products

SPIDER Surgical System

Prior to 2015, TransEnterix Surgical developed and commercialized the SPIDER[®] Surgical System (the "SPIDER System"), a manual laparoscopic system, in the United States, Europe and the Middle East. The SPIDER System utilized flexible instruments and articulating channels that were controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System was cleared by the FDA in 2009 and CE Marked in August 2011. The Company also manufactured multiple instruments that could be deployed using the disposable SPIDER System. As of December 31, 2014, we ceased all commercialization efforts with respect to the SPIDER System in order to fully focus our efforts on our other products, including the SurgiBot System.

Surgical Instruments

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

In April 2014, we launched a flexible energy device. This product received 510(k) clearance in March 2013 from the FDA, and it provides surgeons with a flexible instrument that can be used to perform tissue ligation. We believe the flexibility of our instrument provides the surgeon with the ability to create proper angles for tissue ligation that cannot be achieved with the more rigid product alternatives.

In the year ended December 31, 2015, the Company had no revenue and no U.S. customers, as we focused our efforts on the SurgiBot System development. In the year ended December 31, 2014, we had one U.S. customer who accounted for 37% of our revenue of TransEnterix Surgical's products, including the SPIDER System. As noted above, the Company ceased marketing and selling the SPIDER System on December 31, 2014 to focus on its development activities, therefore the Company was not dependent on these customers.

Business Strategy

Our strategy is to focus our resources on the commercialization and further development of the ALF-X System and the development and commercialization of the SurgiBot System. We expect to launch sales of the SurgiBot System, subject to our obtaining the requisite regulatory clearances and approvals.

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 either through a lower cost of capital expenditure or lower operational costs;

- with the ALF-X System, surgeons can benefit from the haptic feedback, enhanced 3DHD vision and open architecture consistent with current laparoscopic surgery procedures;
- with the SurgiBot System, 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, which desires are addressed by both systems.

Research and Development

We are focusing our research and development efforts on the SurgiBot System. Our experience with the SPIDER Surgical System, which the Company discontinued selling as of December 31, 2014, 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 years ended December 31, 2015, 2014 and 2013, we incurred research and development expenses of approximately \$29.7 million, \$27.9 million and \$12.7 million, respectively. In 2015 and 2014 such expenses primarily related to the SurgiBot System development. For 2013, such expenses related to the TransEnterix Surgical and SafeStitch products in development. We fund our research and development expenses primarily from proceeds raised from equity and debt financing transactions. We expect to continue to use equity and debt financing transactions to fund our research and development activities. No customers are obligated to pay any material portion of such research and development expenses.

Intellectual Property

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

The following summarizes our current patent and patent application portfolio.

Patents and Patent Applications Owned by the Company: The Company holds six United States patents, one Italian patent, one Russian patent, a European patent, two Japanese patents, and two Australian patents, and it has more than thirty patent applications filed 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. The Italian and Russian patents resulted from filings related to the ALF-X System and will remain in force until 2030 and 2031, respectively. Three of our United States patents resulted from filings relating to the SPIDER System, which the Company stopped selling as of December 31, 2014, and will remain in force until 2028, 2028 and 2032, respectively. The European, 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, the ALF-X 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 and ALF-X System product development efforts.

Patents and Patent Applications Licensed to the Company: TransEnterix Italia has exclusively licensed technology, know-how, patents and patent applications relating to the ALF-X System from the European Union. This licensed portfolio includes one issued US patent which will remain in force until 2030, and at least fifteen patents issued in other countries, including two European patents, three Korean patents, three Japanese patents and three Chinese patents, which expire in 2027. At least fifteen additional patent applications are pending, including three in the United States.

The license agreement with the European Union has a term which runs until the final licensed patent expires, unless the agreement is terminated earlier by mutual consent of the parties or for breach. The Company is currently in compliance with the terms of this license agreement.

Competition

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

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

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

In addition, our ability to compete may be affected by the failure to fully educate physicians in the use of our products and products in development, or by the level of physician expertise. This may have the effect of making our products less attractive. Among currently available surgical robotic systems, we expect the ALF-X System to differentiate on the basis of its use of standard trocars and lower per procedure costs; we expect the SurgiBot System, once cleared and marketed, to differentiate on the basis of internal triangulation and positioning of the surgeon within the sterile field, as well as a lower capital cost; and we expect each of our systems to differentiate, in most cases, and their ability to provide the surgeon with tactile feedback. Several medical device companies are actively engaged in research and development of robotic systems or other medical devices and tools used in minimally invasive surgery procedures. We cannot predict the basis upon which we will compete with new products marketed by others.

Government Regulation of our Product Development Activities

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

Device Development, Marketing Clearance and Approval

Medical devices are subject to varying levels of pre-market regulatory requirements. 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 receive greater scrutiny from the FDA and have heightened regulatory requirements; and (iii) Class III devices are new, high risk devices, and frequently are permanently implantable or help sustain life and generally require a Pre-Market Approval (“PMA”) by the FDA.

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 a single medical device, the predicate device. If clinical data from human experience are required to support the 510(k) notification, these data must be gathered in compliance with investigational device exemption (“IDE”) regulations for investigations performed in the United States. The 510(k) process is normally used for products of the type that we are developing and propose to market and sell. The FDA review process for premarket notifications submitted pursuant to Section 510(k) takes, pursuant to statutory requirements, 90 days, but it can take substantially longer if the FDA has questions regarding the regulatory submission. It is possible for Section 510(k) clearance procedures to take from six to twenty-four months, depending on the concerns raised by the FDA and the complexity of the device. There is no guarantee that the FDA will “clear” a medical device for marketing, in which case the device cannot be distributed in the United States. There is also no guarantee that the FDA will deem the applicable device subject to the 510(k) process, as opposed to the more time-consuming, resource-intensive and problematic 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.

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 as a Class III device. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to approval, as opposed to clearance, as a Class III device. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device. These regulations permit a company to undertake a clinical study of a “non-significant risk” device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. Second, the FDA must approve the company’s PMA application, which contains, among other things, clinical information acquired under the IDE. Additionally, devices subject to PMA approval may be subject to a panel review to obtain marketing approval and are required to pass a factory inspection in accordance with the current “good manufacturing practices” standards in order to obtain approval. The FDA will approve the PMA application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process, approximately one to two years or more. However, in some instances the FDA may find that a device is new and not substantially equivalent to a predicate device but is also not a high risk device as is generally the case with Class III PMA devices. In these instances FDA may allow a device to be down classified from Class III to Class I or II. The de novo classification option is an alternate pathway to classify novel devices of low to moderate risk that had automatically been placed in Class III after receiving a “not substantially equivalent” (“NSE”) determination in response to a 510(k) notification. The regulations have 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 ALF-X System and the SurgiBot System, and related products to both systems, are Class II devices, and we are in the process of pursuing Section 510(k) clearance for the SurgiBot System. The FDA might find that the 510(k) submission does not provide the evidence required to prove that the SurgiBot System is substantially equivalent to marketed Class II devices. 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. All of these risks also exist for the ALF-X System, which we plan to gain U.S. market access from the FDA in the future. 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 other risks and uncertainties.

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

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

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

Continuing FDA Regulation

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

- establishment registration and device listing with the FDA;
- quality system regulations, which require manufacturers to follow stringent design, testing;
- process control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved, i.e. "off label," uses and impose other restrictions on labeling;
- MDR regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- requirements to conduct postmarket surveillance studies to establish continued safety data.

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

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

Impact of Regulation

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

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refund or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or premarket approval of new products or modifications to existing products;
- withdrawing or suspending clearances or approvals that are already granted;
- criminal prosecution; and
- disgorgement of profits.

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

Health Care Regulation

Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include,

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

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

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

The 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. This excise tax was suspended in December 2015 for two years. If eventually implemented, this excise tax will likely increase our expenses in the future.

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

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

International Regulation and Potential Impact

Through the ALF-X Acquisition, the Company has expanded into international markets and intends to pursue continued expansion. 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, 2015, we had 132 employees, including 130 full time employees. The Company considers its relationships with its employees to be good.

Corporate Information

The Company's principal executive offices are located at 635 Davis Drive, Suite 300, Morrisville, NC 27560. TransEnterix Surgical was originally incorporated under the laws of the State of Delaware on July 12, 2006. On September 3, 2013, TransEnterix Surgical merged with and into a SafeStitch merger subsidiary and became a wholly owned subsidiary of SafeStitch. SafeStitch was originally incorporated on August 19, 1988 as NCS Ventures Corp. under the laws of the State of Delaware. Its name was changed to Cellular Technical Services Company, Inc. on May 31, 1991. On September 4, 2007, SafeStitch acquired SafeStitch LLC, and, in January 2008, changed its name to SafeStitch Medical, Inc. On December 6, 2013, SafeStitch's name was changed to TransEnterix, Inc. On September 21, 2015, TransEnterix International, a wholly owned subsidiary of the Company formed by the Company in conjunction with the ALF-X Acquisition, acquired all of the membership interests of Vulcanos and changed the name of Vulcanos to TransEnterix Italia.

As of December 31, 2015, the active subsidiaries of the Company are TransEnterix Surgical, Inc., SafeStitch LLC, TransEnterix International, Inc. and TransEnterix Italia, S.r.l.

Available Information

The Company maintains a website at www.transenterix.com. Our Code of Business Conduct and Ethics, as reviewed and updated on October 29, 2015, is available on our website. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website as soon as practicable after electronic filing of such material with, or furnishing it to, the U.S. Securities and Exchange Commission (the "SEC"). This information may be read and copied at the Public Reference Room of the SEC at 100 F Street, N.E., Washington D.C. 20549. The SEC also maintains an internet website that contains reports, proxy statements, and other information about issuers, like TransEnterix, Inc., who file electronically with the SEC. The address of the site is <http://www.sec.gov>.

ITEM 1.A. RISK FACTORS

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

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. Substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs as well as past recurring losses and an accumulated deficit. Our net loss for year ended December 31, 2015 was \$46.9 million, and our accumulated deficit as of December 31, 2015 was \$182.9 million. We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will not be sufficient to meet our anticipated cash needs for the next 12 months.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products and product candidates. We will continue to incur research and development and general and administrative expenses related to our operations, and expect to increase our sales and marketing expenses as we increase our sales and marketing activities for the ALF-X System and, once approved, the SurgiBot System. If our products fail in development or do not gain regulatory clearance or approval, or if our products do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

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

The net proceeds of recent equity financings, including the public offering of our common stock completed in June 2015, will not be sufficient to support development of our products and product candidates and provide us with the necessary resources to commercialize these products and product candidates. While we are currently focused on our ALF-X System, and our SurgiBot System product in development, we intend to advance multiple additional products through clinical and pre-clinical development in the future. We will need to raise substantial additional capital in order to continue our operations and achieve our business' objectives.

We have filed shelf registration statements which have been declared effective by the SEC. As of December 31, 2015, we had \$80.8 million available for future financings, however approximately \$43.6 million may now be raised under the ATM offering we initiated in February 2016. We cannot assure you that we will be successful in obtaining such additional financing on terms acceptable to the Company or at all.

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

- the costs of our ALF-X System and SurgiBot System commercialization and development activities;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals for both SurgiBot System and the ALF-X System;
- the costs associated with establishing a sales force and commercialization capabilities;
- the costs associated with the expansion of our manufacturing capabilities;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, products and technologies;
- the economic and other terms and timing of our existing licensing arrangement and any collaboration, licensing or other arrangements into which we may enter in the future;
- our need and ability to hire additional management, scientific, medical and sales and marketing personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, quality systems and information technology systems; and
- our ability to maintain, expand and defend the scope of our intellectual property portfolio.

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

We are highly dependent on the success of the SurgiBot System and the ALF-X System, and we cannot give any assurance that these products will receive regulatory clearance in the U.S. or that they or future products will be successfully commercialized.

We are highly dependent on the success of our products, especially the ALF-X System and the SurgiBot System. We cannot give any assurance that the FDA will grant regulatory clearance for the SurgiBot System or the ALF-X System, nor can we give any assurance that the ALF-X System, the SurgiBot System or any of our other products will be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically effective or cost-effective alternatives, or failure in our sales and marketing efforts. Any failure to obtain market access for our products or to successfully commercialize them would have a material and adverse effect on our business. Regulatory authorities may change requirements for the clearance of a product regardless of previous discussions with the company. These regulatory authorities may also clear a product for fewer or more limited uses than we request. In addition, the FDA or other non-U.S. regulatory authorities may not approve or clear the labeling claims necessary or desirable for the successful commercialization of our products.

We expect that our sales cycle will be lengthy and unpredictable, which will make it difficult for us to forecast revenue and increase the magnitude of quarterly fluctuations in our operating results.

Purchase of a surgical robotic system such as the ALF-X System and, once cleared, the SurgiBot System represents a capital purchase by hospitals and other potential customers. The capital purchase nature of the transaction, the complexity of our product, the relative newness of surgical robotics and the competitive landscape requires us to spend substantial time and effort to assist potential customers in evaluating our robotic systems. We must communicate with multiple surgeons, administrative staff and executives within each potential customer in order to receive all approvals on behalf of such organizations. We may face difficulty identifying and establishing contact with such decision makers. Even after initial acceptance, the negotiation and documentation processes can be lengthy. Additionally, our customers may have stricter limitations on spending given the current economic climate. We expect our sales cycle to typically range between six and twelve months, but it may be longer. Any delay in completing sales in a particular quarter could cause our operating results to fall below expectations. We also expect such lengthy sales cycle makes it more difficult for us to accurately forecast revenue in future periods and may cause revenues and operating results to vary significantly in future periods.

We may fail to realize some or all of the anticipated benefits of the acquisition of the ALF-X technology, which may adversely affect the value of our common stock.

Our ability to successfully integrate the business of our Italian subsidiary, TransEnterix Italia, which relates to the manufacture, development and commercialization of the ALF-X System with our existing business will depend, in part, on our ability to realize the anticipated benefits and cost savings from the expanded market opportunity presented by the acquisition of the technology and the establishment of international operations. To realize these anticipated benefits and cost savings, we must successfully integrate TransEnterix Italia with our other operations and combine our respective operations, technologies and personnel, which is particularly

challenging given the geographic and cultural differences between the personnel and facilities based in North Carolina and Italy. If we are not able to achieve these objectives within a reasonable time frame, or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected.

In addition, the overall integration of the businesses is a complex, time-consuming and expensive process that, without proper planning and effective and timely implementation, could significantly disrupt our operations. Further, it is possible that the integration process could adversely affect our ability to maintain the pace of our SurgiBot System research and development operations, result in the loss of key employees and other senior management, or to otherwise achieve the anticipated benefits of the acquisition.

Risks in integrating TransEnterix Italia into our operations in order to realize the anticipated benefits of the acquisition include, among other factors:

- coordinating research and development activities to enhance the commercialization of newly acquired technology;
- incorporating acquired technologies or products with our existing product lines;
- incurring higher than anticipated costs in continuing support and development of acquired products, and in general and administrative functions that support such products;
- failing to successfully integrate and harmonize financial reporting and information technology systems of the two companies;
- retaining each company's relationships with its customers, suppliers and partners;
- retaining and integrating key employees;
- managing the increased scope, geographic diversity and complexity of our operations;
- managing the diversion of management's attention from business matters to integration issues; and
- complying with regulatory and business requirements both globally and in the U.S.

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

Our global operations expose us to additional risks and challenges associated with conducting business internationally.

The international expansion of our business through the addition of an Italian subsidiary may expose us to risks inherent in conducting foreign operations. These risks include:

- challenges associated with managing geographically diverse operations, which require an effective organizational structure and appropriate business processes, procedures and controls;
- the increased cost of doing business in foreign jurisdictions, including compliance with international and U.S. laws and regulations that apply to our international operations;
- currency exchange and interest rate fluctuations and the resulting effect on our revenue and expenses, and the cost and risk of entering into hedging transactions, if we chose to do so in the future;

- potentially adverse tax consequences;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- compliance with additional regulations and government authorities in a highly regulated business; and
- general economic and political conditions in Italy.

The risks that the Company faces in its international operations may continue to intensify as the Company further develops and expands its international operations.

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

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

- difficulties in compliance with U.S. and non-U.S. laws and regulations;
- changes in U.S. and non-U.S. regulations and customs;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws; and
- difficulties associated with staffing and managing foreign operations, including differing labor relations.

If we cannot achieve sufficient margins for our SurgiBot System, it may not be commercially successful.

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

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

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

Applied Medical, Titan Medical, Medtronic plc, Intuitive Surgical, Johnson & Johnson, Google and a number of minimally invasive surgical device, robotic surgical device manufacturers and providers of products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many other universities and private and public research institutions are or may become active in research involving surgical devices for minimally invasive and robotic-assisted surgery.

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

- the efficacy, safety and reliability of our products;
- the speed at which we develop our products;
- our ability to commercialize and market any of our products that may receive regulatory clearance or approval;
- the cost of our products in relation to alternative devices;
- the timing and scope of regulatory clearances or approvals;
- whether our competitors substantially reduce the cost of ownership of an alternative device;
- our ability to protect and defend intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any approved products to the market;
- the availability of adequate coverage and reimbursement by third-party payors for the procedures in which our products are used;
- the effectiveness of our sales and marketing efforts; and
- acceptance of future products by physicians and other health care providers.

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

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

We are party with Silicon Valley Bank and Oxford Finance LLC (the “Lenders”), to, and jointly and severally liable with certain of our U.S. subsidiaries for, \$20.0 million of outstanding debt under term loans issued under the Amended and Restated Loan Agreement, as amended (the “Loan Agreement”). Under the Loan Agreement, the maximum borrowing potential is up to \$30.0 million. We were entitled to make interest-only payments until January 31, 2016. The maturity date of the outstanding term loan is July 1, 2018. Our resulting substantial level of indebtedness and other financial obligations increase the possibility that we may be unable to pay, when due, the principal of, interest on, or other amounts due in respect of, our indebtedness.

