

TRANSENERIX INC.  
Form S-3/A  
March 31, 2014  
Table of Contents

As filed with the Securities and Exchange Commission on March 31, 2014

Registration No. 333-193235

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

AMENDMENT NO. 2  
TO  
FORM S-3  
REGISTRATION STATEMENT  
*UNDER*  
*THE SECURITIES ACT OF 1933*

TRANSENERIX, INC.  
(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
**(State or Other Jurisdiction of**

**11-2962080**  
**(I.R.S. Employer**

**Incorporation or Organization)**

**Identification Number)**

**635 Davis Drive, Suite 300**

**Morrisville, NC 27560**

**(919) 765-8400**

**(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)**

**Joseph P. Slattery**

**EVP and Chief Financial Officer**

**635 Davis Drive, Suite 300**

**Morrisville, NC 27560**

**(919) 765-8400**

**(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)**

*With a copy to:*

**Mary J. Mullany, Esquire**

**Ballard Spahr LLP**

**1735 Market Street, 51<sup>st</sup> Floor**

**Philadelphia, PA 19103**

**(215) 864-8631**

**Approximate date of commencement of proposed sale to the public:** From time to time after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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 definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer  Accelerated Filer   
 Non-Accelerated Filer  Smaller Reporting Company

**CALCULATION OF REGISTRATION FEE**

Title of Securities to be Registered	Amount to be Registered(1)(2)	Proposed	Proposed	Amount of Registration Fee
		Maximum Offering Price Per Security(2)	Maximum Aggregate Offering Price(3)	
Common stock, par value \$0.001 per share				
Preferred stock, par value \$0.01 per share				
Debt securities				

Warrants  
Units  
TOTAL

\$100,000,000      \$12,880.00(4)

- (1) There are being registered hereunder such indeterminate number of securities of TransEnterix, Inc. as shall have an aggregate initial offering price not to exceed \$100,000,000. In addition, pursuant to Rule 416 under the Securities Act, the securities registered hereunder include such indeterminate number of securities as may be issuable with respect to the securities being registered hereunder as a result of stock splits, stock dividends or similar transactions.
- (2) Not specified pursuant to General Instruction II.D. of Form S-3. The proposed maximum offering price per share will be determined from time to time by the Registrant in connection with, and at the time of, the issuance of the securities.
- (3) Estimated solely for the purpose of calculating the amount of the registration fee required pursuant to Rule 457(o) thereof, which permits the registration fee to be calculated on the basis of the maximum aggregate offering price of all securities listed.
- (4) Previously paid.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

**Table of Contents**

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, Dated March 31, 2014**

**PROSPECTUS**

**\$100,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Debt Securities**

**Units**

We may offer and sell from time to time, in one or more offerings, up to \$100,000,000 of any combination of common stock, preferred stock, warrants and debt securities, either individually or units consisting of any two or more of such securities. We may also offer securities upon the exercise of warrants.

Each time we sell securities pursuant to this prospectus, we will provide the specific terms of the securities offered in a supplement to this prospectus. The prospectus supplements will also describe the specific manner in which we will offer these securities and may also supplement, update or amend information contained in this prospectus. You should read this prospectus and any related prospectus supplement carefully before you invest in our securities.

The securities may be sold on a delayed or continuous basis directly by us, through dealers, agents or underwriters designated from time to time, or through any combination of these methods. If any dealers, agents or underwriters are involved in the sale of the securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in any prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in the applicable prospectus supplement.

Our common stock is traded on the OTC Bulletin Board under the symbol TRXC. On March 28, 2014, the closing price of our common stock was \$2.065 per share.

Investing in our securities involves a high degree of risk. See **RISK FACTORS** on page 8.

**This prospectus may not be used to offer or sell securities unless accompanied by a prospectus supplement for the securities being sold.**

**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**The date of this Prospectus is .**

Table of Contents

TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	3
<u>ABOUT THIS PROSPECTUS</u>	6
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	7
<u>RISK FACTORS</u>	8
<u>USE OF PROCEEDS</u>	35
<u>PLAN OF DISTRIBUTION</u>	35
<u>DESCRIPTION OF CAPITAL STOCK</u>	38
<u>DESCRIPTION OF DEBT SECURITIES</u>	40
<u>DESCRIPTION OF WARRANTS</u>	46
<u>DESCRIPTION OF UNITS</u>	48
<u>RATIO OF EARNINGS TO FIXED CHARGES</u>	48
<u>LEGAL MATTERS</u>	48
<u>EXPERTS</u>	48
<u>INCORPORATION BY REFERENCE</u>	48
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	49

**You should rely only on the information contained in this prospectus and in any prospectus supplement (including in any documents incorporated by reference herein or therein). We have not authorized anyone to provide you with any different information. We are offering to sell our securities, and seeking offers to buy, only in jurisdictions where offers and sales are permitted.**

**Table of Contents**

**PROSPECTUS SUMMARY**

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, especially the **Risk Factors** section beginning on page 8 and our financial statements and the related notes incorporated by reference into this prospectus, before making an investment decision.

**Company Overview**

On September 3, 2013, SafeStitch Medical, Inc. completed a merger with TransEnterix Surgical, Inc. under which TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. and its trading symbol to TRXC. In connection with the merger, we also consummated a financing by the sale of shares of Series B Convertible Preferred Stock.

In this prospectus, when we refer to the registrant as a combination of SafeStitch and TransEnterix Surgical after giving effect to the merger, we use the terms TransEnterix, the Company, we, us, and ours. When we refer to the historical business, operations and corporate status of the parent in the merger we use the term SafeStitch and when we refer to the historical business, operations and corporate status of the subsidiary in the merger, we use the term TransEnterix Surgical.

**The Merger**

On August 13, 2013, SafeStitch, a wholly owned subsidiary of SafeStitch named Tweety Acquisition Corp., and TransEnterix Surgical entered into an agreement and plan of merger, amended on August 30, 2013, under which the parties agreed to enter into the merger described above. The main rationale for the merger was to strengthen capital raising opportunities for TransEnterix Surgical's primary product candidate, the SurgiBot System (described below), through the private placement financing described in the prospectus, and the ability to access public markets for future financings. Pursuant to the merger agreement, each share of TransEnterix Surgical's capital stock issued and outstanding immediately before the merger was converted into the right to receive 1.1533 shares of SafeStitch's common stock, other than those shares of TransEnterix Surgical's common stock held by non-accredited investors. The shares held by non-accredited investors of TransEnterix Surgical were instead converted into the right to receive cash in the amount of \$1.08 per share of SafeStitch's common stock. This cash-out price of \$1.08 per share, without interest, was the volume-weighted average price of a share of SafeStitch common stock on the OTC Bulletin Board, or OTCBB, for the 60-trading day period that ended on August 30, 2013, which was one business day prior to the effective date of the merger. Additionally, upon consummation of the merger, SafeStitch assumed all of the outstanding TransEnterix Surgical stock options and warrants. The same exchange ratio of 1.1533 was applied to the assumption of such outstanding stock options and warrants, and impacted the number of shares and the exercise price of such stock options and warrants.

All references to share amounts in this prospectus have been retroactively adjusted to reflect the impact of the exchange ratio of 1.1533 per share.

## **Table of Contents**

### **The Private Financing**

On September 3, 2013, we consummated a private placement transaction with certain of our investors who were accredited investors. We sold shares of our Series B Convertible Preferred Stock to provide funding to support our operations following the merger. Pursuant to a securities purchase agreement dated September 3, 2013, an aggregate of 7,544,704.4 shares of our Series B Preferred Stock were sold in the private placement for a purchase price of \$4.00 per share of Series B Preferred Stock. The purchase price was paid in cash, cancellation of indebtedness of TransEnterix Surgical or a combination of cash and cancellation of indebtedness. Each share of Series B Preferred Stock was convertible into ten (10) shares of our common stock. In accordance with the securities purchase agreement, we sold an additional 25,000 shares of Series B Preferred Stock on September 17, 2013. Proceeds from the sale of the Series B Preferred Stock shares, net of issuance costs, were \$28.2 million.

