TRANSENTERIX INC.
Form 10-Q
August 06, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC. 20549

FORM 10-Q

(Mark One)

x **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the Quarterly Period ended June 30, 2015**

or

¨ **Transition Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the Transition Period from _____ to _____**

Commission File Number 0-19437

TRANSENTERIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**11-2962080**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

84,557,243 shares of the Company s common stock, par value $0.001 per share, were outstanding as of August 4, 2015.

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TRANSENTERIX, INC.

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FORWARD-LOOKING STATEMENTS

In addition to historical financial information, this report 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) that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact contained in this report, including statements regarding future events, our future financial performance, our future business strategy and the plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including anticipates, believes, can, continue, could, estim expects, intends, may, plans, potential, predicts, should or will or the negative of these terms or other co terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Readers are urged to carefully review and consider the various disclosures made by us, which attempt to advise interested parties of the risks, uncertainties, and other factors that affect our business, operating results, financial condition and stock price, including without limitation the disclosures made under the captions Management s Discussion and Analysis of Financial Condition and Results of Operations , Financial Statements and Notes to Consolidated Financial Statements in this report, as well as the disclosures made in the TransEnterix, Inc. Annual Report on Form 10-K for the year ended December 31, 2014 filed

on February 20, 2015, and other filings we make with the Securities and Exchange Commission. Furthermore, such forward-looking statements speak only as of the date of this report. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations except as required by applicable law. References in this report to we , our , us , or the Company refer to TransEnterix, Inc. and the combined enterprise of SafeStitch Medical, Inc. and TransEnterix Surgical, Inc.

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TransEnterix, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Sales	$	$ 113	$	$ 206
Operating Expenses				
Cost of goods sold		238		458
Research and development	6,579	7,882	14,063	12,893
Sales and marketing	373	461	748	867
General and administrative	2,116	1,913	4,096	3,527
Total Operating Expenses	9,068	10,494	18,907	17,745
Operating Loss	(9,068)	(10,381)	(18,907)	(17,539)
Other Expense				
Interest Expense, net	(280)	(206)	(561)	(527)
Total Other Expense, net	(280)	(206)	(561)	(527)
Net Loss	$ (9,348)	$ (10,587)	$ (19,468)	$ (18,066)
Other comprehensive income (loss)				
Comprehensive loss	$ (9,348)	$ (10,587)	$ (19,468)	$ (18,066)
Net loss per share - basic and diluted	$ (0.14)	$ (0.18)	$ (0.30)	$ (0.33)
Weighted average common shares outstanding - basic and diluted	68,105	59,673	65,937	54,264

See accompanying notes to consolidated financial statements.

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TransEnterix, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	June 30, 2015 (unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 71,112	$ 34,766
Accounts receivable, net	8	133
Interest receivable	1	1
Other current assets	586	789
Total Current Assets	71,707	35,689
Restricted cash		250
Property and equipment, net	2,914	3,120
Intellectual property, net	1,991	2,241
Trade names, net	6	7
Goodwill	93,842	93,842
Other long term assets	90	62
Total Assets	$ 170,550	$ 135,211
Liabilities and Stockholders Equity		
Current Liabilities		
Accounts payable	$ 1,606	$ 1,768
Accrued expenses	2,259	1,769
Notes payable - current portion	2,487	610
Total Current Liabilities	6,352	4,147
Long Term Liabilities		
Notes payable - less current portion, net of debt discount	7,427	9,275
Total Liabilities	13,779	13,422
Commitments and Contingencies		
Stockholders Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2015 and December 31, 2014; and 82,481,722 and 63,182,806 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	82	63

Additional paid-in capital	312,073	257,642
Accumulated deficit	(155,384)	(135,916)
Total Stockholders Equity	156,771	121,789
Total Liabilities and Stockholders Equity	$ 170,550	$ 135,211

See accompanying notes to consolidated financial statements.

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TransEnterix, Inc.

Consolidated Statements of Stockholders Equity

(in thousands)

(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity
Balance, December 31, 2014	63,183	$ 63	$ 257,642	$ (135,916)	$ 121,789
Stock-based compensation			1,667		1,667
Issuance of common stock, net of issuance costs	18,681	19	52,514		52,533
Exercise of stock options	618		250		250
Net loss				(19,468)	(19,468)
Balance, June 30, 2015	82,482	$ 82	$ 312,073	$ (155,384)	$ 156,771

See accompanying notes to consolidated financial statements.