Further, under the Loan Agreement, we are subject to certain restrictive covenants that, among other things, may limit our ability to obtain additional financing for working capital requirements, product development activities, debt service requirements, and general corporate or other purposes. These restrictive covenants include, without limitation, restrictions on our ability to: (1) change the nature of our business; (2) incur additional indebtedness; (3) incur liens; (4) make certain investments; (5) make certain dispositions of assets; (6) merge, dissolve, consolidate or sell all or substantially all of our assets; (7) enter into transactions with affiliates; and (8) transfer more than designated amounts to TransEnterix Italia during the term of the Loan Agreement.

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

Our product development activities could be delayed or stopped.

We do not know whether our current product development activities will result in products that meet necessary standards and performance criteria and whether the development will be completed on schedule. Delays could occur based on a number of issues that could arise. For example, should clinical trials be required, their completion could be substantially delayed and their outcome could lead to realization that the devices are not ready for commercialization.

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

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

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

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

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

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

In the future, we may need to conduct clinical trials to support approval or commercialization of new products, and any future clinical trial activities that we undertake will be subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad.

Clinical studies intended to support a 510(k) or PMA must be conducted in compliance with the FDA's Good Clinical Practice regulations and similar requirements in foreign jurisdictions. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and Notified Bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot

be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of associated product submissions and, ultimately, our ability to commercialize products requiring submission of clinical data. It is also possible that patients enrolled in a clinical trial will experience adverse side effects that are not currently part of the product candidate's safety profile, which could cause us to delay or abandon development of such product.

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

The product development and design, testing, manufacturing, labeling, approval, clearance, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our products in the United States until we receive a clearance letter under the 510(k) process or approval of a PMA from the FDA, depending on the nature of the device. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews a premarket notification in 90 days, there is no guarantee that our future products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, even if a device is reviewed under the 510(k) premarket notification process, that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. If the FDA asks questions during a 510(k) process, the time required to answer the questions can extend the time to market up to an additional six months. If the company cannot sufficiently answer the questions, or for a variety of other reasons the FDA does not provide clearance for a product candidate, such as the SurgiBot System, we cannot market the device.

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

- a medical device candidate may not be deemed safe or effective, in the case of a PMA application;
- a medical device candidate may not be deemed to be substantially equivalent to a device lawfully marketed either as a grandfathered device or one that was cleared through the 510(k) premarket notification process;
- a medical device candidate may not be deemed to be in conformance with applicable standards and regulations;
- FDA or other regulatory officials may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA might not approve our processes or facilities or those of any of our third-party manufacturers for our Class III PMA devices;
- other non-U.S. regulatory authorities may not approve our processes or facilities or those of any of our third-party manufacturers, thereby restricting export; or

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

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

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

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

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

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

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations ("Form 483"), warning letters, non-warning letters incorporating inspectional observations;
- civil or criminal penalties or fines;

- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory clearances or approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- refusal to clear or approve pending applications or premarket notifications; and
- import and export restrictions.

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

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

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

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

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

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

Under the FDA’s medical device reporting (“MDR”) regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations.

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

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

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

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

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

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance

are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, the FDA recently held a public workshop to gather input on evidentiary requirements for new and modified robotically-assisted surgical devices. The company would need to align its submissions and business practices with any resulting guidance documents published by the agency.

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

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

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

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

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

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

Most significantly, in March 2010, President Obama signed into law both the Patient Protection and Affordable Care Act (the “Affordable Care Act”) and the reconciliation law known as Health Care and Education

Reconciliation Act (the “Reconciliation Act”, and, with the Affordable Care Act, the “2010 Health Care Reform Legislation”). The Supreme Court of the United States upheld fundamental aspects of the 2010 Health Care Reform Legislation in June 2012 and again in June 2015. Specifically, the Supreme Court upheld the individual mandate included changes regarding the extension of medical benefits to those who currently lack insurance coverage, and affirmed that subsidies are available to participants enrolled in both state and federally created health care exchanges. Thus, the 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, or some combination of both, as well as other changes.

Beyond coverage and reimbursement changes, the 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. This excise tax was suspended in December 2015 for two years, however, if eventually implemented, this excise tax will likely increase our expenses in the future.

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

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

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

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

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

- timing of market introduction of competitive products;
- safety and efficacy of our products;
- physician training in the use of our products;

- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support; and
- price of our future products, both in absolute terms and relative to alternative treatments.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. In the United States, we, or one of our subsidiaries, have or licensed 7 issued patents and over 40 pending patent applications. Many of these relate to the SPIDER System, the SurgiBot System, the ALF-X System, instruments useful with those systems, or alternatives to those systems. We have also filed patent applications abroad for the SurgiBot System, ALF-X System and the SPIDER System. Because certain U.S. patent applications are confidential until patents

issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

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

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

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

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

For our ALF-X System, we rely on our license from the European Union, and any loss of our rights under such license agreement, or failure to properly prosecute, maintain or enforce the patent applications underlying such license agreement, could materially adversely affect our business prospects for the ALF-X System.

Some of the patents and patent applications in our patent portfolio related to the ALF-X System are licensed to TransEnterix Italia under a license agreement with the European Union. Presently, we rely on such licensed technology for our ALF-X System products and may license additional technology from the European Union or other third parties in the future. The EU license agreement gives us rights for the commercial exploitation of the

licensed patents, patent applications and know-how, subject to certain provisions of the license agreement. Failure to comply with these provisions could result in the loss of our rights under the EU license agreement. Our inability to rely on these patents and patent applications which are the basis of certain aspects of our ALF-X System technology would have an adverse effect on our business.

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

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

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

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

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

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

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

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

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

As of December 31, 2015, the net carrying value of our goodwill and other intangible assets totaled approximately \$194.3 million, which was 78% of total assets. In accordance with generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

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

In the June 2015 public offering, and in the ALF-X Acquisition, we issued a significant number of new shares of common stock to increase our outstanding shares of common stock to over 100,000,000 shares. The issuance of these shares caused existing stockholders at the time of the public offering and ALF-X Acquisition to experience immediate and significant dilution in their percentage ownership of our outstanding common stock. In addition, from February 2015 through February 2016, we offered and sold, through Cantor Fitzgerald & Co., as sales agent, \$25 million in shares of common stock in an at-the-market offering. On February 9, 2016, we entered into a new "at-the-market" facility with Cantor under which we can offer and sell, through Cantor, up to approximately \$43.6 million in shares of common stock.

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

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

During the two year period ended December 31, 2015, the market price of our common stock fluctuated from a high of \$14.00 per share to a low of \$1.40 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the medical device industry;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

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

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

Trading of our common stock is currently conducted on the NYSE MKT. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all. As of December 31, 2015, approximately 46% of the issued and outstanding shares of our common stock were held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

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

As of December 31, 2015, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 46% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

In connection with the ALF-X Acquisition, we entered into a lock-up agreement with SOFAR.

In connection with the ALF-X Acquisition, we entered into a Registration Rights Agreement, dated as of September 21, 2015, with SOFAR, pursuant to which the Company agreed to register the for resale following the end of the lock-up periods described below.

In connection with the ALF-X Acquisition, SOFAR entered into a Lock-Up Agreement pursuant to which it agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the 15,543,413 shares of the Company's common stock issued to it as part of the transaction (the "Securities Consideration") for one year following the Closing Date. The Lock-up Agreement provides that SOFAR may sell, transfer or convey: (i) no more than 50% of the Securities Consideration 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) no more than 75% of the Securities Consideration 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 Agreement cease to apply to the Securities Consideration following the second anniversary of the Closing Date, or earlier upon certain other conditions. Once such lock-up restrictions end, it is possible that SOFAR will sell shares of our common stock in underwritten or private placement transactions.

ITEM 1.B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

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

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

		Bid Prices	
		High	Low
2016			
	First Quarter (through February 29, 2016)	\$ 4.79	\$1.54
2015			
	First Quarter	\$ 3.50	\$2.52
	Second Quarter	4.87	2.70
	Third Quarter	3.66	2.07
	Fourth Quarter	2.90	2.10
2014			
	First Quarter	\$ 2.59	\$1.51
	Second Quarter	14.00	1.87
	Third Quarter	5.50	3.43
	Fourth Quarter	4.54	1.40

As of February 29, 2016, there were approximately 248 record holders of our common stock (counting all shares held in single nominee registration as one stockholder).

We paid no dividends or made any other distributions in respect of our common stock during our fiscal years ended December 31, 2015 and 2014, and we have no plans to pay any dividends or make any other distributions in the future.

Securities Authorized for Issuance Under Equity Compensation Plans.

The Company currently has one equity compensation plan under which it makes awards, the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, as amended (the Plan). In connection with the Merger, SafeStitch assumed all of TransEnterix Surgical's options that were issued and outstanding immediately prior to the Merger at the Exchange Ratio, which are now exercisable for approximately 2,070,362 shares of common stock. Such options were granted under the TransEnterix, Inc. 2006 Stock Plan (the 2006 Plan) which was assumed by the Company in the Merger. The 2006 Plan is maintained solely for the purpose of the stock options granted under such 2006 Plan that remain outstanding; no future awards are authorized to be made under the 2006 Plan. The Plan was originally approved by the Board of Directors and adopted by the majority of our stockholders on November 13, 2007, and amended and restated and approved by the Board of Directors and

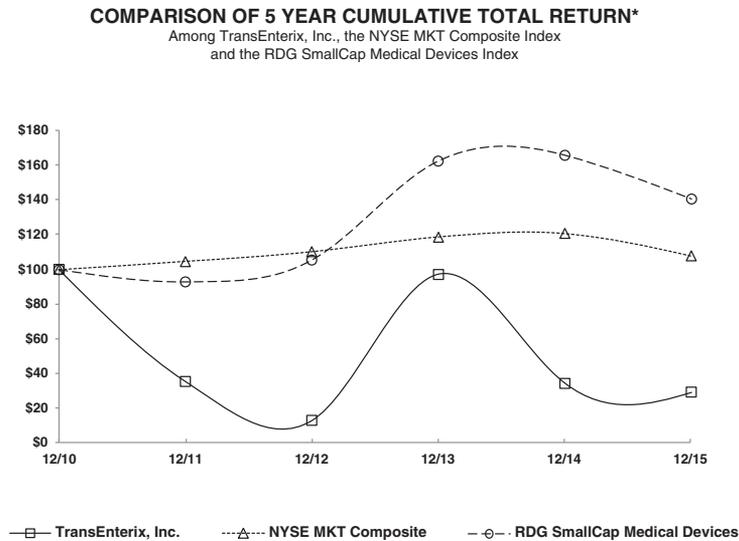
approved by the majority of our stockholders on May 7, 2015 to increase the number of shares of common stock authorized under the Plan to 11,940,000 shares, and to make other changes. The Plan is used for plan-based awards for officers, other employees, consultants, advisors and non-employee directors.

The following table gives information about the Company's common stock that may be issued upon the exercise of options and other equity awards as of December 31, 2015:

Plan Category	Number of securities to be issued upon exercise of outstanding options (1)	Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance (2)
Equity compensation plans approved by security holders	6,586,291	\$3.07	5,369,193
Equity compensation plans not approved by security holders (3)	2,137,028	\$0.73	0
Total	8,723,319		5,369,193

- (1) Includes 6,582,958 shares underlying outstanding stock options awarded under the 2007 Plan and 3,333 restricted stock units awarded under the 2007 Plan.
- (2) These shares are all available for future awards under the 2007 Plan.
- (3) Represents 2,070,362 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger, and 66,666 restricted stock units remaining under a new hire award to our Chief Financial Officer.

The graph below summarizes our stock performance over the past five years compared to the NYSE MKT Composite Index and the RDG Small Cap Medical Devices Index.



*\$100 invested on 12/31/10 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Unregistered Sales of Equity Securities and Use of Proceeds.

The Company issued no unregistered securities during the fourth quarter of 2015.

The following table summarizes the Company's purchases of its common stock for the quarter ended December, 2015:

<u>Period</u>	<u>Total Number of Shares Purchased (1)</u>	<u>Average Price Paid per Share</u>
October 1-31, 2015	30,246	\$2.30
November 1-30, 2015	—	
December 1-31, 2015	—	

- (1) Consists of shares we acquired from employees associated with the withholding of shares to pay certain withholding taxes upon the vesting of RSUs by delivering to us shares of our common stock in accordance with the terms of our equity compensation plan that were previously approved by our stockholders. We purchased these shares at their fair market value, as determined by reference to the closing price of our common stock on the day of vesting of the RSUs.

ITEM 6. SELECTED FINANCIAL DATA

The table below shows selected consolidated financial data. The statements of operations and comprehensive loss data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data at December 31, 2015 and 2014 are derived from our financial statements included elsewhere in this report. The statements of operations and comprehensive loss data for the years ended December 31, 2012 and 2011 and the balance sheet data at December 31, 2013, 2012 and 2011 are derived from our financial statements not included in this report. The historical results presented below are not necessarily indicative of financial results to be achieved in future periods.

Year ended December 31,	2015 (1)	2014 (2)	2013 (3)(4)	2012 (4)	2011 (4)
	(in thousands)				
Statement of Operations and Comprehensive Loss Data:					
Sales	\$ —	\$ 401	\$ 1,431	\$ 2,115	\$ 1,628
Income (loss) from continuing operations	\$ (46,948)	\$ (37,652)	\$ (28,358)	\$ (15,425)	\$ (17,030)
Income (loss) from continuing operations per common share	\$ (0.59)	\$ (0.64)	\$ (2.23)	\$ (2.86)	\$ (3.73)
Balance Sheet Data:					
Total assets	\$248,602	\$135,111	\$116,714	\$ 17,560	\$ 22,885
Long-term obligations and redeemable preferred stock (5)	\$ 40,253	\$ 9,175	\$ 4,602	\$ 83,595	\$ 74,813

- (1) Includes the assets and liabilities of TransEnterix Italia acquired and assumed in the ALF-X Acquisition, which occurred on September 21, 2015. See the description of the ALF-X Acquisition beginning on page 42 of this Annual Report.
- (2) On March 31, 2014, we effectuated a reverse stock split of our issued and outstanding shares of common stock at a ratio of 1 for 5. As a result of the Reverse Stock Split, our issued and outstanding stock decreased from 244,276,923 to 48,855,255 shares of common stock, all with a par value of \$0.001. All information related to common stock, preferred stock and earnings per share for prior periods has been retroactively adjusted to give effect to the Reverse Stock Split.
- (3) On September 3, 2013, TransEnterix Surgical and SafeStitch consummated the Merger transaction. The Merger was a reverse merger for accounting purposes with TransEnterix Surgical as the acquiring company. Therefore, from September 3, 2013 forward the financial statements of the Company are the historical financial statements of TransEnterix Surgical with the addition of SafeStitch as of the date of the Merger. See the description of the Merger on page 44 of this Annual Report.
- (4) Represent the financial statements of TransEnterix Surgical for the years ended December 31, 2012 and 2011, and for the period from January 1, 2013 to September 2, 2013.
- (5) Long-term obligations include: (1) Cash Consideration installments to be paid to SOFAR in connection with the ALF-X Acquisition; (2) outstanding amounts under our Loan Agreement, first entered into by TransEnterix Surgical in January 2012 and amended from time to time since such time; and (3) in 2013,

promissory notes of SafeStitch, which were converted into equity securities of the Company in 2013. In addition, concurrent with the closing of the Merger 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 Company issued 7,544,704.4 shares of Series B Preferred Stock, each share of which was convertible, subject to certain conditions. Each share of Series B Preferred Stock was converted into two shares of our common stock on December 6, 2013. For more information, see Notes 13 and 18 of the Notes to Consolidated Financial Statements contained in Item 8 of this Annual Report.

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

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

Overview

TransEnterix, Inc. (the “Company,” “we” or “us”) is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical challenges associated with current laparoscopic and robotic options. We are focused on the commercialization and further development of the ALF-X® Surgical Robotic System (the “ALF-X System”), a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology, and on the development and commercialization of the SurgiBot™ System (the “SurgiBot System”), a single-port, robotically enhanced laparoscopic surgical platform. The ALF-X System has been granted a CE Mark in Europe for laparoscopic abdominal and pelvic surgery, as well as limited thoracic operations excluding cardiac and vascular surgery, but is not available for sale in the U.S. The SurgiBot System has been submitted for clearance to the U.S. Food and Drug Administration (“FDA”), and is not yet available for sale in any market.

The ALF-X System is a multi-port robotic surgery system which allows multiple robotic arms to control instruments and a camera. The system features advanced technology to enable surgeons with haptic feedback and the ability to move the camera via eye movement. The system replicates laparoscopic motion that is familiar to experienced surgeons, and integrates three-dimensional high definition (“3DHD”) vision technology. The ALF-X System also offers responsible economics to hospitals by offering robotic technology with reusable instruments thereby reducing additional costs per surgery when compared to laparoscopy.

The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for 3DHD vision technology.

Our strategy is to focus our resources on the commercialization and further development of the ALF-X System and the development and commercialization of the SurgiBot System. We expect to launch sales of the SurgiBot System, 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 either through a lower cost of capital expenditure or lower operational costs;
- with the ALF-X System, surgeons can benefit from the haptic feedback, enhanced 3DHD vision and open architecture consistent with current laparoscopic surgery procedures
- with the SurgiBot System, 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, which desires are addressed by both systems.

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

Since inception, we have been unprofitable. As of December 31, 2015 we had an accumulated deficit of \$182.9 million.