On December 6, 2013, we filed an Amended and Restated Certificate of Incorporation to change our name to TransEnterix, Inc. and to increase the authorized shares of our common stock from 225,000,000 to 750,000,000. In accordance with the Certificate of Designation that defines the terms of the Series B Preferred Stock, upon such filing each outstanding share of Series B Preferred Stock was automatically converted into ten (10) shares of our common stock. An aggregate of 75,697,094 shares of common stock were issued in the conversion of the Series B Preferred Stock on December 6, 2013.

### **Accounting Impact of the Merger**

The merger is treated as a reverse acquisition of SafeStitch for financial accounting and reporting purposes. As such, TransEnterix Surgical is treated as the acquirer for accounting and financial reporting purposes while SafeStitch is treated as the acquired entity for accounting and financial reporting purposes. Further, as a result, the assets and liabilities and the historical operations that are reflected in this prospectus and will be reflected in our future financial statements filed with the SEC will be those of TransEnterix Surgical, and SafeStitch assets, liabilities and results of operations will be consolidated with the assets, liabilities and results of operations of TransEnterix Surgical as of and after September 3, 2013, the date of the merger.

The report of BDO USA LLP, our independent registered public accounting firm, on our consolidated financial statements as of December 31, 2013 and 2012 and for each of the two years in the period ended December 31, 2013 contains an explanatory paragraph regarding the substantial doubt about our ability to continue as a going concern. Such consolidated financial statements are incorporated by reference into this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2013.

### **Reverse Stock Split**

On February 12, 2014, the holders of approximately 66% of our common stock authorized a Certificate of Amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split in the range of one-for-two to one-for-ten, with the

## **Table of Contents**

actual ratio to be determined within such range by our Board of Directors in its sole discretion. Subsequently, our Board of Directors approved a one-for-five reverse stock split of our common stock.

The reverse stock split was contemplated in connection with our application to list our common stock for trading on the NYSE MKT to assist in meeting the NYSE MKT minimum bid price requirement of a stock price of at least \$2.00 per share. We submitted an application to have our common stock listed for trading on the NYSE MKT on March 17, 2014. Our proposed listing on the NYSE MKT is dependent upon meeting all relevant quantitative and qualitative listing criteria of the NYSE MKT. We anticipate approval of our listing application with the NYSE MKT subject to completion of a public offering under this Registration Statement, and other relevant requirements, including the finalization of the reverse stock split.

On March 31, 2014, we filed the Certificate of Amendment to our Certificate of Incorporation to begin the process to effect the reverse stock split. The outstanding share numbers in this prospectus do not reflect the impact of the reverse stock split.

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

### **Overview**

We are a medical device company that is focused on the development and future commercialization of a robotic assisted surgical system called the SurgiBot System. The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains scrubbed within the sterile field. The flexible nature of the SurgiBot System would allow for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once in the body. The SurgiBot System also integrates three-dimensional (3-D) high definition vision technology. We have also commercialized the SPIDER® Surgical System, a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilizes flexible instruments and articulating channels that are controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. We also currently manufacture multiple instruments that can be deployed using the SPIDER System currently and which are being adapted for use with the SurgiBot System.

Prior to the merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity and gastroesophageal reflux disease. SafeStitch has developed other surgical devices, including the SMART Dilator, to be utilized in treating obesity, gastroesophageal reflux disease and esophageal strictures. SafeStitch also developed and was commercializing a surgical stapler called the AMID Hernia Fixation Device, or AMID stapler.

Each of the SurgiBot System and Gastroplasty Device is, and the SMART Dilator was, a product candidate in development for which regulatory clearance or approval has not yet been sought from the U.S. Food and Drug Administration, or FDA, or other regulatory bodies. The SPIDER System was cleared for commercialization as a Class II medical device by the FDA in July 2009. The AMID stapler received FDA clearance in November 2009. Each of the SPIDER

## **Table of Contents**

System and the AMID stapler received CE Mark approval to be commercialized in the European Union. Following the merger, we made the decision to cease commercialization efforts for the AMID stapler and allowed its FDA clearance and CE Mark status to lapse.

On a going-forward basis, we intend to focus on developing the SurgiBot System and on continuing the development of the Gastroplasty Device for the treatment of obesity.

We operate in one business segment.

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

## **Company Information**

We were organized as a Delaware corporation on August 19, 1988. Our principal executive offices are located at 635 Davis Drive, Suite 300, Morrisville, NC 27560. Our phone number is (919) 765-8400 and our Internet address is [www.transenterix.com](http://www.transenterix.com). In December 2013, we changed our name to TransEnterix, Inc. from SafeStitch Medical, Inc. The information on our website or any other website is not incorporated by reference in this prospectus and does not constitute a part of this prospectus.

## **ABOUT THIS PROSPECTUS**

This prospectus is part of a shelf registration statement that we filed with the SEC. By using a shelf registration statement, we may, from time to time, issue any combination of the securities described in this prospectus in one or more offerings up to an aggregate maximum offering price of \$100,000,000. Each time we sell any of our securities, we will provide a prospectus supplement that will contain more specific information about the offering and the terms of the securities being sold. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus or the documents incorporated by reference.

This prospectus provides you with a general description of the Company and our securities. For further information about our business and our securities, you should refer to the registration statement and the reports incorporated by reference in this prospectus, as described in **Where You Can Find More Information**.

You should rely only on the information contained in this prospectus and in any prospectus supplement (including in any documents incorporated by reference herein or therein). We have not authorized anyone to provide you with any different information. We are offering to sell our securities, and seeking offers to buy, only in jurisdictions where offers and sales are permitted.

Table of Contents

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words believes, anticipates, estimates, plans, expects, intends, may, could, should, potential, likely, projects, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under the heading **Risk Factors**. These factors and the other cautionary statements made in this prospectus should be read as being applicable to all related forward-looking statements whenever they appear in this prospectus. In addition, any forward-looking statements represent our estimates only as of the date that this prospectus is filed with the SEC, and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

**Table of Contents**

**RISK FACTORS**

An investment in the Company involves a significant level of risk. Investors should carefully consider the risk factors described below together with the other information included in this prospectus. If any of the risks described below occurs, or if other risks not identified below occur, our business, financial condition, and results of operations could be materially and adversely affected.

**Risks Related to our Business**

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

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. Substantial doubt exists about our ability to continue as a going concern as a result of recurring losses and an accumulated deficit. We continue to incur research and development and general and administrative expenses related to our operations. Our net loss for the year ended December 31, 2013 was \$28.4 million, and our accumulated deficit as of December 31, 2013 was \$93.3 million.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we prepare for clinical trials of our products and continue to commercialize our cleared or approved products. If our products fail in clinical trials or do not gain regulatory clearance or approval, or if our products do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Absent a significant increase in revenue or additional equity or debt financing, we may not be able to sustain our ability to continue as a going concern. On March 31, 2014, we filed this prospectus as part of a Registration Statement on Form S-3 to register \$100,000,000 of our securities for sale from time to time. Once such Registration Statement is declared effective by the SEC, we do anticipate proceeding with offerings of our securities in accordance with the shelf registration statement requirements. We cannot assure you that we will be successful in obtaining such additional financing on terms acceptable to us or at all.

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

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

**Table of Contents**

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

the costs associated with the integration of the respective businesses and operations of SafeStitch and TransEnterix Surgical;

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

the costs associated with the expansion of our manufacturing capabilities;

our need to expand our research and development activities;

the rate of progress and cost of our clinical trials;

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

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

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

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

the effect of competing technological and market developments;

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

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

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

collaboration and licensing arrangements, it may be necessary to relinquish some rights to our products or grant licenses on terms that may not be favorable to us.

**Table of Contents**

***We may fail to realize some or all of the anticipated benefits of the business combination of SafeStitch and TransEnterix Surgical, which may adversely affect the value of our common stock.***

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

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

failure to effectively coordinate research and development efforts and capabilities effectively;

failure to adequately communicate our product capabilities and expected product roadmap;

failure to compete effectively against companies already serving the broader market opportunities expected to be available to us and our potential expanded product offerings;

coordinating research and development activities to enhance the introduction of new devices and platforms acquired in the acquisition;

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

integrating a senior management team as well as directors from both companies on our Board of Directors;

retaining and integrating key employees from TransEnterix Surgical and SafeStitch;

**Table of Contents**

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

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

transitioning all facilities to a common information technology environment.

