TRANSENTERIX INC.
Form S-3/A
April 02, 2014
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As filed with the Securities and Exchange Commission on April 2, 2014

Registration No. 333-193235

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 3

TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

TRANSENTERIX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**11-2962080**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer 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, 51st 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. x

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 x

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price Per Security(2)	Proposed Maximum Aggregate Offering Price(3)	Amount of Registration Fee
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.

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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 April 2, 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 April 1, 2014, the closing price of our common stock was $9.70 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 .

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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.

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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.

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 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 effected 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. On April 1, 2014, we received authorization to list our shares on the NYSE MKT, subject to completion of a public offering of common shares and meeting all relevant quantitative and qualitative listing criteria of the NYSE MKT. Trading of our common stock on the OTCBB will reflect the reverse stock split on April 2, 2014.

On March 31, 2014, we filed the Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The relevant common share and per common share information in this prospectus have been retroactively adjusted to reflect the impact of the reverse stock split.

The following table reflects, for the fiscal years presented therein, the retroactive impact of the reverse stock split on selected common share and per-common share information and includes selected financial data for such periods. As a smaller reporting company, we are presenting such financial data for the past two fiscal years.

	For the year ended December 31, (in thousands)	
	2013	2012
Total assets	$ 116,714	$ 17,560

Long-term liabilities	$	4,602	$	8,590
Redeemable convertible preferred stock	$		$	75,005
Sales	$	1,431	$	2,115
Operating loss	$	(25,604)	$	(15,074)
Net loss	$	(28,358)	$	(15,425)
Net loss per share basic and diluted	$	(2.23)	$	(14.31)
Weighted average common shares outstanding basic and diluted		12,731		1,078

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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. The exchange ratio and the cash-out price have not been adjusted to reflect the reverse stock split.

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 two (2) 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 two (2) shares of our common stock. An aggregate of 15,139,409 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.

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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

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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. 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.

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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.

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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.

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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.

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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;

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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,

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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.

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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

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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.

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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

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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.

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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;

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- 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 an