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

In 2013 we incurred \$2.9 million of Merger-related expenses (described below), and in 2015 we incurred \$4.2 million of ALF-X Acquisition-related expenses (described below), which were included in operating expenses, for the years ended December 31, 2013 and 2015, respectively.

We operate in one business segment.

Recent Events

Controlled Equity Offering

On February 20, 2015, we entered into a Controlled Equity OfferingSM Sales Agreement (the “2015 Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), as sales agent, pursuant to which we offered and sold, through Cantor, \$25 million in shares of common stock in an at-the-market offering from February 2015 through February 2016 (the “2015 ATM Offering”). All sales of shares were made pursuant to an effective shelf registration statement on Form S-3 filed with the Securities and Exchange Commission (the “SEC”). We paid Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2015 Sales Agreement. On February 9, 2016, we entered into a new “at-the-market” facility with Cantor under which we can offer and sell, through Cantor, up to approximately \$43.6 million in shares of common stock (the “2016 ATM Offering”).

The following table summarizes the total sales under the 2015 ATM Offering for the periods indicated (in thousands, except per share amounts):

	Twelve Months Ended December 31, 2015	February 24, 2015 to February 12, 2016 (Unaudited)
Total shares of common stock sold	2,014.3	7,724.5
Average price per share	\$ 3.25	\$ 3.24
Gross proceeds	\$ 6,546	\$ 25,000
Commissions earned by Cantor	\$ 197	\$ 750
Other issuance costs	\$ 259	\$ 259

Public Offering

On June 11, 2015, we sold 16,666,667 shares of common stock at a public offering price of \$3.00 per share for aggregate gross proceeds of \$50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,500,000 shares of common stock to cover over-allotments. The common stock was offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-199998) registering an aggregate of \$100.0 million of our designated securities. The closing of the public offering occurred on June 17, 2015. On July 10, 2015, the underwriters

exercised a portion of their over-allotment option to acquire an additional 2,075,000 shares at the public offering price of \$3.00 per share for aggregate additional gross proceeds of \$6.2 million. The purchase of the over-allotment shares closed on July 15, 2015. Total proceeds were \$52.2 million, net of issuance costs of \$4.0 million.

ALF-X Acquisition and Related Transactions

Membership Interest Purchase Agreement

On September 21, 2015, the Company announced that it had entered into a Membership Interest Purchase Agreement, dated September 18, 2015 (the “Purchase Agreement”) with SOFAR S.p.A., (the “Seller”), Vulcanos S.r.l., as the acquired company, and TransEnterix International, Inc., a wholly owned subsidiary of the Company (the “Buyer”). The closing of the transactions contemplated by the Purchase Agreement occurred on September 21, 2015 (the “Closing Date”) pursuant to which the Buyer acquired all of the membership interests of the acquired company from the Seller, and changed the name of the acquired company to TransEnterix Italia S.r.l (“TransEnterix Italia”). On the Closing Date, pursuant to the Purchase Agreement, the Company completed the strategic acquisition from SOFAR S.p.A. of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery known as TELELAP ALF-X (the “ALF-X Acquisition”).

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of 15,543,413 shares of the Company’s common stock (the “Securities Consideration”) and approximately \$25,000,000 U.S. Dollars and 27,500,000 Euro in cash consideration (the “Cash Consideration”). The Securities Consideration was issued in full at closing of the acquisition; the Cash Consideration was or will be paid in four tranches, with US \$25,000,000 paid at closing and the remaining Cash Consideration of 27,500,000 Euro to be paid in three additional tranches based on achievement of negotiated milestones.

The issuance of the Securities Consideration was effected as a private placement of securities under Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), and Regulation D promulgated thereunder.

The Purchase Agreement contains customary representations and warranties of the parties and the parties have customary indemnification obligations, which are subject to certain limitations described further in the Purchase Agreement.

Registration Rights and Lock-Up Agreements

In connection with the ALF-X Acquisition, we also entered into a Registration Rights Agreement, dated as of September 21, 2015, with the Seller, pursuant to which we agreed to register the Securities Consideration shares for resale following the end of the lock-up periods described below.

In connection with the ALF-X Acquisition, the Seller entered into a Lock-Up Agreement with the Company pursuant to which the Seller agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Securities Consideration for one year following the Closing Date. The Lock-up Agreement provides that the Seller may sell, transfer or convey: (i) no more than 50% of the Securities Consideration 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) no more than 75% of the Securities Consideration 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 Agreement cease to apply to the Securities Consideration following the second anniversary of the Closing Date, or earlier upon certain other conditions.

Amendment to Loan Agreement

In connection with entry into the Purchase Agreement, we sought the consent of Silicon Valley Bank (“SVB”), as a Lender, and Oxford Finance LLC (“Oxford”), as Lender and Collateral Agent under our existing Amended and Restated Loan and Security Agreement, dated as of September 26, 2014, as amended by the First Amendment, dated August 14, 2015 (collectively, the “Loan Agreement”), and entered into the Consent and Second Amendment to Amended and Restated Loan Agreement (the “Second Amendment”). Under the Second Amendment, the Lenders and Collateral Agent consented to the formation of the Buyer, the entry of the Company and Buyer entering into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. We agreed to pledge 100% of the common stock of the Buyer as additional security for the borrowings under the Loan Agreement. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Loan Agreement. Further, the Second Amendment modified the period in which we could make interest-only payments on the term loans until January 31, 2016.

2014 Events

Reverse Stock Split

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

Public Offering

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

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

2013 Merger Transaction and Related Events

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

Pursuant to the Merger Agreement, each share of TransEnterix Surgical’s capital stock issued and outstanding immediately preceding the Merger was converted into the right to receive 1.1533 shares (the “Exchange Ratio”)

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

In connection with the Merger Agreement and the Private Placement, certain of TransEnterix Surgical's and SafeStitch's former stockholders, agreed to enter into Lock-up and Voting Agreements, and the Company and the Investors entered into a Registration Rights Agreement. The voting agreements were fully satisfied and the lock-up periods under the Lock-up and Voting Agreements fully expired in September 2015. In February 2016, the Company filed the resale registration statement required under the Registration Rights Agreement, satisfying the Company's obligations under the Registration Rights Agreement.

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, 2015, the net carrying value of our goodwill and other intangible assets related to this Merger totaled approximately \$93.8 million. In accordance with generally accepted accounting principles, we annually assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized. We performed our annual impairment analysis as of December 31, 2015. Based upon the results of our analysis, we determined that no impairment of goodwill existed as of this date.

Results of Operations

Our results of operations include the acquired SafeStitch operations from the Merger date, September 3, 2013, forward and the operations of TransEnterix Italia from the ALF-X Acquisition date of September 21, 2015 forward.

Revenue

Prior to 2015, we derived sales from our SPIDER System and other distributed products through limited direct sales in the United States and international distributors. We recorded revenue when persuasive evidence of an arrangement existed, delivery had occurred which was typically at shipping point, the fee was fixed or determinable and collectability was reasonably assured. Shipping and handling costs billed to customers are included in revenue.

Sales for the year ended December 31, 2015 decreased to \$0.0 million compared to \$0.4 million for the year ended December 31, 2014. The \$0.4 million decrease was primarily the result of our decision to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014. We discontinued sales of the SPIDER System on December 31, 2014.

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

Cost of Goods Sold

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

Cost of goods sold for the year ended December 31, 2015 decreased to \$0.0 million as compared to \$1.1 million for the year ended December 31, 2014. The \$1.1 million decrease was primarily the result of our reduction in sales as we limited sales of our SPIDER System to our existing customers and discontinued the production of our SPIDER System.

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

Research and Development

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

R&D expenses for the year ended December 31, 2015 increased 6% to \$29.7 million as compared to \$27.9 million for the year ended December 31, 2014. The \$1.8 million increase resulted primarily from increased preclinical lab expense of \$1.4 million, increased personnel related costs of \$0.8 million, increased stock compensation costs of \$0.3 million, increased other costs of \$0.4 million, offset by decreased supplies expense of \$1.5 million, and decreased contract engineering services, consulting and other outside services of \$0.8 million related to product development of our SurgiBot System. In addition, R&D expenses incurred for development of the ALF-X System from September 21, 2015 to December 31, 2015 were \$1.2 million.

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

Sales and Marketing

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

Sales and marketing expenses for the year ended December 31, 2015 increased 71% to \$2.9 million compared to \$1.7 million for the year ended December 31, 2014. The \$1.2 million increase was primarily related to increased tradeshow costs of \$0.3 million, increased personnel related costs of \$0.2 million, increased travel related expenses of \$0.1 million, and increased stock compensation costs of \$0.1 million. In addition, sales and marketing expenses related to the ALF-X Acquisition from September 21, 2015 to December 31, 2015 were \$0.5 million.

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

General and Administrative

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

General and administrative expenses for the year ended December 31, 2015 increased 37% to \$7.8 million compared to \$5.7 million for the year ended December 31, 2014. The \$2.1 million increase was primarily due to increased personnel costs of \$1.0 million, increased stock compensation costs of \$1.0 million, increased consulting expenses of \$0.1 million, offset by decreased legal, accounting, and investor relation fees and other public company costs of \$0.2 million. In addition, general and administrative expenses related to the ALF-X Acquisition from September 21, 2015 to December 31, 2015 were \$0.2 million.

General and administrative expenses for the year ended December 31, 2014 increased 54% to \$5.7 million compared to \$3.7 million for the year ended December 31, 2013. The \$2.0 million increase was primarily due to increased personnel costs of \$0.3 million, increased stock compensation costs of \$0.9 million, increased legal, accounting, and investor relation fees and other public company costs of \$0.8 million, and increased insurance costs of \$0.2 million, offset by decreased other expenses of \$0.2 million.

Amortization of Intangible Assets

Amortization of intangible assets for the year ended December 31, 2015 increased to \$2.2 million compared to \$0.5 million for the year ended December 31, 2014. The \$1.7 million increase was primarily the result of amortization of developed technology related to the acquisition of the ALF-X System on September 21, 2015.

Amortization of intangible assets for the year ended December 31, 2014 of \$0.5 million related to acquired patents was consistent with the amount reported for the year ended December 31, 2013.

Impairment Loss on Disposal of Property and Equipment

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

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration in connection with the ALF-X Acquisition was \$0.4 million for the year ended December 31, 2015 related primarily to the foreign currency translation impact.

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.

Acquisition Related Costs

Acquisition related costs consist primarily of legal, accounting and other professional fees related to the ALF-X Acquisition. We incurred \$4.2 million of acquisition-related expenses for the year ended December 31, 2015.

Other Expense, Net

Other expense is primarily composed of interest expense on notes payable and the remeasurement of fair value of preferred stock warrant liability.

Other expense for the year ended December 31, 2015 increased to \$1.6 million compared to \$1.0 million for the year ended December 31, 2014. The \$0.6 million increase was related to the increase in notes payable of approximately \$10.0 million in August 2015.

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

Income Tax Benefit

Income tax benefit consist primarily of taxes related to the amortization of purchase accounting intangibles in connection with the Italian taxing jurisdiction for TransEnterix Italia as a result of the acquisition of the ALF-X System. We recognized \$1.0 million of income tax benefit for the year ended December 31, 2015.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception we have incurred significant losses and, as of December 31, 2015, we had an accumulated deficit of \$182.9 million. We have not yet achieved profitability and we cannot assure investors that we will achieve profitability with our existing capital resources. Our recurring losses raise substantial doubt about our ability to continue as a going concern. As a result, the Company's independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the years ended December 31, 2015, 2014 and 2013 with respect to this uncertainty. We expect to continue to fund research and development, sales and marketing and general and administrative expenses at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash to date have been proceeds from public offerings of common stock, private placements of common and preferred stock, incurrence of debt and the sale of equity securities held as investments.

We currently have two effective shelf registration statements on file with the SEC, each of which were initially filed to register up to \$100.0 million of debt securities, common stock, preferred stock, or warrants, or any combination thereof for future financing transactions. From April 2014 through February 2016, we have raised \$137.7 million in gross proceeds and approximately \$128.6 million in net proceeds under such shelf registration statements through public offerings of our securities as described above. As of December 31, 2015, we had \$80.8 million available for future financings under such shelf registration statements, however approximately \$18.5 million was raised under the 2015 ATM Offering and \$43.6 million may now be raised under the 2016 ATM Offering we initiated in February 2016. As of March 1, 2016, we have approximately \$18.8 million available under such effective shelf registration statements for future financings.

At December 31, 2015, we had cash and cash equivalents of approximately \$38.4 million. As of February 29, 2016, we had cash and cash equivalents of approximately \$47.1 million.

Consolidated Cash Flow Data

	Years Ended December 31,		
	2015	2014	2013
(in thousands)			
Net cash provided by (used in)			
Operating activities	\$(38.5)	\$(33.2)	\$(21.2)
Investing activities	(26.2)	4.0	(6.5)
Financing activities	68.4	54.0	28.8
Net increase in cash and cash equivalents	\$ 3.7	\$ 24.8	\$ 1.1

Operating Activities

For the year ended December 31, 2015, cash used in operating activities of \$38.5 million consisted of net loss of \$46.9 million, offset by non-cash items of \$5.5 million and cash provided by working capital of \$2.9 million. The non-cash items primarily consisted of \$3.3 million of stock-based compensation expense, \$1.3 million of depreciation, \$2.3 million of amortization, offset by \$1.0 million deferred income tax benefit and \$0.4 million change in fair value of contingent consideration. The increase in cash from changes in working capital included \$1.9 million increase in inventories, and \$2.0 million increase in other current and long term assets. These amounts were partially offset by \$1.1 million increase in accounts payable, \$5.4 million increase in accrued expenses, \$0.3 million decrease in restricted cash, and \$0.1 million decrease in accounts receivable.

For the year ended December 31, 2014, cash used in operating activities of \$33.2 million consisted of net loss of \$37.7 million, offset by non-cash items of \$3.3 million and cash provided by working capital of \$1.2 million. The non-cash items primarily consisted of \$1.8 million of stock-based compensation expense, \$0.8 million of depreciation, \$0.6 million of amortization, and \$0.1 million loss on disposal of property and equipment. The increase in cash from changes in working capital included \$0.7 million decrease in inventories, \$0.4 million increase in accrued expenses, \$0.1 million decrease in restricted cash, \$0.1 decrease in accounts receivable, and \$0.1 decrease in interest receivable, partially offset by \$0.2 million increase in other current and long term assets.

For the year ended December 31, 2013, cash used in operating activities of \$21.2 million consisted of net loss of \$28.4 million, offset by non-cash items of \$4.9 million and cash provided by working capital of \$2.3 million. The non-cash items primarily consisted of \$1.8 million remeasurement of fair value of preferred stock warrant liability, \$0.9 million of stock-based compensation expense, \$1.0 million of depreciation, \$0.7 million of amortization, and \$0.5 million impairment loss of property and equipment. The increase in cash from changes in working capital included \$0.7 million decrease in inventories, \$0.4 million decrease in accounts receivable, and \$0.9 million increase in accrued expenses, and \$0.6 million increase in accounts payable, partially offset by \$0.3 million increase in other current and long term assets.

Investing Activities

For the year ended December 31, 2015, net cash used in investing activities was \$26.2 million. This amount reflected the \$25.0 million payment for the ALF-X Acquisition and \$1.2 million paid for the purchases of property and equipment.

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

For the year ended December 31, 2013, net cash used in investing activities was \$6.5 million. This amount reflected the \$6.2 million for the purchase of investments and \$1.4 million for the purchases of property and equipment, offset by \$0.9 million proceeds from the sale and maturities of investments and \$0.2 million cash received in acquisition of a business, net of cash paid.

Financing Activities

For the year ended December 31, 2015, net cash provided by financing activities was \$68.4 million. This amount was primarily related \$58.3 million in proceeds from the issuance of common stock, net of issuance costs, and \$9.9 million proceeds from the issuance of debt, and \$0.2 million proceeds from the issuance of stock options and warrants.

For the year ended December 31, 2014, net cash provided by financing activities was \$54.0 million. This amount was primarily related to \$52.5 million in proceeds from the issuance of common stock, net of issuance costs, and

\$4.3 million proceeds from the issuance of debt, and \$0.1 million proceeds from the issuance of stock options and warrants, offset by \$2.9 million payments on debt.

For the year ended December 31, 2013, net cash provided by financing activities was \$28.8 million. This amount was primarily related to \$28.2 million in proceeds from the issuance of common stock, net of issuance costs, \$2.0 million proceeds from the issuance of debt, and \$0.1 million proceeds from the issuance of stock options and warrants, offset by \$1.5 million payments on debt.

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, 2016. We intend to spend substantial amounts on commercial activities, 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, and on contingent consideration payments in connection with the acquisition of the ALF-X System. 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, including the ongoing at-the-market offering, 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.

Cash and cash equivalents held by our foreign subsidiary totaled \$0.8 million at December 31, 2015. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiary. If these funds are needed in the U.S., we believe that the potential U.S. tax impact to repatriate these funds would be immaterial.

Loan Agreement

In connection with the Merger, in September we assumed and became the borrower under TransEnterix Surgical's then outstanding credit facility (the "Loan Agreement"). We have entered into a number of amendment and restatements of the Loan Agreement since that time, including the Consent and Second Amendment (the "Second Amendment") in connection with the ALF-X Acquisition in September 2015. Under the Loan Agreement, as amended, our borrowing capacity is \$20 million, all of which is borrowed under term loans. A second tranche of \$10 million is available to the Company upon recognition of at least \$10 million of trailing six-month revenues from the SurgiBot System and SurgiBot-related products no later than March 31, 2017. We have had periods of interest-only payments during the Loan Agreement, as amended. Under the Second Amendment we could make interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The Second Amendment has a maturity date of July 1, 2018.