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

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

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

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

In connection with the merger we became a party to, and jointly and severally liable for, \$9.4 million of outstanding debt of TransEnterix Surgical, and the associated obligations owed by TransEnterix Surgical under a Loan and Security Agreement, dated January 17, 2012, among TransEnterix Surgical, Silicon Valley Bank and Oxford Finance LLC, as amended by a First, Second and Third Amendment, dated February 11, 2013, September 3, 2013 and October 31,

**Table of Contents**

2013, respectively. The amended Loan and Security Agreement evidences a term loan, which will mature on January 1, 2016. Our resulting substantial level of indebtedness and other financial obligations increase the possibility that we may be unable to pay, when due, the principal of, interest on, or other amounts due in respect of, our indebtedness.

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

If we breach any of these restrictive covenants or are unable to pay our indebtedness under the amended Loan and Security Agreement when due, this could result in an event of default. 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 term loan, to be immediately due and payable. Any such occurrence would have an immediate and materially adverse impact on our business and results of operations.

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

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

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

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

**Table of Contents**

*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.*

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application unless the device is specifically exempt from those requirements.

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) submission, 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) submission must provide information supporting a claim of substantial equivalence to the predicate device. If clinical data from human clinical trials are required to support the 510(k) submission, these data must be gathered in compliance with investigational device exemption, or IDE, regulations for investigations performed in the United States. The FDA review process for premarket notifications submitted pursuant to Section 510(k) takes, on average, about ninety (90) days, but it can take substantially longer if the FDA has concerns regarding the application. There is no guarantee that the FDA will clear a medical device for marketing, in which case the device cannot be distributed in the United States. There is also no guarantee that the FDA will deem the applicable device subject to the 510(k) process, as opposed to the more time-consuming, resource-intensive and problematic, pre-market approval, or PMA, process described below.

The second, more comprehensive, PMA 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 PMA process. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to approval, as opposed to clearance, as a Class III device. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device. These regulations permit a company to undertake a clinical study of a non-significant risk device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. Second, the FDA must review the company's PMA application. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Additionally, devices subject to PMA approval may be subject to a panel review to obtain market approval and are required to pass a factory inspection in

**Table of Contents**

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. 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 Food and Drug Administration Modernization Act of 1997 added the *de novo* classification option as 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 determination in response to a premarket notification 510(k) submission. Under current law, a company can 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.

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.



---

**Table of Contents**

While we have already received FDA clearance for the SPIDER System, we continue in discussions with the FDA regarding the appropriate regulatory pathway for our SurgiBot System and our Gastroplasty Device. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews a premarket notification in ninety (90) days, there is no guarantee that our future products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, even if a device is reviewed under the 510(k) premarket notification process, that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. In the past we have been successful in receiving 510(k) clearance within the 90-day review period, but it can take longer (six to twelve months) to obtain 510(k) clearance for a Class II device. If the FDA fails to provide clearance for a product candidate, such as the SurgiBot System, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product.

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

Positive results from limited animal trials and other early development work we have conducted or early clinical experience with the test articles or with similar devices should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our future Class III products are safe and effective for their intended uses. Generally, clinical data is not required to support a 510(k) application, but if applicable for our Class II products, we may require clinical data to demonstrate that the devices are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under Section 510(k). We have participated in discussions with the FDA regarding the appropriate regulatory pathway for our products, primarily for the SurgiBot System. While clinical trial data for Class II devices are generally not required, we have received information from the FDA that clinical trial data may be required for the SurgiBot System to enable market clearance. Such requirements could be expensive and could delay the clearance of the SurgiBot System.

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

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

We are highly dependent on the success of our products, especially the SurgiBot System. We cannot give any assurance that the FDA will grant regulatory clearance for the SurgiBot System, or will not require the more burdensome PMA submission and approval, nor can we

**Table of Contents**

give any assurance that the SurgiBot System or any of our other products will be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically effective or cost-effective alternatives, or failure in our sales and marketing efforts. Any failure to obtain clearance or approval of our products or to successfully commercialize them would have a material and adverse effect on our business.

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

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address minimally invasive and robotic assisted surgery. We are currently developing and commercializing medical devices that will compete with other medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other medical devices and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical device companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than we do. Some of the medical device companies we expect to compete with include Applied Medical, Covidien, Intuitive Surgical, Johnson & Johnson, Olympus, Stryker, USGI Medical, Endo Gastric Solutions, Inc., ValenTx, Inc., GI Dynamics, Inc., Medigus, Ltd., and a number of minimally invasive surgical device, robotic surgical device manufacturers and providers of products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many other universities and private and public research institutions are or may become active in research involving surgical devices for minimally invasive and robotic assisted surgery.

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

the efficacy, safety and reliability of our products;

the speed at which we develop our products;

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

our ability to design and successfully execute appropriate clinical trials;

the timing and scope of regulatory clearances or approvals;

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

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

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

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

lack of efficacy evidenced during clinical trials;

slower than expected rates of patient recruitment and enrollment;

failure of patients to complete the clinical trial;

unforeseen safety issues;

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

**Table of Contents**

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

inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities or the institutional review board for any given clinical trial site. Any failure or significant delay in completing clinical trials for our products could materially harm our financial results and the commercial prospects for our products.

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

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

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

restrictions on the products, manufacturers or manufacturing process;

adverse inspectional observations, known as Form 483 notices, warning letters, non-warning letters incorporating inspectional observations;

civil or criminal penalties or fines;

injunctions;

**Table of Contents**

product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory clearances or approvals;

total or partial suspension of production;

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

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

import and export restrictions.

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

***Current legislation and future legislative or regulatory reform of the FDA clearance and approval process 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 or the reimbursement thereof. 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 under development. 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. In 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device



**Table of Contents**

regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the Refuse to Accept guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

***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 be sure 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.

Devices used in surgical procedures that are not classified as durable medical equipment, DME, are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. Healthcare providers are, however, reimbursed by third-party payors for the surgical procedures performed using non-DME devices. 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. To the extent that any of our products are deemed to be durable medical equipment, they may be subject to distribution under Medicare's Competitive Acquisition regulations, which could adversely affect the amount that we can seek from payors. Additionally, our business operations and activities may be directly, or indirectly, subject to various federal, state and local healthcare laws, including but not limited to, laws prohibiting kickbacks and false claims. Any changes in the health reimbursement system that lowers reimbursement for surgical procedures using our devices or changes in healthcare laws generally or the enforcement of such laws could materially affect our business.

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

**Table of Contents**

Education Affordability Reconciliation Act. We refer to such laws in this prospectus as the 2010 Health Care Reform Legislation. The constitutionality of the 2010 Health Care Reform Legislation was confirmed on June 28, 2012 by the Supreme Court of the United States. Specifically, the Supreme Court upheld the individual mandate included changes regarding the extension of medical benefits to those who currently lack insurance coverage. Thus, the 2010 Health Care Reform Legislation has changed, and will continue to change, the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, or some combination of both, as well as other changes.

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

Further, the 2010 Health Care Reform Legislation includes the Physician Payments Sunshine Act, which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursable by Medicare, Medicaid and the Children's Health Insurance Program to report certain payments or transfers of value provided to physicians and teaching hospitals and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. The Centers for Medicare & Medicaid Services, known as CMS, issued its final rule implementing the Physician Payments Sunshine Act in February 2013, and required data collection commenced as of August 1, 2013. Manufacturers must report aggregated data for August through December of 2013 to CMS in the first quarter of 2014 and more detailed information regarding the specific payments and transfers of value in the second quarter of 2014. CMS will release the data on a public website by September 30, 2014. The Company has complied with its initial reporting obligations under the Physician Payments Sunshine Act and intends to continue to comply with such requirements. The failure to report appropriate data could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

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

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

**Table of Contents**

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

Even if our products obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. To date, we have experienced minimal sales of the AMID stapler and SPIDER System and have not made any sales of the SurgiBot System or the Gastroplasty Device. We have decided to focus our efforts on the development of the SurgiBot System and substantially decreased our SPIDER System sales and stopped sales of the AMID stapler. We believe that the degree of market acceptance of a commercialized product 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;

coverage and adequate reimbursement for surgical procedures in which our products are used;

strength of marketing and distribution support; and

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

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

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

There is significant uncertainty related to the third-party coverage and reimbursement of newly cleared or approved medical devices. Normally, surgical devices are not directly covered; instead, the procedure using the device is subject to a coverage determination by the insurer. We believe that hospitals and ambulatory surgery centers will be our direct customers for our product candidates, and that our revenue is not directly dependent upon the receipt of reimbursement codes or reimbursement coverage by payors. Thus, our customers' ability to obtain coverage and adequate reimbursement for surgical procedures utilizing our products will affect demand for our current and future products. The commercial success of our existing and future products in both



**Table of Contents**

domestic and international markets also may depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our existing and future products. These payors may conclude that our products are not as safe or effective as existing devices or that procedures using our devices are not as safe or effective as the existing procedures using other devices. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our products for coverage and adequate reimbursement. The failure to obtain coverage and adequate reimbursement for our existing and future products or our customers' inability to obtain coverage and adequate reimbursement for surgical procedures using our products or health care cost containment initiatives that limit or restrict such reimbursement may reduce any future product revenue.

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

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

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

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

Rule 14a-21 under the Exchange Act requires us to seek a separate stockholder advisory vote at our annual meeting at which directors are elected to approve the compensation of our named executive officers, not less frequently than once every three years (say-on-pay vote), and,

---

**Table of Contents**

at least once every six years, to seek a separate stockholder advisory vote on the frequency with which we will submit advisory say-on-pay votes to our stockholders (say-on-frequency vote). In 2013, the year in which Rule 14a-21 became applicable to smaller reporting companies, we did not submit to our stockholders a say-on-pay vote to approve an advisory resolution regarding our compensation program for our named executive officers, or a say-on-frequency vote. Consequently, the Board of Directors has not considered the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers. At our 2014 annual meeting of stockholders, we will be asking our stockholders to vote on a proposal to approve an advisory resolution regarding our compensation program for our named executive officers, and presenting a separate say-on-frequency vote. Following such annual meeting, the Board will consider the outcome of our say-on-pay vote results when determining future compensation policies and pay levels for our named executive officers, and will report on the results of the say-on-pay vote and the say-on-frequency vote as required by applicable SEC rules. In our Annual Report on Form 10-K, as amended, we disclosed that our disclosure controls and procedures did not lead to our identification of the requirement to provide these advisory say-on-pay and say-on-frequency votes, and we adjusted our disclosure controls and procedures processes accordingly.

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

In 2013 we operated manufacturing facilities for production of the SPIDER System and maintained manufacturing facilities for the AMID stapler product. In the future, we may choose to use a third-party manufacturer for our other products. In addition, certain of our SPIDER System product component parts come from third-party suppliers. If these manufacturing partners are unable to produce our products or component parts in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require.

Our products require precise, high quality manufacturing. We and our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with the FDA's Quality System Regulation, 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 the FDA's Quality System Regulation, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure by us or on the part of our contract manufacturers could delay product development or regulatory clearance or approval of our products, or commercialization of our products and future products, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on any third party for manufacturing could adversely affect our future profit margins. Our ability to replace any then-existing manufacturer

**Table of Contents**

may be difficult because the number of potential manufacturers is limited and, in the case of Class III devices, the FDA must approve any replacement manufacturer before manufacturing can begin. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

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

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

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

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

**Table of Contents**

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

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

Further, our success will depend in part on the ability of us, Creighton University and other third-party licensors to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights. We, Creighton University 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 obtain and enforce patent protection for our products, our business could be materially harmed.***

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

## **Table of Contents**

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 we or 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, or the USPTO, may commence interference proceedings involving our patents or patent applications. Any such challenge to our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, future court decisions may introduce uncertainty in the enforceability or scope of any patent, including those owned by medical device companies.

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

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

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain

**Table of Contents**

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 patents or 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

**Table of Contents**

efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

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

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

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

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

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

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

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

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

negative consequences from changes in tax laws; and

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

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

As of December 31, 2013, the net carrying value of our goodwill and other intangible assets totaled approximately \$96.6 million, which represents approximately 82.8% of our 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

**Table of Contents**

significant changes or planned changes in use of the assets, divestitures and market capitalization declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

***In connection with the September 2013 merger transaction, we entered into lock-up and voting agreements with certain of our stockholders pursuant to which such stockholders agreed not to transfer their shares for designated periods and to vote to approve certain corporate actions following the merger.***

In connection with the merger and the private placement financing described in this prospectus, each of the investors participating in the private placement, the largest stockholders of each of SafeStitch and TransEnterix Surgical prior to the merger (many of whom were investors in the private placement), and members of our Board of Directors, agreed to enter into a lock-up and voting agreement, pursuant to which such persons agreed not to sell, transfer or otherwise convey any of the Company's securities held by them for designated periods following the merger closing date. The total number of our shares subject to the lock-up and voting agreements at the time of the merger was 226,835,825 shares, comprising approximately 93% of our stock on the effective date of the merger. The lock-up and voting agreements provide that such persons may sell, transfer or convey: (1) up to 50% of the locked-up shares (113,417,913 shares) after September 3, 2014 (the one-year anniversary of the merger closing date); (2) an additional 56,708,956 shares after March 3, 2015 (the eighteen-month anniversary of the merger closing date); and (3) the remaining 56,708,956 shares on September 3, 2015 (the two-year anniversary of the merger closing date). The restrictions on transfer contained in the lock-up and voting agreements cease to apply to all of the locked-up shares following the second anniversary of the merger closing date. These limitations may add to the low volume of shares of our common stock that trade on the OTCBB during the time periods described.

Any waiver of the lock-up restrictions under a lock-up and voting agreement requires the consent of the Company and all of the investors party to the lock-up and voting agreements.

Additionally, pursuant to the lock-up and voting agreements, each investor who signed an agreement agreed, for the period commencing on the merger closing date and ending on September 3, 2014, to vote all of such investor's shares in favor of: (i) amending our Amended and Restated Certificate of Incorporation to change our name to TransEnterix, Inc.; (ii) effecting a reverse stock split of the common stock on terms approved by our Board of Directors; and (iii) amending our 2007 Incentive Compensation Plan in order to increase the number of shares of common stock available for issuance. The corporate actions described in (i) and (iii) above were approved by a majority of stockholders and effected on December 6, 2013. The corporate action described in (ii) above was approved by a majority of our stockholders on February 12, 2014. Therefore, all voting requirements under the lock-up and voting agreements have been completed as of the date of this prospectus.

**Table of Contents**

**Risks Related to Offerings under this Prospectus and our Common Stock**

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

During the two years ended December 31, 2013, the market price of our common stock fluctuated from a high of \$1.78 per share to a low of \$0.21 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

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

developments concerning intellectual property rights and regulatory approvals;

variations in our and our competitors' results of operations;

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

developments in the medical device industry;

the results of product liability or intellectual property lawsuits;

future issuances of common stock or other securities;

the addition or departure of key personnel;

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

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

Our Board of Directors has the authority, under Delaware law, to approve the issuance of additional shares of our common stock, or shares of our preferred stock, that are authorized for issuance but not yet issued, without the need for stockholder approval. As of March 28, 2014, there were 750,000,000 shares of common stock authorized for issuance and 25,000,000 shares of preferred stock authorized for issuance, and 244,276,923 shares of common stock and zero shares of preferred stock outstanding. Any approval by our Board of Directors of the issuance of additional shares of common stock or preferred stock is likely to have an immediate and

**Table of Contents**

substantial dilutive effect on the percentage ownership of the holders of our outstanding shares. As described below, we have filed an application to list our common stock on the NYSE MKT. If such listing occurs, we will be subject to the listing rules of the NYSE MKT, which include stockholder approval requirements for issuances of common stock exceeding 20% of the then-outstanding shares of common stock in transactions other than public offerings. However, until such listing occurs, such stockholder approval requirement is not applicable to us.