In connection with the entry into the Loan Agreement and amendments, we became obligated to pay final payment and facility fees. The final payment fee obligation payable under the Second Amendment is 6.5% of the original principal amount of each term loan.

In addition, in connection with the borrowings, we issued warrants to the Lenders to purchase shares of the Company's common stock as follows:

<u>Date of issuance</u>	<u>Common stock underlying warrants</u>	<u>Expiration date</u>
01/17/2012	279,588	01/17/2019
09/26/2014	38,324	09/26/2021
08/14/2015	112,903	08/14/2022
TOTAL	<u>430,815</u>	

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

Further, under the Second Amendment, the Lenders consented to the formation of TransEnterix International, the entry of the Company into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. We agreed to pledge 100% of the common stock of TransEnterix International as additional security for the borrowings under the Amended and Restated Loan Agreement, as amended. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Amended and Restated Loan Agreement. This provision for the transfer of designated amount was amended on November 13, 2015 with the Third Amendment to the Amended and Restated Loan Agreement.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2015 (in millions):

	Total	Payments due by period			
		Less than 1 year	1 to 3 years	3 to 5 years	Thereafter
Long-term debt obligations	\$23.4	\$8.2	\$15.2	—	\$—
Operating leases	\$ 1.5	\$0.6	\$ 0.9	\$—	\$—
License and supply agreements	\$ 7.5	\$0.7	\$ 2.4	\$ 1.7	\$ 2.7
Total contractual obligations*	<u>\$32.4</u>	<u>\$9.5</u>	<u>\$18.5</u>	<u>\$ 1.7</u>	<u>\$ 2.7</u>

* We recorded contingent consideration liabilities of \$23.5 million as of December 31, 2015, of which \$12.5 million was recorded as the current portion of contingent consideration. Due to uncertainty regarding the timing and amount of future payments related to these liabilities, these amounts are excluded from the contractual obligations table above.

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

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

License and supply agreements include agreements assumed as part of the ALF-X Acquisition.

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth above under the headings “Results of Operations” and “Liquidity and Capital Resources” have been prepared in accordance with U.S. GAAP and should be read in conjunction with our financial statements and notes thereto appearing in Item 8

of this Annual Report. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our critical accounting policies and estimates, including identifiable intangible assets and goodwill, in-process research and development, contingent consideration, stock-based compensation, and inventory. 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, 2015, 2014, and 2013 which are included as Item 8 of this Annual Report. Actual results may differ from these estimates under different assumptions and conditions.

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

Identifiable Intangible Assets and Goodwill

Identifiable intangible assets consists of purchased patent rights recorded at cost and developed research and development acquired as part of a business acquisition recorded at estimated fair value. Intangible assets are amortized over 7 to 10 years. We periodically evaluate identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists by performing either a qualitative evaluation or a two-step quantitative test. The qualitative evaluation is an assessment of factors, including industry, market and general economic conditions, market value, and future projections to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. The Company may elect to bypass this qualitative assessment and perform a two-step quantitative test. The quantitative goodwill impairment test is performed by comparing the estimated fair value of the associated reporting unit to its carrying value. We performed a qualitative assessment during the annual impairment review for fiscal 2015 as of December 31, 2015 and concluded that it is not more likely than not that the fair value of our single reporting unit is less than its carrying amount. Therefore, the two-step goodwill impairment test for the reporting unit was not necessary in fiscal 2015.

Business Acquisitions

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

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results. The purchase price allocation presented herein has been updated since September 30, 2015 and is preliminary as the Company is finalizing its compilation and review of certain market data used in the valuation of the intangible assets acquired. The final purchase price allocation will be determined after completion of this analysis to determine the fair value of all assets acquired and liabilities assumed, but in no event later than one year following completion of the ALF-X Acquisition. Accordingly, the final acquisition accounting adjustments could differ materially from the preliminary amounts presented herein. Any increase or decrease in the fair value of the assets acquired and liabilities assumed, as compared to the information shown herein, could also change the portion of purchase price allocated to goodwill, and could impact the operating results of the Company following the acquisition due to differences in purchase price allocation, depreciation and amortization related to some of these assets and liabilities.

In-Process Research and Development

In-process research and development, or IPR&D, assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that we acquire, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if we become aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when we have regulatory approval and are able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, we may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

Contingent Consideration

Contingent consideration is recorded as a liability and measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration at each reporting date will be updated by reflecting the changes in fair value reflected in our statement of operations.

Accounting for Stock-Based Compensation

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

assumed to be zero. We estimates forfeitures based on our historical experience and adjust the estimated forfeiture rate based upon actual experience.

Inventory

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

Recent Accounting Pronouncements

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

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

General

We have limited exposure to market risks from instruments that may impact the Balance Sheets, Statements of Operations and Comprehensive Loss, and Statements of Cash Flows. Such exposure is due primarily to changing interest rates.

Interest Rates

The primary objective for our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing excess cash in money market funds and Treasury securities. As of December 31, 2015, approximately 96% of the investment portfolio was in cash equivalents with very short term maturities and therefore not subject to any significant interest rate fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
TransEnterix, Inc.
Morrisville, North Carolina

We have audited the accompanying consolidated balance sheets of TransEnterix, Inc. (the “Company”) as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive loss, preferred stock and stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of TransEnterix, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), TransEnterix, Inc.’s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 3, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 3, 2016

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
TransEnterix, Inc.
Morrisville, North Carolina

We have audited TransEnterix Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). TransEnterix Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, "Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

As indicated in the accompanying Item 9a, Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of TransEnterix Italia S.r.l. ("TransEnterix Italia"), which was acquired on September 21, 2015, and which is included in the consolidated balance sheet of TransEnterix, Inc. as of December 31, 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year then ended. TransEnterix Italia constituted approximately 28% of the Company's total consolidated assets, excluding goodwill, as of December 31, 2015 and 8% of consolidated operating expenses for the year then ended. Management did not assess the effectiveness of internal control over financial reporting of TransEnterix Italia because of the timing of the acquisition which was completed on September 21, 2015. Our audit of internal control over financial reporting of TransEnterix, Inc. also did not include an evaluation of the internal control over financial reporting of TransEnterix Italia.

In our opinion, TransEnterix, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of TransEnterix, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 3, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 3, 2016

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

	December 31,	
	2015	2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 38,449	\$ 34,766
Accounts receivable, net	76	133
Inventories	3,923	—
Interest receivable	6	1
Other current assets	6,689	740
Total Current Assets	49,143	35,640
Inventories	709	—
Restricted cash	—	250
Property and equipment, net	4,408	3,120
Intellectual property, net	46,898	2,241
In-process research and development	16,511	—
Goodwill	130,869	93,842
Other long term assets	64	18
Total Assets	\$ 248,602	\$ 135,111
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 4,450	\$ 1,768
Accrued expenses	7,395	1,769
Contingent consideration – current portion	12,500	—
Notes payable – current portion	6,727	610
Total Current Liabilities	31,072	4,147
Long Term Liabilities		
Contingent consideration – less current portion	11,000	—
Net deferred tax liabilities	16,263	—
Notes payable – less current portion, net of debt discount	12,990	9,175
Total Liabilities	71,325	13,322
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2015 and 2014; 100,180,872 and 63,182,806 shares issued at December 31, 2015 and December 31, 2014, respectively; and 100,149,453 and 63,182,806 shares outstanding at December 31, 2015 and December 31, 2014, respectively	100	63
Additional paid-in capital	363,280	257,642
Accumulated deficit	(182,864)	(135,916)
Treasury stock at cost, 31,419 and 0 shares at December 31, 2015 and December 31, 2014, respectively	(73)	—
Accumulated other comprehensive loss	(3,166)	—
Total Stockholders' Equity	177,277	121,789
Total Liabilities and Stockholders' Equity	\$ 248,602	\$ 135,111

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands except per share amounts)

	Years Ended December 31,		
	2015	2014	2013
Sales	\$ —	\$ 401	\$ 1,431
Operating Expenses			
Cost of goods sold	—	1,095	4,810
Research and development	29,669	27,944	12,700
Sales and marketing	2,855	1,727	1,943
General and administrative	7,831	5,741	3,721
Amortization of intangible assets	2,185	503	500
Impairment loss on property and equipment	—	—	450
Change in fair value of contingent consideration	(400)	—	—
Merger expenses	—	—	2,911
Acquisition related costs	4,231	—	—
Total Operating Expenses	<u>46,371</u>	<u>37,010</u>	<u>27,035</u>
Operating Loss	<u>(46,371)</u>	<u>(36,609)</u>	<u>(25,604)</u>
Other Expense			
Remeasurement of fair value of preferred stock warrant liability	—	—	(1,800)
Interest expense, net	(1,601)	(1,043)	(954)
Total Other Expense, net	<u>(1,601)</u>	<u>(1,043)</u>	<u>(2,754)</u>
Loss before income taxes	(47,972)	\$(37,652)	\$(28,358)
Income tax benefit	1,024	—	—
Net loss	<u>\$(46,948)</u>	<u>\$(37,652)</u>	<u>\$(28,358)</u>
Other comprehensive loss			
Foreign currency translation loss	(3,166)	—	—
Comprehensive loss	<u>\$(50,114)</u>	<u>\$(37,652)</u>	<u>\$(28,358)</u>
Net loss per share – basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.64)</u>	<u>\$ (2.23)</u>
Weighted average common shares outstanding - basic and diluted	<u>79,628</u>	<u>58,714</u>	<u>12,731</u>

See accompanying notes to consolidated financial statements.

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

	Series A		Preferred Stock Series B		Series B-1		Preferred Stock Series B		Common Stock (1)		Treasury Stock	Additional Paid-in Capital (1)	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares				
Balance, December 31, 2012	5,696	\$ 19,885	11,490	\$ 40,016	45,998	\$ 15,104	—	\$ —	1,078	\$ 1	\$ —	\$ 1,292	\$ (69,906)	\$ —	\$ (68,613)
Accretion of issuance costs	—	—	—	—	—	—	9	—	—	—	—	(40)	—	—	(40)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	941	—	—	941
Exercise of stock options	—	—	—	—	—	—	—	—	68	—	—	54	—	—	54
Exercise of warrants	—	—	—	—	—	—	—	—	167	—	—	90	—	—	90
Reverse acquisition recapitalization adjustment	(5,696)	(19,885)	(11,490)	(40,047)	(45,998)	(15,113)	—	—	32,444	33	—	168,810	—	—	168,843
Redemption of TransEnterix Surgical shares for cash to non-accredited investors	—	—	—	—	—	—	—	—	(54)	—	—	—	—	—	—
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	—	—	—	—	—	—	—	1,909	—	—	1,909
Issuance of preferred stock	—	—	—	—	—	—	7,570	30,197	—	—	—	—	—	—	30,197
Conversion of preferred stock to common stock	—	—	—	—	—	—	(7,570)	(30,197)	15,139	15	—	30,182	—	—	(28,358)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(28,358)	—	(28,358)
Balance, December 31, 2013	—	\$ —	—	\$ —	—	\$ —	—	\$ —	48,842	\$ 49	\$ —	\$ 203,238	\$ (98,264)	\$ —	\$ 105,023
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	1,840	—	—	1,840
Issuance of common stock, net of issuance costs	—	—	—	—	—	—	—	—	14,110	14	—	52,419	—	—	52,433
Exercise of stock options and restricted stock units	—	—	—	—	—	—	—	—	221	—	—	75	—	—	75
Exercise of warrants	—	—	—	—	—	—	—	—	10	—	—	16	—	—	16
Issuance of warrants	—	—	—	—	—	—	—	—	—	—	—	54	—	—	54
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(37,652)	—	(37,652)
Balance, December 31, 2014	—	\$ —	—	\$ —	—	\$ —	—	\$ —	63,183	\$ 63	\$ —	\$ 257,642	\$ (135,916)	\$ —	\$ 121,789
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	3,311	—	—	3,311
Issuance of common stock, net of issuance costs	—	—	—	—	—	—	—	—	20,756	21	—	58,310	—	—	58,331
Issuance of common stock, acquisition	—	—	—	—	—	—	—	—	15,543	15	—	43,662	—	—	43,677
Exercise of stock options and vesting of restricted stock units	—	—	—	—	—	—	—	—	698	1	—	258	—	—	259
Return of common stock to pay withholding taxes on restricted stock	—	—	—	—	—	—	—	—	(31)	—	(73)	—	—	—	(73)
Issuance of warrants	—	—	—	—	—	—	—	—	—	—	—	97	—	—	97
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(46,948)	(3,166)	(3,166)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(46,948)	—	(46,948)
Balance, December 31, 2015	—	\$ —	—	\$ —	—	\$ —	—	\$ —	100,149	\$ 100	\$ (73)	\$ 363,280	\$ (182,864)	\$ (3,166)	\$ 177,277

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

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

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

	Years End December 31,		
	2015	2014	2013
Operating Activities			
Net loss	\$(46,948)	\$(37,652)	\$(28,358)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:			
Depreciation	1,248	807	983
Amortization of intangible assets	2,185	503	500
Amortization of debt discount and debt issuance costs	142	83	103
Remeasurement of fair value of preferred stock warrant liability	—	—	1,800
Accretion/amortization of bond discount/premium	—	—	52
Stock-based compensation	3,311	1,840	941
Loss on disposal of property and equipment	34	86	31
Impairment loss on property and equipment	—	—	450
Deferred tax benefit	(1,024)	—	—
Change in fair value of contingent consideration	(400)	—	—
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	133	55	402
Interest receivable	(5)	67	(52)
Inventories	(1,928)	701	731
Other current and long term assets	(1,974)	(170)	(328)
Restricted cash	250	125	—
Accounts payable	1,096	(36)	641
Accrued expenses	5,371	363	868
Net cash and cash equivalents used in operating activities	<u>(38,509)</u>	<u>(33,228)</u>	<u>(21,236)</u>
Investing Activities			
Purchase of investments	—	—	(6,240)
Proceeds from sale and maturities of investments	—	6,191	904
Cash received in acquisition of a business, net of cash paid	—	—	246
Proceeds from sale of property and equipment	—	25	—
Payments for acquisition of a business	(25,000)	—	—
Purchase of property and equipment	(1,234)	(2,174)	(1,377)
Net cash and cash equivalents (used in) provided by investing activities	<u>(26,234)</u>	<u>4,042</u>	<u>(6,467)</u>
Financing Activities			
Payment of debt	—	(2,877)	(1,519)
Proceeds from issuance of common stock, net of issuance costs	58,331	52,433	—
Proceeds from issuance of debt, net of debt discount	9,887	4,291	1,998
Proceeds from issuance of preferred stock, net of issuance costs	—	—	28,199
Taxes paid related to net share settlement of vesting of restricted stock units	(73)	—	—
Proceeds from exercise of stock options and warrants	259	91	143
Net cash and cash equivalents provided by financing activities	<u>68,404</u>	<u>53,938</u>	<u>28,821</u>
Effect of exchange rate changes on cash and cash equivalents	<u>22</u>	<u>—</u>	<u>—</u>
Net increase in cash and cash equivalents	3,683	24,752	1,118
Cash and Cash Equivalents, beginning of period	34,766	10,014	8,896
Cash and Cash Equivalents, end of period	<u>\$ 38,449</u>	<u>\$ 34,766</u>	<u>\$ 10,014</u>
Supplemental Disclosure for Cash Flow Information			
Interest paid	\$ 973	\$ 904	\$ 824
Supplemental Schedule of Noncash Investing and Financing Activities			
Issuance of common stock warrants	\$ 97	\$ 54	\$ —
Contingent consideration related to acquisition	\$ 23,900	\$ —	\$ —
Issuance of common stock related to acquisition	\$ 43,677	\$ —	\$ —
Conversion of bridge notes to preferred stock	\$ —	\$ —	\$ 1,998
Conversion of preferred stock warrants to common stock warrants	\$ —	\$ —	\$ 1,909
Conversion of preferred stock to common stock	\$ —	\$ —	\$ 30,197

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Capitalization

TransEnterix, Inc. (the “Company”) is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical challenges associated with current laparoscopic and robotic options. The Company is focused on the commercialization and further development of ALF-X[®] Surgical Robotic System (the “ALF-X System”), a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology, and the development and commercialization of the SurgiBot[™] System, a single-port, robotically enhanced laparoscopic surgical platform. The ALF-X System has been granted a CE Mark in Europe for use in urology, general surgery, gynecology and thoracic surgery, but is not available for sale in the U.S. The SurgiBot System has been submitted for clearance to the FDA, and is not yet available for sale in any market.

The ALF-X System is a multi-port robotic surgery system which allows multiple arms to control robotic instruments and a camera. The system features advanced technology to enable surgeons with haptic feedback and the ability to move the camera via eye movement. The system replicates laparoscopic motion that is familiar to experienced surgeons, and features three-dimensional high definition (“3DHD”) vision technology. The ALF-X System also offers responsible economics to hospitals by offering robotic technology with reusable instruments with minimal additional costs per surgery.

The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for 3DHD vision technology.

On September 3, 2013, TransEnterix Surgical, Inc. a Delaware corporation (“TransEnterix Surgical”), and SafeStitch Medical, Inc., a Delaware corporation (“SafeStitch”) consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the “Merger”). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. and increased the authorized shares of common stock from 225,000,000 to 750,000,000, and authorized 25,000,000 shares of preferred stock, par value \$0.01 per share. Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity, gastroesophageal reflux disease (“GERD”) and Barrett’s Esophagus. In the second quarter of 2014, the Company ceased internal development of the Gastroplasty Device and is currently evaluating strategic alternatives for the former SafeStitch products.