***We are in the process of effecting a reverse stock split of our common stock, which could result in increased volatility in the price and trading volume of our common stock and cause a decline in the value of our common stock.***

On February 12, 2014, the holders of approximately 66% of our voting securities authorized a Certificate of Amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split in the range of one-for-two to one-for-ten, with the actual ratio to be determined within such range by the Board of Directors in its sole discretion. Subsequently, the Board of Directors approved a one-for-five reverse stock split of our common stock. On March 31, 2014, we filed the Certificate of Amendment to our Certificate of Incorporation to begin the process to effect the reverse stock split.

The reverse stock split was contemplated in connection with our application to list our common stock for trading on the NYSE MKT to assist in meeting the NYSE MKT minimum bid price requirement of a stock price of at least \$2.00 per share. We believe the one-for-five reverse stock split will allow us to achieve and maintain a stock price above the minimum bid requirements, but we cannot provide assurance that such stock price will be maintained. We submitted an application to have our common stock listed for trading on the NYSE MKT on March 17, 2014. Our proposed listing on the NYSE MKT is dependent upon meeting all relevant quantitative and qualitative listing criteria of the NYSE MKT. We anticipate approval of our listing application with the NYSE MKT subject to completion of a public offering under this Registration Statement, and other relevant requirements, including the finalization of the reverse stock split. Although we believe our common stock will be accepted for listing on the NYSE MKT, we cannot assure you that the NYSE MKT will ultimately approve our application for listing or that we will be able to sustain such listing.

The reverse stock split will not result in any change in a stockholder's economic interest in the Company, but stockholders may not view the reverse stock split in a favorable manner. If the reverse stock split is not viewed favorably by stockholders, this could result in increased volatility in the price and trading volume of our common stock, which could also cause a decline in the value of our common stock. There can be no assurance that the per share market price of our common stock following the reverse stock split will increase and be maintained in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split.

While the Board of Directors believes that a higher stock price per share, and a lower number of outstanding shares may help generate investor interest, there can be no assurance that the reverse stock split will result in a per-share price that will attract institutional investors or

**Table of Contents**

investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve.

***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 OTC Bulletin Board, or OTCBB. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all. As described above, the holders of approximately 93% of our outstanding stock at the time of the merger agreed to lock-up restrictions on such shares until at least September 3, 2014. In addition, as of the date of this prospectus approximately 65% of the issued and outstanding shares of our common stock are held by officers, directors and beneficial owners of at least 10% of our outstanding shares. These holders are subject to certain restrictions, including transfer restrictions set forth in the lock-up and voting agreements, and restrictions imposed by the Securities Act with regard to trading our common stock. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

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

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

Our common stock may be a penny stock if, among other things, the stock price is below \$5.00 per share, it is not listed on a national securities exchange or approved for quotation on the Nasdaq Stock Market or any other national stock exchange or it has not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This risk-disclosure document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and

**Table of Contents**

salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

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

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

As of the date of this prospectus, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 65% of our outstanding common stock. 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.

***Our management will have broad discretion as to the use of the proceeds of offerings under this prospectus.***

We have not designated the amount of net proceeds we will receive from an offering under this prospectus for any particular purpose. Accordingly, our management will have broad discretion as to the application of net proceeds. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds.

***We may issue preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.***

We are authorized to issue shares of preferred stock in one or more series. Our Board of Directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue preferred stock, it could affect your rights or reduce the value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party.

**Table of Contents**

*We do not expect to pay any cash dividends on our common stock.*

We have not declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Because we do not anticipate paying cash dividends for the foreseeable future, our stockholders will not realize a return on their investment in our common stock except to the extent of any appreciation in the value of our common stock. Our common stock may not appreciate in value, or may decline in value.

**USE OF PROCEEDS**

Unless otherwise indicated in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus together with our existing cash resources, for working capital and other general corporate purposes. At this time, we have not determined the specific uses of any offering proceeds, or the amounts we plan to spend on any particular use or the timing of such expenditures, which may vary significantly depending on various factors such as our research and development activities, regulatory approvals, competition, marketing and sales, and the market acceptance of any products introduced by us or our partners. Pending application of the net proceeds from any particular offering, we intend to invest such proceeds in short-term, interest-bearing, investment-grade securities.

Each time we issue securities, we will provide a prospectus supplement that will contain information about how we intend to use the proceeds from each such offering.

We cannot guarantee that we will receive any proceeds in connection with any offering hereunder because we may choose not to issue any of the securities covered by this prospectus.

**PLAN OF DISTRIBUTION**

We may sell the securities being offered hereby from time to time in one or more of the following ways:

through one or more underwriters;

through dealers, who may act as agents or principal (including a block trade in which a broker or dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction);

directly to one or more purchasers;

through agents;

through registered direct offerings;

as part of a collaboration with a third party;

**Table of Contents**

through at the market offerings, within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market on an exchange or otherwise;

in privately negotiated transactions; and

in any combination of these methods of sale.

We will set forth in a prospectus supplement the terms of the offering of securities, including:

the name or names of any agents, underwriters or dealers;

the terms of the securities being offered, including the purchase price and the proceeds we will receive from the sale;

any underwriting discounts and commissions or agency fees and other items constituting underwriters or agents compensation;

any over-allotment options under which underwriters may purchase additional securities from us; and

any discounts or concessions allowed or reallocated or paid to dealers.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, or at negotiated prices.

Underwriters, dealers, agents and others that participate in the distribution of the securities may be underwriters as defined in the Securities Act and any discounts or commissions they receive from us and any profit on their resale of the securities may be treated as underwriting discounts and commissions under the Securities Act. In no event will the total amount of cash compensation paid to underwriters, placement agents, dealers or brokers exceed 10% of the gross proceeds of the offering. We will identify in the applicable prospectus supplement any underwriters, dealers, agents and others and will describe their compensation. We may have agreements with underwriters, dealers, agents and others to indemnify them against specified civil liabilities, including liabilities under the Securities Act. Underwriters, dealers, agents and others may engage in transactions with or perform services for us in the ordinary course of their businesses.

If required under applicable state securities laws, we will sell the securities only through registered or licensed brokers or dealers. In addition, in some states, we may not sell securities unless they have been registered or qualified for sale in the applicable state or unless we have complied with an exemption from any registration or qualification requirements.



## **Table of Contents**

### **Agents**

We may designate agents who agree to solicit purchases for the period of their appointment or to sell securities on a continuing basis. Unless the prospectus supplement provides otherwise, agents will act on a best efforts basis for the period of their appointment. Agents may receive compensation in the form of commissions, discounts or concessions from us. Agents may also receive compensation from the purchasers of the securities for whom they sell as principals. Each particular agent will receive compensation in amounts negotiated in connection with the sale, which might be in excess of customary commissions.

### **Underwriters**

If we use underwriters for a sale of securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. Unless the prospectus supplement provides otherwise, underwriters will be obligated to purchase all of the securities offered by the prospectus supplement. We may change from time to time any initial public offering price and any discounts or concessions the underwriters allow or reallow or pay to dealers. We may use underwriters with whom we have a material relationship, and we may offer the securities to the public through an underwriting syndicate or through a single underwriter. We will describe in the prospectus supplement naming the underwriter the nature of any such relationship and underwriting arrangement.

### **Dealers**

We also may sell securities to a dealer as principal. If we sell our securities to a dealer as a principal, then the dealer may resell those securities to the public at varying prices to be determined by such dealer at the time of resale. The name of the dealer and the terms of the transactions will be set forth in the applicable prospectus supplement.

### **Direct Sales and Institutional Purchases**

We may also sell securities directly to one or more purchasers, in which case underwriters or agents would not be involved in the transaction.

Further, we may authorize agents, underwriters or dealers to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in an applicable prospectus supplement.

### **Stabilization Activities**

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act.

## **Table of Contents**

Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Such activities may cause the price of the securities to be higher than they would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on the OTC Bulletin Board or otherwise.

## **Passive Market Making**

Any underwriters who are qualified market makers on the OTC Bulletin Board may engage in passive market making transactions on the OTC Bulletin Board in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

## **Costs**

We will bear all costs, expenses and fees in connection with the registration of the securities, as well as the expense of all commissions and discounts, if any, attributable to sales of the securities by us.