On September 18, 2015, the Company entered into a Membership Interest Purchase Agreement, (the “Purchase Agreement”) with SOFAR S.p.A., (“SOFAR”) as seller, Vulcanos S.r.l. (“Vulcanos”), as the acquired company, and TransEnterix International, Inc. (“TransEnterix International”), a direct, wholly owned subsidiary of the Company which was incorporated in September 2015, as buyer. The closing of the transactions occurred on September 21, 2015 (the “Closing Date”) pursuant to which the Company acquired all of the membership interests of Vulcanos from SOFAR (the “ALF-X Acquisition”), and changed the name of Vulcanos to TransEnterix Italia S.r.l (“TransEnterix Italia”). The acquisition included all of the assets, employees and contracts related to the ALF-X System. See Note 3 for a description of the related transactions.

As used herein, the term “Company” refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, and TransEnterix International and TransEnterix Italia after giving effect to the ALF-X Acquisition, the term “SafeStitch” refers to the historic business of SafeStitch Medical, Inc. prior to the

Merger, and the term “TransEnterix Surgical” refers to the historic business of TransEnterix Surgical, Inc. prior to the Merger.

The Company operates in one business segment.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and include the accounts of the Company and its direct and indirect wholly owned subsidiaries, SafeStitch LLC, TransEnterix Surgical, Inc., TransEnterix International, Inc. and TransEnterix Italia. All inter-company accounts and transactions have been eliminated in consolidation.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has accumulated a deficit of approximately \$182.9 million as of December 31, 2015, a net loss of approximately \$46.9 million for the year ended December 31, 2015, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

Use of Estimates

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

Reverse Merger

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

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

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

Reverse Stock Split

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

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

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

Restricted cash, consisting of a money market account used as collateral securing a letter of credit under the terms of the corporate office operating lease that commenced in 2010.

The Company's investments at December 31, 2013 consisted of corporate bonds and were classified as available for sale. Investments classified as available for sale are measured at fair value, and net unrealized gains and losses are recorded as a component of accumulated other comprehensive loss on the balance sheet until realized. Realized gains and losses on sales of investment securities are determined based on the specific-identification method and are recorded in interest expense, net. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization and accretion is included in interest expense, net. The Company held no investments as of December 31, 2015 and 2014 as it sold all its investment securities during 2014.

Fair Value of Financial Instruments

The carrying values of cash equivalents, accounts receivable, interest receivable, accounts payable, and certain accrued expenses at December 31, 2015 and 2014, approximate their fair values due to the short-term nature of these items. The Company's notes payable balance approximates fair value as of December 31, 2015 and 2014, as the Company's notes payable were amended and modified in the third quarter of 2015.

Concentrations and Credit Risk

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

The Company's accounts receivable are derived from net revenue to customers and distributors located throughout the world. The Company evaluates its customers' financial condition and, generally, requires no collateral from its customers. The Company provides reserves for potential credit losses but has not experienced significant losses to date. The Company had one customer who constituted 100% of the Company's net accounts receivable at December 31, 2015 and one customer who constituted 74% of the Company's net accounts receivable at December 31, 2014. The Company had two customers who accounted for 37% and 10% of sales in 2014 and one customer who accounted for 37% of sales in 2013.

Accounts Receivable

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

Inventories

Inventories are stated at the lower of cost or market. Cost is based on the first in, first out method. The Company records reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. 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. Any inventory on hand at the measurement date in excess of the Company's current requirements based on anticipated levels of sales is classified as long-term on the Company's consolidated balance sheets. The Company's classification of long-term inventory requires it to estimate the portion of on-hand inventory that can be realized over the next 12 months.

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 7 to 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed at December 31, 2015, 2014, or 2013.

Intellectual property consists of purchased patent rights and developed research and development acquired as part of a business acquisition. Amortization of the patent rights is recorded using the straight-line method over the estimated useful life of the patents of 10 years. Amortization of the developed research and development is recorded using the straight-line method over the estimated useful life of 7 years. This method approximates the period over which the Company expects to receive the benefit from these assets.

Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at December 31st or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value based test. The Company continues to operate in one segment, which is considered to be the sole reporting unit and therefore, goodwill was tested for impairment at the enterprise level. No impairment existed at December 31, 2015, 2014, or 2013.

In-Process Research and Development

In-process research and development ("IPR&D") assets represent the fair value assigned to technologies that were acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. The IPR&D was acquired on September 21, 2015. No impairment existed at December 31, 2015.

Property and Equipment

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

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

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

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

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for possible impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine the recoverability of its long-lived assets, the Company evaluates the probability that future estimated undiscounted net cash flows will be less than the carrying amount of the assets. If such estimated cash flows are less than the carrying amount of the long-lived assets, then such assets are written down to their fair value. The Company's estimates of anticipated cash flows and the remaining estimated useful lives of long-lived assets could be reduced in the future, resulting in a reduction to the carrying amount of long-lived assets.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration at each reporting date is updated by reflecting the changes in fair value in our statement of operations and comprehensive loss.

Translation of Foreign Currencies

The functional currency of the Company's foreign subsidiary, TransEnterix Italia, is its local currency. The assets and liabilities of the Company's foreign subsidiary are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items are translated at the average exchange rates prevailing during the period. The cumulative translation effect for a subsidiary using a functional currency other than the U.S. dollar is included in accumulated other comprehensive income or loss as a separate component of stockholders' equity.

The Company's intercompany accounts are denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany receivables that the Company considers to be of a long-term investment nature are recorded as a cumulative translation adjustment in accumulated other comprehensive income or loss as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany receivables from a foreign subsidiary for which the Company

anticipates settlement in the foreseeable future are recorded in the consolidated statement of operations and comprehensive loss. The net gains and losses included in net loss in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2015 were not significant.

Business Acquisitions

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

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

Risk and Uncertainties

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

Preferred Stock Warrant Liability

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

Revenue Recognition

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

Cost of Goods Sold

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

Research and Development Costs

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

Stock-Based Compensation

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

The Company recognizes compensation expense for stock-based awards based on estimated fair values on the date of grant for awards granted to employees. The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The fair value of other stock-based compensation awards is determined by the market price of the Company’s common stock on the date of grant. The expense associated with stock-based compensation is recognized on a straight-line basis over the requisite service period of each award.

The Company records as expense the fair value of stock-based compensation awards, including stock options and restricted stock units. Compensation expense for stock-based compensation was approximately \$3,311,000, \$1,840,000 and \$941,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

Income Taxes

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

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

Segments

The Company operates in one business segment – the research, development and sale of medical device robotics to improve minimally invasive surgery. The Company’s chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company’s consolidated operating results. Approximately 57% of the Company’s total consolidated assets are located within the U.S. as of December 31, 2015. The remaining assets are mostly located in Europe and are primarily related to the Company’s ALF-X System facility in Italy, and include goodwill, intellectual property, in-process research and development and inventory of \$106.3 million at December 31, 2015, associated with the ALF-X Acquisition in September 2015. Total assets outside of the U.S. excluding goodwill amounted to 28% of total consolidated assets at December 31, 2015. There were no assets outside the U.S. as of December 31, 2014. For the years ended December 31, 2015, 2014, and 2013, 0%, 90%, and 60%, respectively, of net revenue were generated in the United States.

Impact of Recently Issued Accounting Standards

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

The updated guidance is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the Standard in 2018.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern* (“ASU 2014-15”). The amendments in ASU 2014-15 are intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. Under U.S. GAAP, financial statements are prepared under the presumption that the reporting organization will continue to operate as a going concern, except in limited circumstances. The going concern basis of accounting is critical to financial reporting because it establishes the fundamental basis for measuring and classifying assets and liabilities. Currently, U.S. GAAP lacks guidance about management’s responsibility to evaluate whether there is substantial doubt about the organization’s ability to continue as a going concern or to provide related footnote disclosures. This ASU provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not expect this ASU will have a material impact on its consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* (“ASU 2015-03”). ASU 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the

carrying amount of the related debt liability, rather than an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. Upon adoption, this guidance requires retrospective application. The Company early adopted this standard for the year ended December 31, 2015. Although the new guidance had no impact on the Company's results of operations, the debt issuance costs presented as assets within the Company's consolidated balance sheet as of December 31, 2014 of \$100,000 has been reclassified as a reduction of the related debt liability.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory* (Topic 330). This update requires inventory within the scope of the standard to be measured at the lower of cost and net realizable value. Previous guidance required inventory to be measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin). This update is effective for annual and interim periods beginning after December 15, 2016, which will require us to adopt these provisions in the first quarter of fiscal year 2017. Early adoption is permitted. The Company is currently evaluating the impact the guidance will have on our consolidated financial statements.

In September 2015, the FASB issued ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments* (ASU 2015-16), which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. For public business entities, ASU 2015-16 is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. Our early adoption of ASU 2015-16 in the third quarter of 2015 did not have a material impact on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual report period. The amendments in this ASU may be applied either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We adopted this standard as of December 31, 2015 with prospective application. As a result, we reclassified our deferred tax assets classified as current to noncurrent and our deferred tax liabilities classified as current to noncurrent in our December 31, 2015 consolidated balance sheet. Prior balance sheets were not retrospectively adjusted.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements

and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements or related footnote disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the impact of our pending adoption of the new standard on our consolidated financial statements.

Reclassifications

As a result of a recent acquisition, certain financial statement captions have been added and we have reclassified certain prior-period amounts on our consolidated statement of operations and comprehensive loss to conform to the presentation for the current period. Such reclassifications have no effect on previously reported total assets, liabilities, stockholders' equity or net loss.

As previously disclosed, in April 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest* (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. This guidance requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability, rather than an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. Upon adoption, this guidance requires retrospective application. The Company early adopted this standard for the year ended December 31, 2015. Although the new guidance had no impact on the Company's results of operations, the debt issuance costs presented as assets within the Company's consolidated balance sheet as of December 31, 2014 of \$100,000 has been reclassified as a reduction of the related debt liability.

3. Acquisition of ALF-X Surgical Robotic System

On September 21, 2015, the Company completed the strategic acquisition, through its wholly owned subsidiary TransEnterix International, from SOFAR, of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery known as the ALF-X System and changed the name of the acquired company from Vulcanos S.r.l. to TransEnterix Italia S.r.l.

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of 15,543,413 shares of the Company's common stock (the "Securities Consideration") and approximately \$25.0 million U.S. Dollars and €27.5 million Euro in cash consideration (the "Cash Consideration"). The Securities Consideration was issued in full at the closing of the ALF-X Acquisition; the Cash Consideration was or will be paid in four tranches, as follows:

- (1) \$25.0 million of the Cash Consideration was paid at closing;
- (2) The second tranche of the Cash Consideration (the "Second Tranche") of €10 million shall be payable after the achievement of both of the following milestones (i) the earlier of approval from the FDA for the ALF-X System or December 31, 2016, and (ii) the Company having cash on hand of at least \$50.0 million, or successfully completing a financing, raising at least \$50.0 million in gross proceeds; with payment of

simple interest at a rate of 9.0% per annum between the achievement of the first milestone event and the payment date;

(3) The third tranche of the Cash Consideration (the “Third Tranche”) of €15.0 million shall be payable upon achievement of trailing revenues from sales or services contracts of the ALF-X System of at least €25.0 million over a calendar quarter; and

(4) The fourth tranche of the Cash Consideration of €2.5 million shall be payable by December 31, 2016 as reimbursement for certain debt payments made by SOFAR under an existing SOFAR loan agreement.

The Third Tranche will be payable even if the Second Tranche is not then payable. In addition, the Second Tranche and Third Tranche payments will be accelerated in the event that (i) the Company or TransEnterix International is acquired, (ii) the Company significantly reduces or suspends selling efforts of the ALF-X System, or (iii) the Company acquires a business that offers alternative products that are directly competitive with the ALF-X System.

Under the Purchase Agreement, 10% of the Securities Consideration is being held in escrow to support SOFAR’s representations and warranties under the Purchase Agreement. The Company and SOFAR also entered into a Security Agreement, which provides that 10% of the membership interests of TransEnterix Italia have a lien placed thereon by and in favor of SOFAR to support the Company’s representations and warranties under the Purchase Agreement. The escrow period and security interest period are each twenty-four months after the closing of the ALF-X Acquisition.

The Purchase Agreement contains customary representations and warranties of the parties and the parties have customary indemnification obligations, which are subject to certain limitations described further in the Purchase Agreement.

In connection with the ALF-X Acquisition, the Company also entered into a Registration Rights Agreement, dated as of September 21, 2015, with SOFAR, pursuant to which the Company agreed to register the Securities Consideration shares for resale following the end of the lock-up periods described below.

In connection with the ALF-X Acquisition, SOFAR entered into a Lock-Up Agreement with the Company pursuant to which SOFAR agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Securities Consideration for one year following the Closing Date. The Lock-up Agreement provides that SOFAR may sell, transfer or convey: (i) no more than 50% of the Securities Consideration 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) no more than 75% of the Securities Consideration 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 Agreement cease to apply to the Securities Consideration following the second anniversary of the Closing Date, or earlier upon certain other conditions.

The ALF-X Acquisition was accounted for as a business combination utilizing the methodology prescribed in ASC 805. The purchase price for the ALF-X Acquisition has been allocated to the assets acquired and liabilities assumed based on their estimated fair values. The purchase price allocation presented herein has been updated since September 30, 2015 and is preliminary as the Company is finalizing its compilation and review of certain market data used in the valuation of the intangible assets acquired. The final purchase price allocation will be determined after completion of this analysis to determine the fair value of all assets acquired and liabilities assumed, but in no event later than one year following completion of the ALF-X Acquisition. Accordingly, the final acquisition accounting adjustments could differ materially from the preliminary amounts presented herein. Any increase or decrease in the fair value of the assets acquired and liabilities assumed, as compared to the information shown herein, could also change the portion of purchase price allocated to goodwill, and could impact the operating results of the Company following the acquisition due to differences in purchase price allocation, depreciation and amortization related to some of these assets and liabilities.

The ALF-X Acquisition-date fair value of the consideration is as follows (in thousands, except for per share amounts):

Common shares issued	15,543
Closing price per share	<u>\$ 2.81</u>
	<u>\$43,677</u>
Cash consideration	<u>25,000</u>
Contingent consideration	<u>23,900</u>
Total consideration	<u><u>\$92,577</u></u>

The following table summarizes the preliminary estimated fair values of the assets acquired and liabilities assumed on September 21, 2015, the date of acquisition (in thousands):

Accounts receivable	\$ 78
Inventories	2,800
Current deferred tax asset	526
Other current assets	4,180
Property and equipment	1,384
Intellectual property	48,500
In-process research and development	17,100
Goodwill	<u>38,348</u>
Total assets acquired	<u>\$112,916</u>
Accounts payable and other liabilities	1,915
Long-term deferred tax liabilities	<u>18,424</u>
Net assets acquired	<u><u>\$ 92,577</u></u>

The Company allocated \$48.5 million of the preliminary purchase price to identifiable intangible assets of intellectual property that met the separability and contractual legal criterion of ASC 805. The intellectual property will be amortized using the straight-line method over 7 years.

IPR&D is principally the estimated fair value of the ALF-X System technology which had not reached commercial technological feasibility nor had alternative future use at the time of the acquisition and therefore the Company considered IPR&D, with assigned values to be allocated among the various IPR&D assets acquired.

Goodwill is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition arises largely from synergies expected from combining the operations of TransEnterix Italia with the Company's existing operations. The goodwill is not deductible for income tax purposes.

All legal, consulting and other costs related to the acquisition, aggregating approximately \$4.2 million, have been expensed as incurred and are included in operating expenses in the Company's consolidated statements of operations and comprehensive loss. The results of operations for TransEnterix Italia are included in the Company's consolidated statements of operations and comprehensive loss for the period from the September 21, 2015 acquisition date to December 31, 2015. The Company has no revenues and incurred \$2.5 million in net losses from September 21, 2015 through December 31, 2015 associated with the operations of TransEnterix Italia.

The following unaudited pro forma information presents the combined results of operations for the years ended December 31, 2015 and 2014, as if the Company had completed the ALF-X Acquisitions at the beginning of

fiscal 2014. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma consolidated financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs and amortization of intellectual property.

	Year Ended December 31,	
	2015	2014
	(In thousands except per share amounts)	
Revenue	\$ 77	\$ 401
Net loss	53,994	46,874
Net loss per share	\$ 0.57	\$ 0.63

4. Cash, Cash Equivalents, Restricted Cash and Short-Term Investments

Cash, cash equivalents and restricted cash consist of the following:

	December 31,	
	2015	2014
	(In thousands)	
Cash	\$ 1,666	\$ 1,511
Money market	36,783	33,255
Total cash and cash equivalents	<u>\$38,449</u>	<u>\$34,766</u>
Restricted cash	<u>\$ —</u>	<u>\$ 250</u>
Total	<u>\$38,449</u>	<u>\$35,016</u>

Restricted cash, consisting of a money market account used as collateral securing a letter of credit under the terms of the corporate office operating lease that commenced in 2010 and expired in April 2015, was \$0 and \$250,000 as of December 31, 2015 and December 31, 2014, respectively.

The Company held no investments at December 31, 2015 and 2014 as it sold all its investment securities during 2014. There were no realized gains or losses for the years ended December 31, 2015, 2014 or 2013. There have been no unrealized gains or losses reclassified to accumulated other comprehensive loss.

5. Fair Value

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

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

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

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

The carrying values of accounts receivable, inventories, interest receivable, accounts payable, and certain accrued expenses at December 31, 2015 and 2014, approximate their fair values due to the short-term nature of these items. The Company's notes payable balance also approximates fair value as of December 31, 2015 and 2014, as they were modified in each of the years.