## **DESCRIPTION OF CAPITAL STOCK**

Our authorized capital stock consists of 750,000,000 shares of common stock, par value \$0.001 per share and 25,000,000 shares of preferred stock, par value \$0.01 per share.

## **Common Stock**

Of the authorized common stock, as of March 28, 2014, there are 244,276,923 shares outstanding and there are 30,283,577 shares of our common stock reserved for the exercise of outstanding stock options, warrants and restricted stock units. There were approximately 280 record holders as of February 28, 2014. Subject to the prior rights of the holders of any shares of preferred stock which may be issued in the future, the holders of our common stock are entitled to receive dividends from our funds legally available therefor when, as and if declared by our Board of Directors, and are entitled to share ratably in all of our assets available for distribution to holders of our common stock upon the liquidation, dissolution or winding-up of our affairs, subject to the liquidation preference, if any, of any then outstanding shares of preferred stock. Holders of our common stock do not have any preemptive, subscription, redemption or conversion rights. Holders of our common stock are entitled to one vote per share on all matters which they are entitled to vote upon at meetings of stockholders or upon actions taken by written consent pursuant to Delaware corporate law. The holders of our common stock do not have cumulative voting rights, which mean that the holders of a plurality of the outstanding shares can

## **Table of Contents**

elect all of our directors. All of the shares of our common stock currently issued and outstanding are fully-paid and nonassessable. No dividends have been paid to holders of our common stock since our incorporation, and no cash dividends are anticipated to be declared or paid in the reasonably foreseeable future.

### *Transfer Agent.*

The transfer agent for our common stock is Continental Stock & Transfer Company.

### *Listing.*

The shares of our common stock are currently listed on the OTC Bulletin Board under the symbol TRXC.

## **Preferred Stock**

Our Board has the authority, without further action by the holders of the outstanding common stock, to issue preferred stock from time to time in one or more classes or series, to fix the number of shares constituting any class or series and the stated value thereof, if different from the par value, as to fix the terms of any such series or class, including dividend rights, dividend rates, conversion or exchange rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price and the liquidation preference of such class or series.

## **Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, our By-Laws and Delaware Law**

### *Delaware Statute*

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

prior to such date, our board of directors approves either the business combination or the transaction that resulted in the stockholder's becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owns at least 85% of our outstanding voting stock, excluding shares held by directors, officers and certain employee stock plans; or

on or after the consummation date, the business combination is approved by our board of directors and by the affirmative vote at an annual or special meeting of stockholders holding of at least two-thirds of our outstanding voting stock that is not owned by the interested stockholder.

## **Table of Contents**

For purposes of Section 203, a business combination includes, among other things, a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is generally a person who, together with affiliates and associates of such person:

owns 15% or more of outstanding voting stock; or

is an affiliate or associate of ours and was the owner of 15% or more of our outstanding voting stock at any time within the prior three years.

### *Certificate of Incorporation and Bylaw Provisions*

Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that, among others, could have the effect of delaying, deferring or discouraging potential acquisition proposals and could delay or prevent a change of control of us. The provisions in our certificate of incorporation and bylaws that may have such effect include:

Preferred Stock. As noted above, our board of directors, without stockholder approval, has the authority under our certificate of incorporation to issue preferred stock with rights superior to the rights of the holders of common stock. As a result, we could issue preferred stock quickly and easily, which could adversely affect the rights of holders of our common stock and could be issued with terms calculated to delay or prevent a change of control or make removal of management more difficult.

Stockholder Meetings. Under our certificate of incorporation, as amended, and bylaws, special meetings of our stockholders may be called only by the vote of a majority of the entire Board of Directors or the chairman of the Board of Directors. Our stockholders may not call a special meeting of the stockholders.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our Board of Directors or a committee thereof.

## **DESCRIPTION OF DEBT SECURITIES**

### **General**

The debt securities that we may issue will constitute debentures, notes, bonds or other evidences of indebtedness of the Company, to be issued in one or more series. The particular terms of any series of debt securities we offer, including the extent to which the general terms set forth below may be applicable to a particular series, will be described in a prospectus supplement relating to such series.

Debt securities that we may issue will be issued under an indenture between us and a trustee qualified to act as such under the Trust Indenture Act of 1939. When we refer to the



## **Table of Contents**

indenture in this prospectus, we are referring to the indenture under which debt securities are issued as supplemented by any supplemental indenture applicable to such debt securities. We will provide the name of the trustee in any prospectus supplement related to the issuance of debt securities, and we will also provide certain other information related to the trustee, including describing any relationship we have with the trustee, in such prospectus supplement.

Unless otherwise specified in a prospectus supplement, the debt securities will be direct secured or unsecured obligations of the Company. The senior debt securities will rank equally with any of our other unsecured senior and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment to any senior indebtedness.

We may issue debt securities from time to time in one or more series, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable indenture and will be equal in ranking.

The following statements relating to the debt securities and the indenture are summaries and do not purport to be complete, and are subject in their entirety to the detailed provisions of the indenture.

### **Information to be provided in a Prospectus Supplement**

The prospectus supplement would set forth the following terms of the debt securities in respect of which this prospectus is delivered:

the title and denominations of the debt securities of the series;

any limit on the aggregate principal amount of the debt securities of the series;

the date or dates on which the principal and premium, if any, with respect to the debt securities of the series are payable or the method of determination thereof;

the rate or rates, which may be fixed or variable, at which the debt securities of the series shall bear interest, if any, or the method of calculating and/or resetting such rate or rates of interest;

the dates from which such interest shall accrue or the method by which such dates shall be determined and the duration of the extensions and the basis upon which interest shall be calculated;

the interest payment dates for the series of debt securities or the method by which such dates will be determined, the terms of any deferral of interest and any right of ours to extend the interest payments periods;



**Table of Contents**

the terms and conditions upon which debt securities of the series may be redeemed, in whole or in part, at our option or otherwise;

our obligation, if any, to redeem, purchase, or repay debt securities of the series pursuant to any sinking fund or other specified event or at the option of the holders and the terms of any such redemption, purchase, or repayment;

the terms, if any, upon which the debt securities of the series may be convertible into or exchanged for preferred stock or common stock, including, among other things, the initial conversion or exchange price or rate and the conversion or exchange period;

if the amount of principal, premium, if any, or interest with respect to the debt securities of the series may be determined with reference to an index or formula, the manner in which such amounts will be determined;

if any payments on the debt securities of the series are to be made in a currency or currencies (or by reference to an index or formula) other than that in which such securities are denominated or designated to be payable, the currency or currencies (or index or formula) in which such payments are to be made and the terms and conditions of such payments;

any changes or additions to the provisions of the indenture dealing with defeasance, including any additional covenants that may be subject to our covenant defeasance option;

the currency or currencies in which payment of the principal and premium, if any, and interest with respect to debt securities of the series will be payable, or in which the debt securities of the series shall be denominated, and the particular provisions applicable thereto in accordance with the indenture;

the portion of the principal amount of debt securities of the series which will be payable upon declaration of acceleration or provable in bankruptcy or the method by which such portion or amount shall be determined;

whether the debt securities of the series will be secured and, if so, on what terms;

any events of default with respect to the debt securities of the series;

the identity of any trustees, authenticating or paying agents, transfer agents or registrars;

the applicability of, and any addition to or change in, the covenants currently set forth in the indenture;

the subordination, ranking or priority, if any, of the debt securities of the series and terms of the subordination;

## **Table of Contents**

any other terms of the debt securities of the series which are not prohibited by the indenture; and

whether securities of the series shall be issuable as registered securities or bearer securities (with or without interest coupons), and any restrictions applicable to the offering, sale or delivery of such bearer securities and the terms upon which such bearer securities of a series may be exchanged for registered securities, and vice versa.

## **Interest Rate**

Debt securities that bear interest will do so at a fixed rate or a floating rate. We may sell, at a discount below the stated principal amount, any debt securities which bear no interest or which bear interest at a rate that at the time of issuance is below the prevailing market rate. The relevant prospectus supplement will describe the special United States federal income tax considerations applicable to any discounted debt securities and any debt securities issued at par which are treated as having been issued at a discount for United States federal income tax purposes.

## **Transfer and Exchange**

We may issue debt securities that would be represented by either:

- (a) book-entry securities, which means that there will be one or more global securities registered in the name of The Depository Trust Company, as depository, or a nominee of the depository; or
- (b) certificated securities, which means that they will be represented by a certificate issued in definitive registered form.

We would specify in the prospectus supplement applicable to a particular offering whether the debt securities offered will be book-entry or certificated securities. Except as set forth under **Global Debt Securities and Book-Entry System** below, book-entry debt securities would not be issuable in certificated form.

## **Certificated Debt Securities**

If you hold certificated debt securities that have been offered by this prospectus, you may transfer or exchange them at the trustee's office or at the paying agency in accordance with the terms of the indenture. You would not be charged a service charge for any transfer or exchange of certificated debt securities, but may be required to pay an amount sufficient to cover any tax or other governmental charge payable in connection with the transfer or exchange.

The transfer of certificated debt securities and of the right to receive the principal of, premium and/or interest, if any, on your certificated debt securities can occur only by surrendering the certificate representing your certificated debt securities and having us or the trustee issue a new certificate to the new holder.

**Table of Contents**

**Global Debt Securities and Book Entry System**

If we decided to issue debt securities in the form of one or more global securities, then we would register the global securities in the name of the depository for the global securities or in the nominee of the depository, and the global securities would be delivered by the trustee to the depository for credit to the accounts of the holders of beneficial interest in the debt securities. Each global security would:

be registered in the name of a depository, or its nominee, that we would identify in a prospectus supplement;

be deposited with the depository or nominee or custodian; and

bear any required legends.

No global security may be exchanged in whole or in part for debt securities registered in the name of any person other than the depository or any nominee unless:

the depository has notified us that it is unwilling or unable to continue as depository or has ceased to be qualified to act as depository;

an event of default has occurred and is continuing with respect to the debt securities of the applicable series;  
or

any other circumstance described in a prospectus supplement has occurred permitting or requiring the issuance of any such security.

As long as the depository, or its nominee, is the registered owner of a global security, the depository or nominee would be considered the sole owner and holder of the debt securities represented by the global security for all purposes under the indentures. Except in the above limited circumstances, owners of beneficial interests in a global security would not be:

entitled to have the debt securities registered in their names;

entitled to physical delivery of certificated debt securities; or

considered to be holders of those debt securities under the indenture.

Payments on a global security would be made to the depository or its nominee as the holder of the global security. Some jurisdictions have laws that require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may impair the ability to transfer beneficial interests in a global security.

Institutions that have accounts with the depositary or its nominee are referred to as participants. Ownership of beneficial interests in a global security would be limited to participants and to persons that may hold beneficial interests through participants. The depositary would credit, on its book-entry registration and transfer system, the respective principal amounts of debt securities represented by the global security to the accounts of its participants.

## **Table of Contents**

Ownership of beneficial interests in a global security would be shown on and effected through records maintained by the depository, with respect to participants' interests, or any participant, with respect to interests of persons held by participants on their behalf.

Payments, transfers and exchanges relating to beneficial interests in a global security would be subject to policies and procedures of the depository. The depository policies and procedures may change from time to time. Neither any trustee nor we would have any responsibility or liability for the depository's or any participant's records with respect to beneficial interests in a global security.

The prospectus supplement would describe the specific terms of the depository arrangement for debt securities of a series that are issued in global form. The Company and its agents, the trustee, and any of its agents would not have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests in the global debt security or for maintaining, supervising or reviewing any records relating to the beneficial ownership interests.

## **Conversion or Exchange Rights**

Debt securities offered hereby may be convertible into or exchangeable for shares of our common or preferred stock. The terms and conditions of such conversion or exchange will be set forth in the applicable prospectus supplement. Such terms may include, among others, the following:

the conversion or exchange price;

the conversion or exchange period;

provisions regarding our ability or that of the holder to convert or exchange the debt securities;

events requiring adjustment to the conversion or exchange price; and

provisions affecting conversion or exchange in the event of our redemption of such debt securities.

## **Covenants**

Unless otherwise indicated in a prospectus supplement, the debt securities would not have the benefit of any covenants that limit or restrict our business or operations, the pledging of our assets or the incurrence by us of indebtedness. We would describe in the applicable prospectus supplement any material covenants of a series of debt securities.

**Table of Contents**

**Concerning the Trustee**

We would identify the trustee with respect to any series of debt securities in the prospectus supplement relating to the debt securities. You should note that if the trustee becomes a creditor of the Company, the indenture and the Trust Indenture Act of 1939 limit the rights of the trustee to obtain payment of claims in certain cases, or to realize on certain property received in respect of certain claims, as security or otherwise. The trustee and its affiliates may engage in, and would be permitted to continue to engage in, other transactions with us and our affiliates. If, however, the trustee acquires any conflicting interest within the meaning of the Trust Indenture Act of 1939, it must eliminate the conflict or resign.

The holders of a majority in principal amount of the then outstanding debt securities of any series may direct the time, method and place of conducting any proceeding for exercising any remedy available to the trustee. If an event of default occurs and is continuing, the trustee, in the exercise of its rights and powers, must use the degree of care and skill of a prudent person in the conduct of his or her own affairs. Subject to this provision, the trustee would be under no obligation to exercise any of its rights or powers under the indenture at the request of any of the holders of the debt securities, unless they have offered to the trustee reasonable indemnity or security.

**DESCRIPTION OF WARRANTS**

We may issue warrants to purchase preferred stock or common stock. We may offer warrants separately or together with one or more additional warrants, debt securities, shares of preferred stock or common stock, or any combination of those securities in the form of units, as described in the applicable prospectus supplement. If we issue warrants as part of a unit, the prospectus supplement will specify whether those warrants may be separated from the other securities in the unit prior to the warrants' expiration date. We may issue the warrants under warrant agreements to be entered into between us and a bank or trust company, as warrant agent, all as described in the prospectus supplement. If we issue the warrants under warrant agreements, the warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

We will describe the particular terms of any warrants that we offer in the prospectus supplement relating to those warrants. Those terms may include the following:

the specific designation and aggregate number of warrants, and the price at which we will issue the warrants;

the currency or currency units in which the offering price, if any, and the exercise price are payable;

the date on which the right to exercise the warrants will begin and the date on which the right will expire or, if the warrants are not continuously exercisable throughout that period, the specific date or dates on which they are exercisable;

**Table of Contents**

whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms;

any applicable material United States federal income tax considerations;

the identity of the warrant agent, if any, for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

the designation, aggregate principal amount, currency, denomination and terms of any debt securities that may be purchased upon exercise of the warrants;

the designation, amount, currency, denominations and terms of any preferred stock or common stock purchasable upon exercise of the warrants;

if applicable, the designation and terms of the debt securities, preferred stock or common stock with which the warrants are issued and the number of warrants issued with each security;

if applicable, the date from and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;

the principal amount of debt securities or the number of shares of preferred stock or common stock purchasable upon exercise of any warrant and the price at which those shares may be purchased;

provisions for changes to or adjustments in the exercise price;

if applicable, the minimum or maximum number of warrants that may be exercised at any one time;

information with respect to any book-entry procedures;

any antidilution provision of the warrants;

any redemption or call provisions; and

any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Pursuant to the Loan and Security Agreement, dated January 17, 2012, among TransEnterix Surgical, Silicon Valley Bank and Oxford Finance LLC, as amended, on December 21, 2012, TransEnterix Surgical issued warrants to purchase an aggregate of 1,397,937 shares of common stock to the lenders, Silicon Valley Bank and to Oxford Finance LLC. Following the merger, these warrants were assumed by us and are now exercisable for our common stock. Pursuant to a stock purchase agreement dated March 22, 2013 among SafeStitch and the investors executing such agreement, SafeStitch issued warrants to acquire 6,048,000 shares of common stock. As of March 28, 2014, warrants to acquire 6,426,968 shares of our common stock remain outstanding.