The following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2015 and 2014, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

December 31, 2015				
(In thousands)				
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets measured at fair value				
Cash and Cash Equivalents	\$38,449	\$—	\$ —	\$38,449
Total Assets measured at fair value	<u>\$38,449</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$38,449</u>
Liabilities measured at fair value				
Contingent consideration	\$ —	\$—	\$23,500	\$23,500
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$—</u>	<u>\$23,500</u>	<u>\$23,500</u>
December 31, 2014				
(In thousands)				
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets measured at fair value				
Cash and Cash Equivalents	\$34,766	\$—	\$ —	\$34,766
Restricted Cash	250	—	—	250
Total Assets measured at fair value	<u>\$35,016</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$35,016</u>

The Company's financial liabilities consisted of contingent consideration potentially payable to SOFAR related to the ALF-X acquisition in September 2015 (Note 3). This liability is reported as Level 3 as estimated fair value of the contingent consideration related to the acquisition requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome. The change in fair value of the contingent consideration of \$0.4 million for the year ended December 31, 2015 was primarily due to the foreign currency changes on the fair value measurement of milestones related to the ALF-X acquisition. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statements of operations and comprehensive loss.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 as of September 21, 2015 and December 31, 2015:

	<u>Valuation Methodology</u>	<u>Significant Unobservable Input</u>	<u>Weighted Average (range, if applicable)</u>
Contingent consideration	Probability weighted income approach	Milestone dates	2016 to 2017
		Discount rate	7.5% to 9.0%
		Probability of occurrence	100%

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the years ended December 31, 2015, 2014 and 2013:

	<u>Fair Value Measurement at Reporting Date (Level 3) (In thousands)</u>
Balance at December 31, 2012	\$ 109
Change in fair value of preferred stock warrant liability recorded in other expense	1,800
Reclassification to additional paid-in capital upon the Merger	<u>(1,909)</u>
Balance at December 31, 2013	\$ —
Additions	<u>—</u>
Balance at December 31, 2014	\$ —
Additions for contingent consideration	23,900
Change in fair value	<u>(400)</u>
Balance at December 31, 2015	<u>\$23,500</u>
Current portion	12,500
Long-term portion	<u>11,000</u>
Balance at December 31, 2015	<u>\$23,500</u>

6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
	(In thousands)	
Gross accounts receivable	\$ 76	\$221
Allowance for uncollectible accounts	<u>—</u>	<u>(88)</u>
Total accounts receivable, net	<u>\$ 76</u>	<u>\$133</u>

7. Inventories

The components of inventories are as follows:

	December 31,	
	2015	2014
	(In thousands)	
Finished goods	\$2,704	\$ 358
Raw materials	1,928	—
Reserve for excess and obsolete inventory	—	(358)
Total inventories	<u>\$4,632</u>	<u>\$ —</u>
Short-term portion	\$3,923	\$ —
Long-term portion	709	—
Total inventories	<u>\$4,632</u>	<u>\$ —</u>

During 2014, the Company discontinued the sale of the SPIDER System. As a result, the inventory balance was fully reserved at December 31, 2014.

8. Other Current Assets

The following table presents the components of other current assets:

	December 31,	
	2015	2014
	(In thousands)	
Advances to vendors	\$5,403	\$—
Prepaid expenses	750	608
Other receivables	536	132
Total	<u>\$6,689</u>	<u>\$740</u>

9. Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2015	2014
	(In thousands)	
Machinery and manufacturing equipment	\$ 5,846	\$ 3,797
Computer equipment	1,875	1,710
Furniture	374	358
Leasehold improvements	1,700	1,405
Total property and equipment	9,795	7,270
Accumulated depreciation and amortization	(5,387)	(4,150)
Property and equipment, net	<u>\$ 4,408</u>	<u>\$ 3,120</u>

Depreciation expense was \$1,248,000, \$807,000 and \$983,000, for the years ended December 31, 2015, 2014 and 2013, respectively.

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

10. Goodwill, In-Process Research and Development and Intellectual Property

Goodwill

Goodwill of \$93.8 million was recorded in connection with the Merger, as discussed in Note 18, and goodwill of \$38.3 million was recorded in connection with the ALF-X Acquisition, as discussed in Note 3. The carrying value of goodwill and the change in the balance for the years ended December 31, 2015 and 2014 is as follows:

	Goodwill (In thousands)
Balance at December 31, 2013	\$ 93,842
Additions	—
Balance at December 31, 2014	93,842
Additions	38,348
Foreign currency translation impact	(1,321)
Balance at December 31, 2015	<u>\$130,869</u>

The Company has no accumulated impairment losses on goodwill. The Company performed a qualitative assessment during the annual impairment review for fiscal 2015 as of December 31, 2015 and concluded that it is not more likely than not that the fair value of the Company's single reporting unit is less than its carrying amount. Therefore, the two-step goodwill impairment test for the reporting unit was not necessary in fiscal 2015.

In-Process Research and Development

As described in Note 3, on September 21, 2015, the Company acquired all of the assets related to the ALF-X System and recorded \$17.1 million of IPR&D. The estimated fair value of the IPR&D was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 45% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The carrying value of the Company's IPR&D assets and the change in the balance for the year ended December 31, 2015 is as follows:

	In-Process Research and Development (In thousands)
Balance at December 31, 2014	\$ —
Additions	17,100
Foreign currency translation impact	(589)
Balance at December 31, 2015	<u>\$16,511</u>

Intellectual Property

In 2009, the Company purchased certain patents from an affiliated company for \$5 million in cash and concurrently terminated a license agreement related to the patents. The patent expiration dates begin in 2027. In addition, as described in Note 3, on September 21, 2015, the Company acquired all of the developed technology related to the ALF-X System and recorded \$48.5 million of intellectual property. The estimated fair value of the intellectual property was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including

estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 45% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The components of gross intellectual property, accumulated amortization, and net intellectual property as of December 31, 2015, and 2014 as follows:

	December 31, 2015				December 31, 2014			
	(In thousands)				(In thousands)			
	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation impact	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation impact	Net Carrying Amount
Patents	\$ 5,000	\$(3,259)	\$ —	\$ 1,741	\$5,000	\$(2,759)	\$—	\$2,241
Developed technology	48,500	(1,672)	(1,671)	45,157	—	—	—	—
Total intellectual property	<u>\$53,500</u>	<u>\$(4,931)</u>	<u>\$(1,671)</u>	<u>\$46,898</u>	<u>\$5,000</u>	<u>\$(2,759)</u>	<u>\$—</u>	<u>\$2,241</u>

The estimated future amortization expense of intangible assets as of December 31, 2015 is as follows:

Fiscal Year	Amount (In thousands)
2016	\$ 7,429
2017	7,429
2018	7,429
2019	7,170
2020	6,929
Thereafter	10,512
Total	<u>\$46,898</u>

11. Income Taxes

The components for the income tax expense (benefit) are as follows for the years ended December 31 (in thousands):

	2015	2014	2013
Current income taxes			
Federal	\$ —	\$—	\$—
State	—	—	—
Foreign	—	—	—
Deferred income taxes			
Federal	—	—	—
State	—	—	—
Foreign	(1,024)	—	—
Total income tax expense (benefit)	<u>\$(1,024)</u>	<u>\$—</u>	<u>\$—</u>

The United States and foreign components of loss from operations before taxes are as follows for the years ended December 31 (in thousands):

	2015	2014	2013
United States	\$(44,438)	\$(37,652)	\$(28,358)
Foreign	(3,534)	—	—
Total loss from operations before taxes	<u>\$(47,972)</u>	<u>\$(37,652)</u>	<u>\$(28,358)</u>

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

	<u>2015</u>	<u>2014</u>
Current deferred tax assets:		
Inventory reserves	\$ —	\$ 537
Accrued expenses	—	373
Deferred rent	—	17
Allowance for uncollectible accounts receivable	—	32
Valuation allowance	—	(959)
Net current deferred tax asset	—	—
Noncurrent deferred tax assets:		
Stock-based compensation	1,543	1,154
Inventory	1,819	—
Accrued expenses and other	936	—
Contribution carryforward	2	2
Research credit carryforward	4,224	3,200
Fixed assets	275	278
Capitalized start-up costs and other intangibles	3,864	4,233
Net operating loss carryforwards	<u>64,867</u>	<u>51,145</u>
	77,530	60,012
Valuation allowance	<u>(75,897)</u>	<u>(60,009)</u>
Net noncurrent deferred tax asset	1,633	3
Noncurrent deferred tax liabilities		
Fixed assets	(973)	—
Purchase accounting intangibles	<u>(16,923)</u>	<u>(3)</u>
Net noncurrent deferred tax liability	<u>(17,896)</u>	<u>—</u>
Net deferred tax asset (liability)	<u><u>\$(16,263)</u></u>	<u><u>\$ —</u></u>

The transaction described in Note 3 was a nontaxable transaction according to ASC 740, and the goodwill recorded under U.S. GAAP purchase accounting is not deductible for tax purposes.

At December 31, 2015 and 2014, the Company has provided a full valuation allowance against its net deferred assets in the US tax jurisdiction, since realization of these benefits is not more likely than not. The valuation allowance increased approximately \$14.9 million from the prior year. At December 31, 2015, the Company had federal and state net operating loss tax carryforwards of approximately \$178.1 million and \$133.7 million, respectively. These net operating loss carryforwards expire in various amounts starting in 2027 and 2018, respectively. The Company's federal and state net operating loss carryforwards include approximately \$0.9 million of excess tax benefits related to deductions from the exercise of stock options. The tax benefit of these deductions has not been recognized in deferred tax assets. If utilized, the benefits from these deductions will be recorded as adjustments to additional paid-in capital. At December 31, 2015, the Company had federal research credit carryforwards in the amount of \$4.2 million. These carryforwards begin to expire in 2027. The utilization of the federal net operating loss carryforwards and credit carryforwards will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership. At December 31, 2015, the Company had foreign operating loss carryforwards of approximately \$2.1 million, which can be carried forward indefinitely. The Company has no unremitted foreign earnings as of December 31, 2015.

The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2015 the Company had gross unrecognized tax benefits of approximately \$0.8 million. Of the total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next twelve months. Furthermore, the Company does not expect any cash settlement with the taxing authorities as a result of these unrecognized tax benefits as the Company has sufficient unutilized carryforward attributes to offset the tax impact of these adjustments.

The following is a tabular reconciliation of the Company's change in gross unrecognized tax positions at December 31 (in thousands):

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Beginning balance	\$606	\$—	\$—
Gross increases for tax positions related to current periods	256	606	—
Gross increases for tax positions related to prior periods	—	—	—
Ending balance	<u>\$862</u>	<u>\$606</u>	<u>\$—</u>

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2015 and 2014, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company has analyzed its filing positions in all significant federal, state, and foreign jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to United States Federal, state, and local tax examinations by tax authorities for years before 2012, although carryforward attributes that were generated prior to 2012 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

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

	<u>2015</u>		<u>2014</u>		<u>2013</u>	
	<u>Amount</u>	<u>% of Pretax Earnings</u>	<u>Amount</u>	<u>% of Pretax Earnings</u>	<u>Amount</u>	<u>% of Pretax Earnings</u>
United States federal tax at statutory rate	\$(16,311)	34.0%	\$(12,801)	34.0%	\$ (9,642)	34.0%
State taxes (net of deferred benefit)	(1,121)	2.3%	(786)	2.0%	(662)	2.3%
Nondeductible expenses	1,797	(3.7%)	253	(0.7%)	1,556	(5.5%)
Research & Development credits	(1,281)	2.7%	(1,532)	4.1%	—	0.0%
Change in unrecognized tax benefits	256	(0.5%)	606	(1.6%)	—	0.0%
Foreign tax rate differential	175	(0.4%)	—	0.0%	—	0.0%
Adjustment for valuation allowance as part of purchase accounting	—	0.0%	—	0.0%	(11,785)	41.6%
Other, net	532	(1.2%)	392	(1.0%)	(200)	0.7%
Change in valuation allowance	<u>14,929</u>	<u>(31.1%)</u>	<u>13,868</u>	<u>(36.8%)</u>	<u>20,733</u>	<u>(73.1%)</u>
Income tax benefit	<u>\$ (1,024)</u>	<u>2.1%</u>	<u>\$ —</u>	<u>0.0%</u>	<u>\$ —</u>	<u>0.0%</u>

12. Accrued Expenses

	December 31,	
	2015	2014
	(In thousands)	
Taxes and other assessments	\$3,112	\$ 189
Compensation and benefits	2,492	1,036
Legal and professional fees	268	145
Consulting and other vendors	553	208
Interest and final payment fee	411	131
Deferred rent	278	46
Other	281	14
Total	<u>\$7,395</u>	<u>\$1,769</u>

13. Notes Payable

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

On September 26, 2014, the Company entered into the Amended and Restated Loan Agreement with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders agreed to make certain term loans (the “Amended and Restated Term Loans”) in an aggregate principal amount of up to \$25,000,000. The first tranche of the Amended and Restated Term Loans increased the Company’s borrowings at September 26, 2014 from \$5,604,000 to \$10,000,000. The Amended and Restated Term Loans allowed for interest-only payment at 7.5% per annum through October 31, 2015 and a maturity date of April 1, 2018.

On August 14, 2015, the Company entered into the First Amendment to the Amended and Restated Loan Agreement (the “First Amendment”) with the Lenders. The first tranche of the First Amendment increased the Company’s borrowings at August 14, 2015 from \$10,000,000 to \$20,000,000. A second tranche of \$10,000,000, is available to the Company upon recognition of at least \$10,000,000 of trailing six-month revenues from the SurgiBot System and SurgiBot-related products no later than March 31, 2017. The First Amendment allowed for interest-only payments at 7.5% per annum through April 30, 2016 and a maturity date of October 1, 2018.

On September 18, 2015, in connection with entry into the Purchase Agreement with SOFAR S.p.A. (see Note 3 for a description of the related transactions), the Company and the Lenders entered into the Consent and Second Amendment to Amended and Restated Loan Agreement (the “Second Amendment”). The Second Amendment modified the period in which the Company can make interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The Second Amendment has a maturity date of July 1, 2018.

In connection with the entry into the loan agreements, the Company became obligated to pay final payment and facility fees. The final payment fee obligation paid under the Original Loan Agreement at 3.33% was \$333,000 and the facility fee payment was \$75,000. The final payment fee obligation paid under the Amended and Restated Loan Agreement at 5.45% was \$165,920 and the facility fee was \$90,000. The facility fee paid under the First Amendment was \$90,000. The final payment fee obligation payable under the Second Amendment is 6.5% of the original principal amount of each term loan without the interest only extension and 8.0% with both interest-only extensions.

In addition, in connection with the borrowings, the Company issued warrants to the Lenders to purchase shares of the Company's common stock amounting to 279,588 warrants under the Original Loan Agreement, 38,324 warrants under the Amended and Restated Loan Agreement and 112,903 under the First Amendment. Additional warrants will be issued if additional tranche term loans are made. The warrants expire seven years from their respective issue date.

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

Further, under the Second Amendment, the Lenders consented to the formation of TransEnterix International, the entry of the Company into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. The Company agreed to pledge 100% of the common stock of TransEnterix International as additional security for the borrowings under the Amended and Restated Loan Agreement, as amended. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Amended and Restated Loan Agreement. This provision for the transfer of designated amount was amended on November 13, 2015 with the Third Amendment to the Amended and Restated Loan Agreement

In accordance with ASC 470-50 *Debt – Modifications and Extinguishments*, it was determined that the debt refinancing on September 26, 2014, was considered to be a debt modification. Accordingly, the Company recorded approximately \$129,000 of debt discount, consisting of the \$75,000 facility fee and the relative fair value of warrants on the issue date of \$54,000. Additionally, approximately \$30,000 of legal fees were recorded as a result of the transaction. The debt discount and deferred financing costs will be amortized over the life of the new debt agreement using the effective interest method into Interest expense, net.

In accordance with ASC 470-50 *Debt – Modifications and Extinguishments*, it was determined that the debt refinancings on August 14, 2015 and September 18, 2015 were considered to be debt modifications. Additionally, during the third quarter of 2015, the Company adopted ASU No. 2015-03, "Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs". ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The Company recorded a debt discount of approximately \$210,000 for these two amendments. Accordingly, the unamortized debt discount is presented as a reduction of the related debt liability in the Company's balance sheet. In accordance with ASU 2015-03, this adopted guidance was applied retrospectively. The December 31, 2014 balance sheet was adjusted by reducing Other current assets by \$49,000, Other long term assets by \$51,000, and the Notes payable - less current portion, net of debt discount by \$100,000. The debt discount will be amortized over the life of the new debt agreement using the effective interest method into Interest expense, net.

In connection with the issuance of the notes payable and its amendments, TransEnterix Surgical incurred approximately \$371,000 in debt issuance costs paid to lenders and third parties and \$280,000 in debt issuance costs related to issuance of warrants to the lenders. The unamortized balance of \$283,000 as of December 31, 2015 will be amortized using the effective interest method.

As of December 31, 2015 future principal payments under the Company's notes payable agreements are as follows:

Years ending December 31, (In thousands)	
2016	\$ 6,903
2017	8,090
2018	<u>5,007</u>
Total	<u><u>\$20,000</u></u>

14. Stock-Based Compensation

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

The Plan was initially approved by the majority of the stockholders on November 13, 2007. The Plan was amended on June 19, 2012 to increase the number of shares of common stock available for issuance to 1,000,000, was amended on October 29, 2013 to (a) increase the number of shares of common stock authorized for issuance under the Plan from 1,000,000 shares of common stock to 4,940,000 shares of common stock, (b) increase the per-person award limitations for options or stock appreciation rights from 200,000 to 1,000,000 shares and for restricted stock, deferred stock, performance shares and/or other stock-based awards from 100,000 to 500,000 shares, and (c) change the name of the Plan to reflect the Merger-related change. The Plan was again amended on May 7, 2015 to (i) increase the number of shares reserved for issuance under the Plan to 11,940,000 shares; (ii) extend the term of the Plan until May 7, 2025; and (iii) make other changes and updates to the Plan and was further amended in October 2015 to add French Sub-Plan amendments applicable to awards made to France-based employees. The October 2013 and May 2015 amendments were approved by the Board of Directors and stockholders; the French Sub-Plan was approved by the Board of Directors. Under the Plan, which is administered by the Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock and/or deferred stock to employees, officers, directors, consultants and vendors. The exercise price of stock options or stock appreciation rights may not be less than the fair market value of the Company's shares at the date of grant. Additionally, no stock options or stock appreciation rights granted under the Plan may have a term exceeding ten years.

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

During the years ended December 31, 2015, 2014 and 2013, the Company recognized \$3,311,000, \$1,840,000 and \$941,000, respectively, of stock-based compensation expense, including stock options and restricted stock units. During 2014, the Company granted options with performance-based features. As of December 31, 2014, the Company determined that achievement of the pre-defined corporate performance goals was not probable and no expense was recognized. The performance options were cancelled in 2015.

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

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

	Years ended December 31,		
	2015	2014	2013
Expected dividend yield	0%	0%	0%
Expected volatility	45%-56%	46%-63%	62%-63%
Risk-free interest rate	1.44% - 1.95%	1.60% - 2.30%	1.64% - 1.98%
Expected life (in years)	5.5 – 6.3	5.2 – 7.0	5.7 – 6.1

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

The following table summarizes the Company's stock option activity, including grants to non-employees, for the year ended December 31, 2015:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Options outstanding at December 31, 2014	5,423,741	\$2.82	7.79
Granted	4,407,758	2.76	
Forfeited	(434,025)	4.70	
Cancelled	(467,985)	6.80	
Exercised	(628,670)	0.41	
Options outstanding at December 31, 2015	<u>8,300,819</u>	<u>2.63</u>	<u>8.23</u>

The following table summarizes information about stock options outstanding at December 31, 2015:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Exercisable at December 31, 2015	3,096,827	\$2.12	6.58
Vested or expected to vest at December 31, 2015	7,953,823	\$2.61	8.18

The aggregate intrinsic value of stock options outstanding, exercisable, and vested or expected to vest at December 31, 2015 was approximately \$3.8 million, \$3.3 million, and \$3.8 million, respectively. This amount is before applicable income taxes and represents the closing market price of the Company's common stock at December 31, 2015 less the grant price, multiplied by the number of stock options that had a grant price that is less than the closing market price. This amount represents the amount that would have been received by the optionees had these stock options been exercised on that date.

The total intrinsic value of options exercised during 2015, 2014 and 2013 was approximately \$1,603,000, \$996,000 and \$348,000, respectively.

The Company granted 4,407,758, 2,422,309 and 603,139 options to employees and non-employees during the years ended December 31, 2015, 2014 and 2013, respectively, with a weighted-average grant date fair value of \$1.37, \$2.87 and \$0.95, respectively.

As of December 31, 2015, the Company had future employee stock-based compensation expense of approximately \$6,081,000 related to unvested share awards, which is expected to be recognized over an estimated weighted-average period of 3.1 years.

15. Restricted Stock Units

In 2013 and 2015, the Company issued Restricted Stock Units ("RSUs") to certain employees which vest over three years. By their terms, the RSUs become immediately vested upon the earlier of (i) a change of control and (ii) defined vesting dates, subject to the continuous service with the Company at the applicable vesting event. When vested, the RSUs represent the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The fair value of each RSU is estimated based upon the closing price of the Company's common stock on the grant date. Share-based compensation expense related to RSUs is recognized over the requisite service period as adjusted for estimated forfeitures.

The following is a summary of the RSU activity for the years ended December 31, 2015, 2014 and 2013:

	Number of Restricted Stock Units Outstanding	Weighted Average Grant Date Fair Value
Unvested, December 31, 2012	—	—
Granted	210,000	\$7.19
Vested	—	—
Unvested, December 31, 2013	210,000	\$7.19
Granted	—	—
Vested	<u>(70,000)</u>	<u>7.19</u>
Unvested, December 31, 2014	140,000	\$7.19
Granted	380,000	2.94
Vested	(70,000)	7.19
Forfeited	<u>(27,500)</u>	<u>2.94</u>
Unvested, December 31, 2015	<u>422,500</u>	<u>\$3.64</u>

As of December 31, 2015, 2014 and 2013, the Company recorded approximately \$816,000, \$503,000 and \$121,000, respectively, in compensation expense for the RSUs. As of December 31, 2015, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$1.1 million, which is expected to be recognized over a weighted average period of approximately 1.9 years. The weighted average grant date fair value of the RSUs granted in 2013 was \$7.19. No restricted stock units were granted in 2014. The weighted average grant date fair value of the RSUs granted in 2015 was \$2.94.

16. Warrants

On March 22, 2013, SafeStitch entered into a stock purchase agreement with approximately 17 investors (the “2013 PIPE Investors”) pursuant to which the 2013 PIPE Investors purchased an aggregate of approximately 2,420,000 shares of common stock at a price of \$1.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of warrants to purchase approximately 1,209,600 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$1.65 per share and five year expiration. Among the 2013 PIPE Investors purchasing shares were related parties who purchased 1.28 million shares and received 640,000 warrants. There were approximately 1.2 million warrants outstanding that were assumed as of the Merger. During the years ended December 31, 2015, 2014 and 2013, 0, 10,000 and 54,000, respectively of these warrants were exercised.

On January 17, 2012, TransEnterix Surgical entered into the Original Loan Agreement (the “Original Loan Agreement”) with Silicon Valley Bank and Oxford Finance LLC. (collectively, the “Lenders”). Pursuant to such agreement, TransEnterix Surgical issued preferred stock warrants to the Lenders on January 17, 2012 and December 21, 2012, respectively, to purchase shares of TransEnterix Surgical preferred stock. The preferred stock warrants expire 10 years from the issue date. The preferred stock warrants were remeasured immediately prior to the Merger. As a result of the remeasurement, the Company recorded approximately \$1.8 million of other expense in the accompanying 2013 consolidated statement of operations and other comprehensive income (loss). As of the Merger, the preferred stock warrants converted to common stock warrants, adjusted based on the Exchange Ratio of 1.1533, and the preferred stock warrant liability was reclassified to additional paid-in capital. These warrants are exercisable for an aggregate of approximately 279,588 shares of common stock, with an exercise price of \$1.45. During the year ended December 31, 2013, 139,794 of these warrants were exercised in a cashless transaction for 112,766 shares of common stock. None of these warrants were exercised during the years ended December 31, 2015 or 2014.

On September 26, 2014, the Company entered into the Amended and Restated Term Loans with the Lenders. In connection with the Amended and Restated Loan Agreement and the first tranche borrowings, the Company issued 38,325 common stock warrants to the Lenders to purchase shares of the Company's common stock, with an exercise price of \$4.015 per share. Additional common stock warrants will be issued if additional tranche Term Loans are made under the Amended and Restated Loan Agreement. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and will be amortized using the effective interest method from issuance to the maturity of the term loans. None of these warrants were exercised during the year ended December 31, 2015 and 2014.

On August 14, 2015, in connection with the First Amendment and the first tranche borrowings, the Company issued 112,903 common stock warrants to the Lenders to purchase shares of the Company's common stock, with an exercise price of \$3.10 per share. Additional common stock warrants will be issued if additional tranche term loans are made under the Amended and Restated Loan Agreement, as amended. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and will be amortized using the effective interest method from issuance to the maturity of the note. None of these warrants were exercised during the year ended December 31, 2015.

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Weighted Average Fair Value
Outstanding at December 31, 2012	279,588	\$1.45	9.1	\$0.45
Warrants assumed in merger with SafeStitch	1,199,600	1.65	4.3	1.15
Exercised	(193,794)	1.45	—	5.25
Outstanding at December 31, 2013	1,285,394	\$1.45	4.7	\$1.75
Granted	38,325	4.02	6.7	1.41
Exercised	(10,000)	1.65	—	—
Outstanding at December 31, 2014	1,313,719	\$1.70	3.9	\$1.75
Granted	112,903	3.10	6.6	0.86
Exercised	—	—	—	—
Outstanding at December 31, 2015	<u>1,426,622</u>	<u>\$1.81</u>	<u>3.2</u>	<u>\$1.54</u>

The aggregate intrinsic value of the common stock warrants in the above table was \$1.0 million, \$1.6 million and \$8.7 million at December 31, 2015, 2014 and 2013, respectively. The aggregate intrinsic value is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the estimated fair market value of the applicable stock as of the respective dates.

17. Controlled Equity Offering and Public Offering of Common Stock

On June 11, 2015, the Company sold 16,666,667 shares of common stock at a public offering price of \$3.00 per share for aggregate gross proceeds of \$50 million in an underwritten firm commitment public offering. Net proceeds after issuance costs were \$46.4 million. The closing of the public offering occurred on June 17, 2015. The Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,500,000 shares of Common Stock.

On July 10, 2015, the underwriters exercised a portion of their option to acquire an additional 2,075,000 shares at the public offering price of \$3.00 per share for aggregate additional gross proceeds of \$6.2 million. Net proceeds after issuance costs were \$5.8 million. The purchase of the option shares closed on July 15, 2015. Total proceeds (including the option) were \$52.2 million, net of issuance costs of \$4.0 million. The common stock was offered and sold pursuant to the Shelf Registration Statement filed in November 2014 (the "November 2014 Shelf

Registration Statement”), which was declared effective on December 19, 2014. The November 2014 Shelf Registration Statement allowed the Company to raise up to \$100.0 million through the sale of debt securities, common stock, preferred stock, warrants, or any combination thereof.

On February 20, 2015, the Company entered into a Controlled Equity Offering SM Sales Agreement (the “2015 Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), as sales agent, pursuant to which the Company can sell through Cantor, from time to time, up to \$25.0 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The Company pays Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the Sales Agreement. Unless otherwise terminated earlier, the 2015 Sales Agreement continues until all shares available under the 2015 Sales Agreement have been sold.

The following table summarizes the total sales under the 2015 Sales Agreement for the periods indicated (in thousands, except per share amounts):

	Year Ended December 31, 2015
Total shares of common stock sold	2,014.3
Average price per share	\$ 3.25
Gross proceeds	\$ 6,546
Commissions earned by Cantor	\$ 197
Other issuance costs	\$ 259

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

18. Closing of 2013 Merger and Financing Transaction

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

Pursuant to the Merger Agreement, each share of TransEnterix Surgical’s capital stock issued and outstanding immediately preceding the Merger was converted into the right to receive 1.1533 shares of the Company’s common stock, par value \$0.001 per share, other than those shares of TransEnterix Surgical’s common stock held by non-accredited investors, which shares were instead converted into the right to receive an amount in cash per share of SafeStitch common stock equal to \$1.08, without interest, which was the volume-weighted average price of a share of common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one

business day prior to the effective date of the Merger). Upon the closing of the Merger, and in accordance with the terms of the Merger Agreement, the Company issued an aggregate of 21,109,949 shares of the Company's common stock as Merger consideration and paid \$293,000 to unaccredited investors in lieu of common stock. Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, the Company assumed all of TransEnterix Surgical's options, whether vested or unvested, and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

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

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

In connection with the Merger Agreement and the September 2013 private placement, certain of SafeStitch's and TransEnterix Surgical's former stockholders, comprising approximately 93% of our stock on the effective date of the Merger, entered into Lock-up and Voting Agreements, pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company's securities held by them (collectively, "Covered Securities") for one year following the September 3, 2013 closing date (the "Merger 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 Merger Closing Date and ending on the eighteen-month anniversary of the Merger Closing Date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on the eighteen-month anniversary of the Merger Closing Date and ending on the two-year anniversary of the Merger Closing Date. The restrictions on transfer contained in the Lock-up and Voting Agreements ceased to apply to the Covered Securities on September 3, 2015.

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

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

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

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

Common shares outstanding at the date of Merger	12,350
Closing price per share	\$ 7.60
	<u>\$93,858</u>
Cash consideration	293
Total consideration	<u>\$94,151</u>

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

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

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

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

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

The results of operations of SafeStitch have been included in the Company's consolidated financial statements from the date of the Merger.

19. Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options and warrants and conversion of preferred stock. In computing diluted net loss per share for the years ended December 31, 2015, 2014, and 2013, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants and conversion of preferred stock would be anti-dilutive.

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

	December 31,		
	2015	2014	2013
Stock options	8,300,819	5,423,741	3,822,887
Stock warrants	1,426,622	1,313,719	1,285,394
Nonvested restricted stock units	422,500	140,000	210,000
Total	<u>10,149,941</u>	<u>6,877,460</u>	<u>5,318,281</u>

20. Stockholders' Equity

TransEnterix Surgical

Common and Preferred Stock

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

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

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

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

Voting Rights

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

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

Dividends

In any calendar year, the holders of outstanding shares of preferred stock were entitled to receive dividends, when, as and if declared by the Board of Directors, out of any assets at the time legally available therefore, at the dividends rate specified for such shares of preferred stock payable in preference and priority to any declaration or payment of any distribution on Common stock of TransEnterix Surgical in such calendar year. No distributions were to be made with respect to the common stock until all declared dividends on preferred stock had been paid or set aside for payment to the preferred stock holders. Payments of any dividends to the holders of the Preferred Stock were to be made on a pro rata basis. The right to receive dividends on shares of preferred stock were not to be cumulative, and no right to such dividends were to accrue to holders of preferred stock by reason of the fact that dividends on said shares were not paid or declared in any calendar year. No dividends were declared during the years ended December 31, 2015, 2014 and 2013.

Liquidation

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

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

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

Conversion

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

Redemption

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

Carrying Value

The preferred stock was initially recorded by TransEnterix Surgical at the total proceeds received upon issuance, less the issuance costs. The difference between the total proceeds and the total redemption value at the redemption date is charged first to paid-in capital, if any, and then to the accumulated deficit over the period from issuance until redemption first becomes available. The amount of accretion during each period is determined by using the effective interest rate method. Accretion amounted to approximately \$0, \$0 and \$40,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

The Company

In connection with the Merger, the Company entered into a securities purchase agreement with accredited investors pursuant to which the investors agreed to purchase an aggregate of 7,569,704.4 shares of the Company's Series B Convertible Preferred Stock for a purchase price of \$ 4.00 per share of Series B Preferred Stock, which was paid in cash, cancellation of certain indebtedness of TransEnterix Surgical or a combination thereof. Each share of Series B Preferred Stock was converted into two shares of our common stock, par value \$ 0.001 per share, on December 6, 2013 amounting to 15,139,409 shares of common stock.

21. Related Person Transactions

Synecor, LLC and its shareholders and officers collectively owned approximately 6% and 9% of the Company's common stock at December 31, 2015 and 2014, respectively. Various research and development services are purchased from Synecor LLC and its wholly owned subsidiary Synchrony Labs LLC pursuant to arms' length terms approved by the Audit Committee and totaled approximately \$435,000, \$66,000 and \$90,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

On September 18, 2015, TransEnterix Italia entered into a six month service agreement for administrative expenses and rent with SOFAR, a shareholder that owned approximately 16% of the Company's common stock at December 31, 2015. Expenses under this agreement were approximately \$89,000 for the year ended December 31, 2015.

22. Commitments and Contingencies

Contingent Consideration

As discussed in Note 3, in September 2015, the Company completed the ALF-X Acquisition using a combination of cash, stock and potential post-acquisition milestone payments. These milestone payments may be payable in the future, depending on the achievement of certain regulatory and commercial milestones. The maximum amount of the aggregate milestone payments could be €27.5 million. As of December 31, 2015, the fair value of the contingent consideration was \$23.5 million.

Operating Leases

On November 2, 2009, TransEnterix Surgical entered into an operating lease for its corporate offices for a period of five years commencing in April 2010. On June 12, 2014, the Company entered into a lease amendment extending the term of the lease for a period of 3 years and 2 months commencing on May 1, 2015 and expiring on June 30, 2018, with an option to renew for an additional three years. On October 25, 2013, the Company entered into an operating lease for its warehouse for a period of four years and four months commencing in January 2014, with an option to renew for an additional six years. Rent expense was approximately \$513,000, \$424,000 and \$360,000 for the years ended December 31, 2015, 2014 and 2013, respectively. The Company's approximate future minimum payments for its operating lease obligations that have initial or remaining noncancelable terms in excess of one year are as follow:

	Years ending December 31, (In thousands)
2016	\$ 592
2017	609
2018	<u>290</u>
Total	<u><u>\$1,491</u></u>

In 2013, TransEnterix Surgical leased a manufacturing facility under a one-year lease from a third party. Rent expense under this lease was \$55,000 for the year ended December 31, 2013. SafeStitch leases various office space on a month to month basis. Rent expense under these leases was \$0, \$89,000 and \$55,000 for the years ended December 31, 2015, 2014 and 2013, respectively, including \$89,000 and \$48,000 to a company controlled by a shareholder for the years ended December 31, 2014 and 2013, respectively.

License and Supply Agreements

As discussed in Note 3, in September 2015, the Company completed the ALF-X Acquisition. As part of this transaction, the Company assumed certain license and supply agreements. Commitments under these agreements amount to approximately \$730,000 in 2016, \$654,000 in 2017, \$872,000 in 2018, \$872,000 in 2019, \$545,000 in 2020 and \$3.8 million thereafter until termination in 2027.