**Table of Contents**

**DESCRIPTION OF UNITS**

We may issue units consisting of one or more of the other securities that may be offered under this prospectus, in any combination. These units may be issuable as, and for a specified period of time may be transferable only as, a single security, rather than as the separate constituent securities comprising such units. The statements made in this section relating to the units are summaries only and are not complete. When we issue units, we will provide the specific terms of the units in a prospectus supplement. To the extent the information contained in the prospectus supplement differs from this summary description, you should rely on the information in the prospectus supplement.

**RATIO OF EARNINGS TO FIXED CHARGES**

If we offer debt securities and/or shares of preferred stock under this prospectus, then we will, if required at that time, provide a ratio of earnings to fixed charges and/or ratio of combined fixed charges and preference dividends to earnings, respectively, in the applicable prospectus supplement for such offering.

**LEGAL MATTERS**

Certain legal matters with respect to the securities offered hereby have been passed upon by Ballard Spahr LLP.

**EXPERTS**

The consolidated financial statements as of December 31, 2013 and 2012 and for each of the two years in the period ended December 31, 2013 incorporated by reference in this Prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

**INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference in this prospectus the information in other documents that we file with it, which means that we can disclose important information to you by referring you to those documents containing such information. This prospectus is part of a registration statement we filed with the SEC. You should rely on the information incorporated by reference in this prospectus and the registration statement. The information incorporated by reference is considered to be part of this prospectus and information we file later with the SEC will automatically update and supersede this information and information contained in documents filed earlier with the SEC. We incorporate by reference the documents listed below and any future filings made with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering; *provided*, that we are not incorporating by reference any documents or information deemed to have been furnished and not filed in accordance with SEC rules. The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 5, 2014, our Annual Report on Form 10-K/A for the year ended December 31, 2013, filed on March 14, 2014, and our Annual Report on Form 10-K/A Amendment No. 2 for the year ended December 31, 2013, filed on March 31, 2014;



**Table of Contents**

our Current Report on Form 8-K/A filed on November 13, 2013 (Item 9.01); and our Current Report on Form 8-K filed on February 19, 2014 (Items 5.02, 5.05, and 5.07);

our definitive Information Statement on Schedule 14C filed February 21, 2014; and

the description of the Company's common stock contained in the Registration Statement on Form 8-A filed on July 30, 1991 and in the Current Report on Form 8-K filed on March 31, 2014 (Item 8.01).

We will furnish to you, on written or oral request, a copy of any or all of the documents that have been incorporated by reference, including exhibits to these documents. You may request a copy of these filings at no cost by writing or telephoning our Secretary at the following address and telephone number:

TransEnterix, Inc.

Attention: Joshua Weingard, Chief Legal Officer and Secretary

635 Davis Drive, Suite 3000

Morrisville, NC 27560

Telephone No.: (919) 765-8400

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-3 under the Securities Act to register our securities being offered in this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement or the exhibits and schedules filed thereto. For further information about us and our securities offered by this prospectus, we refer you to the registration statement and the exhibits and schedules filed with the registration statement. Any statement contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement is not necessarily complete and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. You may read and copy any materials we file with the SEC, including the registration statement, at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements

**Table of Contents**

and other information about issuers, like us, that file electronically with the SEC. The address of that website is <http://www.sec.gov>. You may also inspect our SEC reports and other information at our website at [www.transenterix.com](http://www.transenterix.com). Information on or accessible through our website is not a part of this prospectus. We are subject to the information reporting requirements of the Exchange Act, and file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The costs and expenses payable by the Company in connection with the offerings described in this registration statement are as follows:

SEC registration fee	\$ 12,880.00
Legal fees and expenses	\$ 50,000.00 *
Accounting fees and expenses	\$ 50,000.00 *
Printer costs and expenses	\$ 12,120.00 *
<b>Total</b>	<b>\$ 125,000.00</b>

\* Estimated as permitted under Rule 511 of Regulation S-K.

**Item 15. Indemnification of Directors and Officers.**

The Delaware General Corporation Law (DGCL) and certain provisions of our bylaws under certain circumstances provide for indemnification of our officers, directors and controlling persons against liabilities which they may incur in such capacities. A summary of the circumstances in which such indemnification is provided for is contained herein, but this description is qualified in its entirety by reference to our bylaws.

Section 145 of the DGCL permits a corporation to indemnify any director, officer, employee or agent of the corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful.

A similar standard is applicable in the case of derivative actions (i.e., actions brought by or on behalf of the corporation), except that indemnification only extends to expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of such action, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation, bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our bylaws provide for the indemnification described above and requires that any such indemnification only be made by the Company upon a determination that the applicable standard of conduct has been met, which determination shall be made (a) by the Board of Directors, by a



**Table of Contents**

majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (b) if such a quorum is not obtainable, or, even if obtainable, if a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (c) by the stockholders.

Our bylaws also authorize the Board of Directors, in its discretion, to pay the expenses of any such action in advance of the final disposition of such action upon a written undertaking by such indemnitee to repay such amounts if it shall ultimately be determined that he or she is not entitled to indemnification under the standard set by the DGCL and our bylaws.

Section 102(b)(7) of the DGCL permits, and the Company's Amended and Restated Certificate of Incorporation provide, that no director shall be personally liable to the Company or its stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

from any breach of the director's duty of loyalty to the Company or its stockholders;

from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the DGCL (unlawful payment of dividend or unlawful stock purchase or redemption); and

from any transaction from which the director derived an improper personal benefit.

Indemnification may also be granted pursuant to the terms of agreements which may be entered into in the future or pursuant to a vote of stockholders or directors. Section 145(g) of the DGCL grants the power to us to purchase and maintain insurance which protects our officers and directors against any liabilities incurred in connection with their service in such a position, and such a policy may be obtained by us.

A stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Table of Contents**

**Item 16. Exhibits.**

The following exhibits are filed as part of, or incorporated by reference into this registration statement:

Exhibit Number	Identification of Exhibit
1.1 +	Form of Underwriting Agreement
4.1 **	Specimen Certificate for common stock of Registrant
4.2 **	Form of Indenture
4.3 +	Form of Note
4.4 +	Form of Warrant Agreement (including form of warrant certificate)
4.5 +	Form of Unit Agreement (including form of unit certificate)
5.1 *	Opinion of Ballard Spahr LLP
23.1 *	Consent of BDO USA, LLP
23.4 *	Consent of Ballard Spahr LLP (included in Exhibit 5.1)
24.1 **	Power of Attorney
25.1 +	Statement of Eligibility of Trustee under the Indenture on Form T-1, to be filed separately pursuant to Section 305(b)(2) of the Trust Indenture Act of 1939

+ To be filed as an exhibit to a report filed pursuant to Sections 13(a), 13(c) or 15(d) of the Exchange Act or by post-effective amendment to the Registration Statement if securities are sold through one or more underwriters.

\* Filed herewith.

\*\* Previously filed.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the

**Table of Contents**

information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the **Calculation of Registration Fee** table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however, that:*

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be

**Table of Contents**

deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof, *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness, *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby further undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report

**Table of Contents**

pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in said act and will be governed by the final adjudication of such issue.

(i) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(j) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act ( Act ) in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Morrisville, State of North Carolina on the 31st day of March, 2014.

**TransEnterix, Inc.**

By: /s/ Todd M. Pope  
 Todd M. Pope  
 President and Chief Executive Officer  
 (principal executive officer)

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Todd M. Pope Todd M. Pope	President, Chief Executive Officer and Director (principal executive officer)	March 31, 2014
/s/ Joseph P. Slattery Joseph P. Slattery	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 31, 2014
* Paul A. LaViolette	Chairman of the Board	March 31, 2014
* Dennis J. Dougherty	Director	March 31, 2014
* Phillip Frost	Director	March 31, 2014

**Table of Contents**

*	Director	March 31, 2014
Jane H. Hsiao		
*	Director	March 31, 2014
Aftab R. Kherani		
*	Director	March 31, 2014
David B. Milne		
*	Director	March 31, 2014
Richard C. Pfenniger, Jr.		
*	Director	March 31, 2014
William N. Starling, Jr.		

\*By: /s/ Joseph P. Slattery  
Joseph P. Slattery  
Attorney-in-fact