The Company is obligated to pay royalties to Creighton on the sales of products licensed by SafeStitch from Creighton pursuant to an exclusive license and development agreement. The Company is also obligated under an agreement with Dr. Parviz Amid to pay a royalty, for a period of ten years from the first commercial sale of a licensed product, at the rate of 1.5% for the first three years and then 4% in the following seven years to

Dr. Amid on the net sales of any product developed with Dr. Amid's assistance under such agreement. Such agreements covered products that were previously sold by the Company. No royalties were incurred under either of these agreements during the years ended December 31, 2015, 2014 and 2013.

On February 13, 2014, TransEnterix Surgical, Inc., a wholly owned subsidiary of the Company, entered into a Robotic Development and Supply Agreement (the "Robotic Agreement") with Microline Surgical, Inc. ("Microline"). Under the Robotic Agreement, Microline is developing a flexible sealer product for exclusive use by the Company with the SurgiBot System in open, minimally invasive and laparoscopic surgery. Development of the contemplated products under the Robotic Agreement is ongoing. If such products are successfully developed and applicable regulatory approvals obtained, the Company will owe an aggregate of \$1,000,000 to Microline in milestone fees. Actual payment of such milestone fees is substantially uncertain and is dependent on product development activities. Payments under the Robotic Agreement were \$400,000 for the year ended December 31, 2015. If the products are successfully developed and applicable regulatory approvals obtained, the Company is committed to product supply commitments set forth in the Robotic Agreement.

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

23. Quarterly Results of Operation (Unaudited)

The following is a summary of the Company's unaudited quarterly results of operations for the fiscal years ended December 31, 2015 and 2014 (in thousands, except per share amounts):

	Fiscal Year Ended December 31, 2015				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total Year
Total revenues	\$ —	\$ —	\$ —	\$ —	\$ —
Cost of goods sold	—	—	—	—	—
Amortization of intangible assets	125	126	338	1,596	2,185
Acquisition related costs	—	—	4,003	228	4,231
Other operating expenses	9,714	8,942	9,223	12,076	39,955
Interest expense, net	281	280	436	604	1,601
Loss before income taxes	(10,120)	(9,348)	(14,000)	(14,504)	(47,972)
Income tax benefit	—	—	99	925	1,024
Net loss	<u>\$(10,120)</u>	<u>\$(9,348)</u>	<u>\$(13,901)</u>	<u>\$(13,579)</u>	<u>\$(46,948)</u>
Net loss per share – basic and diluted	\$ (0.16)	\$ (0.14)	\$ (0.16)	\$ (0.13)	\$ (0.59)
	Fiscal Year Ended December 31, 2014				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total Year
Total revenues	\$ 93	\$ 113	\$ 61	\$ 134	\$ 401
Cost of goods sold	220	238	202	435	1,095
Amortization of intangible assets	126	126	125	126	503
Other operating expenses	6,905	10,130	11,004	7,373	35,412
Interest expense, net	321	206	237	279	1,043
Loss before income taxes	(7,479)	(10,587)	(11,507)	(8,079)	(37,652)
Income tax benefit	—	—	—	—	—
Net loss	<u>\$(7,479)</u>	<u>\$(10,587)</u>	<u>\$(11,507)</u>	<u>\$(8,079)</u>	<u>\$(37,652)</u>
Net loss per share – basic and diluted	\$ (0.15)	\$ (0.18)	\$ (0.18)	\$ (0.13)	\$ (0.64)

24. Subsequent Events

Subsequent to year-end, the Company sold an additional 5,710,214 shares under the 2015 Sales Agreement at an average price per share of \$3.23, for gross proceeds of \$18.4 million and net proceeds of \$17.9 million. Sales under the 2015 Sales Agreement have been fully sold, with cumulative shares of 7,724,488, gross proceeds of \$25.0 million and net proceeds of \$24.0 million. In addition, on February 9, 2016, the Company entered into a Controlled Equity Offering SM Sales Agreement (the “2016 Sales Agreement”) with Cantor, as sales agent, pursuant to which the Company can sell through Cantor, from time to time, up to \$43.56 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The Company pays Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2016 Sales Agreement. Unless otherwise terminated earlier, the 2016 Sales Agreement continues until all shares available under the Sales Agreement have been sold.

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

None.

ITEM 9.A. 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, 2015. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

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

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

Management has excluded the September 21, 2015 acquisition of TransEnterix Italia from its assessment of internal controls over financial reporting as permitted in the year of acquisition under Securities and Exchange Commission guidance. TransEnterix Italia constituted approximately 28% of the Company's total assets, excluding goodwill, as of December 31, 2015 and 8% of consolidated operating expenses for the year then ended.

For the year ended December 31, 2015, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, management (with the participation of our principal executive officer and principal financial officer) conducted an evaluation of the effectiveness of our internal control over financial reporting based on the original framework established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the

Treadway Commission (COSO). Based on this evaluation, management concluded that, as of December 31, 2015, our internal control over financial reporting was effective.

The Company's independent registered public accounting firm, BDO USA, LLP, audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. BDO USA, LLP's report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2015 is set forth herein.

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.

Management has excluded the September 21, 2015 acquisition of TransEnterix Italia from its assessment of internal controls over financial reporting as permitted in the year of acquisition under Securities and Exchange Commission guidance. TransEnterix Italia constituted approximately 28% of the Company's total assets, excluding goodwill, as of December 31, 2015 and 8% of consolidated operating expenses for the year then ended.

ITEM 9.B. OTHER INFORMATION

None.

PART III

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

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2016.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2016.

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

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2016.

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

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2016.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2016.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

	<u>Page</u>
<u>Consolidated Financial Statements:</u>	
Reports of Independent Registered Public Accounting Firm	53
Consolidated Balance Sheets as of December 31, 2015 and 2014	56
Consolidated Statements of Operations and Comprehensive Loss for each of the years in the three-year period ended December 31, 2015	57
Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit) for each of the years in the three-year period ended December 31, 2015	58
Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2015	59

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

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

<u>Exhibit No.</u>	<u>Description</u>
1.1	Controlled Equity Offering SM Sales Agreement by and between TransEnterix, Inc. and Cantor Fitzgerald & Co. dated February 20, 2015 (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on February 20, 2015 and incorporated by reference herein).
1.2	Underwriting Agreement by and among TransEnterix, Inc. and Stifel Nicolaus & Company, Incorporated and RBC Capital Markets, LLC dated June 11, 2015 (filed as Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on June 12, 2015 and incorporated by reference herein).
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).
2.2	Membership Interest Purchase Agreement, dated September 18, 2015, by and among SOFAR S.p.A., Vulcanos S.r.l., the Company and TransEnterix International, Inc. filed as Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on September 21, 2015 and incorporated by reference herein).
3.1	Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on April 1, 2014 and incorporated herein by reference).

<u>Exhibit No.</u>	<u>Description</u>
3.2	Amended and Restated Bylaws of TransEnterix, Inc. (filed as Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).
4.1	Certificate of Designation of Series A Preferred Stock (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein).
4.2	Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).
4.3	Specimen Certificate for Common Stock of TransEnterix, Inc. (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-3, File No. 333-193235, filed with the SEC on January 8, 2014 and incorporated by reference herein).
4.4	Form of Common Stock Warrant (filed as Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein).
4.5	Form of Common Stock Warrant (filed as Exhibit A to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on March 26, 2013 and incorporated herein by reference)
4.6	Form of Warrant to Purchase Common Stock for warrants issued to Oxford Finance LLC and Silicon Valley Bank (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed September 30, 2014).
4.7	Form of Common Stock Warrant dated March 22, 2013 (filed as part of Exhibit 10.1 to our Current Report on Form 8-K filed on March 26, 2013 and incorporated by reference herein).
10.1	Securities Purchase Agreement, dated as of August 13, 2013, by and among SafeStitch Medical, Inc. and the Investor parties thereto (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).
10.2	Form of Lock-up and Voting Agreement (filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on August 14, 2013 and incorporated by reference herein).
10.3	Exclusive License and Development Agreement, dated as of May 26, 2006, by and between Creighton University and SafeStitch LLC (filed as Exhibit 10.5 to our Annual Report on Form 10-KSB, as amended, filed with the SEC on March 26, 2008 and incorporated by reference herein).
10.4	Patent Assignment, dated as of June 26, 2009, by and between TransEnterix Surgical, Inc. and Synecor, LLC (filed as Exhibit 10.3 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).
10.5	Patent Acquisition and License Termination Agreement, dated as of June 26, 2009, by and among TransEnterix Surgical, Inc., Synecor, LLC and Barosense, Inc. (filed as Exhibit 10.4 to our Current Report on Form 8-K, filed with the SEC on September 6, 2013 and incorporated by reference herein).
10.6 ++	Licence Contract between the European Union and Vulcanos s.r.l. (now known as TransEnterix Italia S.r.l.), dated September 18, 2015 (filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q, filed with the SEC on November 11, 2015 and incorporated by reference herein).
10.7	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).
10.8	Registration Rights Agreement, dated September 21, 2015, by and between the Company and SOFAR S.p.A. (filed as Exhibit 10.3 to our Current Report on Form 8-K, filed with the SEC on September 21, 2015 and incorporated by reference herein).

<u>Exhibit No.</u>	<u>Description</u>
10.9	Lock-Up Agreement , dated September 21, 2015, by and between the Company and SOFAR S.p.A. (filed as Exhibit 10.4 to our Current Report on Form 8-K, filed with the SEC on September 21, 2015 and incorporated by reference herein).
10.10 +	Employment Agreement, dated as of February 3, 2015, by and between the Registrant and Todd M. Pope (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on February 6, 2015, and incorporated by reference herein).
10.11 +	Offer letter, dated 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 +*	Employment Agreement, dated as of August 14, 2015, by and between the Registrant and Anthony Fernando.
10.13 +	TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, effective as of May 7, 2015 (filed as Exhibit 10.1 to the Registrant’s Registration Statement on Form S-8, File No. 333-203950, filed with the SEC on May 7, 2015 and incorporated by reference herein).
10.13.1 +*	Exhibit A to the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan (French Sub-Plan)
10.14 +	Form of Employee Stock Option Agreement pursuant to the 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).
10.15 +	Form of Employee Stock Option Agreement (performance stock options) pursuant to the 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 Non-Employee Stock Option Agreement pursuant to the 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 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).
10.18 +	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).
10.19	Amended and Restated Loan Agreement, dated September 26, 2014, among the Borrowers and the Lenders and Collateral Agent (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on September 30, 2014 and incorporated by reference herein)
10.19.1	First Amendment to Amended and Restated Loan and Security Agreement, dated August 14, 2015, by and among TransEnterix, Inc., TransEnterix Surgical, Inc. and SafeStitch LLC, as Borrower, and Oxford Finance LLC, as Lender and Collateral Agent, and Silicon Valley Bank, as Lender (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on August 17, 2015 and incorporated by reference herein).
10.19.2	Consent and Second Amendment to Amended and Restated Loan Agreement, dated September 18, 2015, by and among the Company, its subsidiaries TransEnterix Surgical, Inc. and SafeStitch LLC (collectively, the “Borrowers”), and SVB, as Lender, and Oxford, as Lender and Collateral Agent (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on September 21, 2015 and incorporated by reference herein).

<u>Exhibit No.</u>	<u>Description</u>
10.19.3	Third Amendment to Amended and Restated Loan and Security Agreement, dated November 13, 2015, by and among TransEnterix, Inc., TransEnterix Surgical, Inc. and SafeStitch LLC, as Borrower, and Oxford Finance LLC, as Lender and Collateral Agent, and Silicon Valley Bank, as Lender (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on November 16, 2015 and incorporated by reference herein).
10.20	Promissory Note of SafeStitch Medical, Inc. in favor of Hsu Gamma Investments, L.P (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on November 27, 2012 and incorporated by reference herein).
10.21	Promissory Note of SafeStitch Medical, Inc. in favor of Frost Gamma Investments Trust (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on January 2, 2013 and incorporated by reference herein).
10.22	Promissory Note of SafeStitch Medical, Inc. in favor of Jane Hsiao (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on February 28, 2013 and incorporated by reference herein).
10.23	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).
10.23.1	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.
23.1 *	Consent of BDO USA, LLP.
31.1 *	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).
31.2 *	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
32.1 *	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 *	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS *	XBRL Instance Document.
101.SCH *	XBRL Taxonomy Extension Schema Document.
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document.

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

- + A management contract, compensatory plan or arrangement required to be separately identified.
- ++ Confidential treatment has been granted for certain portions of the agreement pursuant to a confidential treatment request filed with the Commission on November 9, 2015. Such provisions have been filed separately with the Commission.
- * Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 3, 2016

TransEnterix, Inc.

By: /s/ Todd M. Pope

Todd M. Pope
President, Chief Executive Officer
and a Director
(principal executive officer)

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

<u>Signature</u>	<u>Title(s)</u>	<u>Date</u>
<u>/s/ Todd M. Pope</u> Todd M. Pope	President, Chief Executive Officer and a Director (principal executive officer)	March 3, 2016
<u>/s/ Joseph P. Slattery</u> Joseph P. Slattery	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 3, 2016
<u>/s/ Paul A. LaViolette</u> Paul A. LaViolette	Chairman of the Board and a Director	March 3, 2016
<u>/s/ Andrea Biffi</u> Andrea Biffi	Director	March 3, 2016
<u>/s/ Dennis J. Dougherty</u> Dennis J. Dougherty	Director	March 3, 2016
<u>/s/ Jane H. Hsaio</u> Jane H. Hsaio, Ph.D.	Director	March 3, 2016
<u>/s/ William N. Kelley</u> William N. Kelley, M.D.	Director	March 3, 2016
<u>/s/ Aftab R. Kherani</u> Aftab R. Kherani	Director	March 3, 2016
<u>/s/ David B. Milne</u> David B. Milne	Director	March 3, 2016
<u>/s/ Richard C. Pfenniger, Jr.</u> Richard C. Pfenniger, Jr.	Director	March 3, 2016
<u>/s/ William N. Starling, Jr.</u> William N. Starling, Jr.	Director	March 3, 2016

CERTIFICATIONS

I, Todd M. Pope, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of TransEnterix, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Todd M. Pope

Todd M. Pope
President and Chief Executive Officer (Principal
Executive Officer)

March 3, 2016

CERTIFICATIONS

I, Joseph P. Slattery, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of TransEnterix, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Joseph P. Slattery

Joseph P. Slattery
Executive Vice President and Chief Financial
Officer (principal financial officer and principal
accounting officer)

March 3, 2016

**CERTIFICATION PURSUANT
TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-K of TransEnterix, Inc. for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TransEnterix, Inc.

By: /s/ Todd M. Pope _____

Todd M. Pope
President and Chief Executive Officer (Principal
Executive Officer)

March 3, 2016

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of TransEnterix, Inc. or the certifying officers.

**CERTIFICATION PURSUANT
TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-K of TransEnterix, Inc. for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TransEnterix, Inc.

By: /s/ Joseph P. Slattery

Joseph P. Slattery
Executive Vice President and Chief Financial
Officer (principal financial officer and principal
accounting officer)

March 3, 2016

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of TransEnterix, Inc. or the certifying officers.

TransEnterix, Inc. Board of Directors
As of April 15, 2016

Paul A. LaViolette – Chairman (1)(3)
Managing Partner and COO, SV Life Sciences Fund IV, L.P.

Todd M. Pope
President and Chief Executive Officer, TransEnterix, Inc.

Andrea Biffi
CEO, SOFAR, S.p.A.

Dennis J. Dougherty (2)
Founder and Managing General Partner, Intersouth Partners

Jane H. Hsiao, Ph.D., MBA (1)(3)
Vice-Chairman and Chief Technical Officer, OPKO Health, Inc.

William N. Kelley, M.D. (1)
Professor of Medicine, The School of Medicine of the University of Pennsylvania

Aftab R. Kherani, M.D. (2)(3)
Partner, Aisling Capital

David B. Milne (1)
Managing Partner, SV Life Sciences Advisors, LLC

Richard C. Pfenniger, Jr. (2)
Former Chairman, CEO and President, Continucare Corporation

William N. Starling, Jr. (3)
*CEO, Synecor, LLC
Managing Director, Synergy Life Science Partners*

- (1) Member of Corporate Governance and Nominating Committee
- (2) Member of Audit Committee
- (3) Member of Compensation Committee

TransEnterix, Inc. Executive Officers
As of April 15, 2016

Todd M. Pope
President and Chief Executive Officer

Anthony Fernando
Chief Technology Officer

Joseph P. Slattery
Executive Vice President & Chief Financial Officer

STOCK AND INVESTOR INFORMATION

Corporate Offices -
*635 Davis Drive, Suite 300
Durham, NC 27713
(919) 765-8400
(919) 765-8459*

Independent Auditors -
*BDO USA, LLP
5430 Wade Park Blvd, Suite 208
Raleigh, NC 27607*

Common Stock -
TransEnterix, Inc. Common Stock, par value \$0.001, is traded on the NYSE MKT under the symbol “TRXC”

Transfer Agent -
*Continental Stock Transfer & Trust Company
17 Battery Place, 8th Floor
New York, New York 10004*

At the written request of each record owner or beneficial owner of our securities we will provide, without charge, a copy of the TransEnterix, Inc. Annual Report on Form 10-K for the year ended December 31, 2015, or any exhibit thereto not included herein. Requests should be sent to Secretary, TransEnterix, Inc., 635 Davis Drive, Suite 300, Durham, NC 27713.

Except for the historical matters contained herein, statements made in this report are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Investors are cautioned that forward looking statements involve risks and uncertainties that may affect our business and prospects, including economic, competitive, governmental, technological, and other factors discussed in this report and in our filings with the Securities and Exchange Commission, including without limitation, the Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 3, 2016.