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TransEnterix, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2015	2014
Operating Activities		
Net loss	$ (19,468)	$ (18,066)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	768	594
Amortization of debt discount	29	
Amortization of debt issuance costs	25	44
Stock-based compensation	1,667	1,202
Loss on disposal of property and equipment		19
Changes in operating assets and liabilities:		
Accounts receivable	125	92
Interest receivable		66
Inventory		263
Other current and long term assets	150	(13)
Restricted cash	250	125
Accounts payable	(162)	1,812
Accrued expenses	490	500
Net cash and cash equivalents used in operating activities	(16,126)	(13,362)
Investing Activities		
Proceeds from sale and maturities of investments		6,191
Purchase of property and equipment	(311)	(910)
Net cash and cash equivalents (used in) provided by investing activities	(311)	5,281
Financing Activities		
Payment of debt		(1,897)
Proceeds from issuance of common stock, net of issuance costs	52,533	52,506
Proceeds from exercise of stock options and warrants	250	24
Net cash and cash equivalents provided by financing activities	52,783	50,633

Net increase in cash and cash equivalents	36,346	42,552
Cash and Cash Equivalents, beginning of period	34,766	10,014
Cash and Cash Equivalents, end of period	$ 71,112	$ 52,566
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 375	$ 337

See accompanying notes to consolidated financial statements.

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TransEnterix, Inc.

Notes to Financial Statements

1. Organization and Capitalization

TransEnterix, Inc. (the Company) is a medical device company that is focused on the development and future commercialization of a robotic assisted surgical system called the SurgiBot System (the SurgiBot System). The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System would allow for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once in the body. The SurgiBot System under development also allows for three-dimensional (3-D) high definition vision technology. The Company previously commercialized the SPIDER ® Surgical System (the SPIDER System), a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilized flexible instruments and articulating channels controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System has been cleared by the U.S. Food and Drug Administration (FDA). The Company also manufactured multiple instruments that can be deployed using the SPIDER System, and which are being adapted for use with the SurgiBot System. The Company discontinued sales of the SPIDER System as of December 31, 2014.

On September 3, 2013, TransEnterix Surgical, Inc., a Delaware corporation formerly known as TransEnterix, Inc. (TransEnterix Surgical) and SafeStitch Medical, Inc., a Delaware corporation (SafeStitch) consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the Merger). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. As used herein, the term Company refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, the term SafeStitch refers to the historic business of SafeStitch Medical, Inc. prior to the Merger, and the term TransEnterix Surgical refers to the historic business of TransEnterix Surgical, Inc. prior to the Merger.

On December 6, 2013, the Company filed an Amended and Restated Certificate of Incorporation (the Restated Certificate) to change its name to TransEnterix, Inc. and to increase the authorized shares of common stock from 225,000,000 to 750,000,000, and to authorize 25,000,000 shares of preferred stock, par value $0.01 per share. The Company s Board of Directors has the authority to fix the designations, powers, preferences and relative participating, optional and other special rights of shares of any series of preferred stock designated by them, and the qualifications, limitations or restrictions of such preferred stock.

Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity, gastroesophageal reflux disease (GERD) and Barrett s Esophagus. In the second quarter of 2014, the Company ceased internal development of the Gastroplasty Device and is currently evaluating strategic alternatives for the former SafeStitch products.

The Company operates in one business segment.

The Company is subject to a number of risks similar to other similarly-sized companies in the medical device industry. These risks include, without limitation, the historical lack of profitability; the Company s ability to raise additional capital; its ability to successfully develop, clinically test and commercialize its products; the timing and outcome of the regulatory review process for our products; changes in the health care and regulatory environments of

the United States and other countries in which the Company intends to operate; its ability to attract and retain key management, marketing and scientific personnel; competition from new entrants; its ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights; its ability to successfully transition from a research and development company to a marketing, sales and distribution concern; competition in the market for robotic surgical devices; and its ability to identify and pursue development of additional products.

2. Summary of Significant Accounting Policies

Basis of presentation

The Company has prepared the accompanying unaudited consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). The consolidated financial statements are unaudited and should be read in conjunction with the audited consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on February 20, 2015. The accompanying unaudited interim consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of the Company s management, necessary for a fair statement of the Company s consolidated financial position, results of operations and cash flows for the periods presented. These principles require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The principal estimates relate to inventory valuation, stock-based compensation, accrued expenses and income tax valuation. Actual results could differ from those estimates. The year-end balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

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For a description of our critical accounting policies and estimates, please refer to the Critical Accounting Policies and Estimates section of the Management s Discussion and Analysis of Financial Condition and Results of Operations section contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on February 20, 2015. There have been no material changes in any of our accounting policies since December 31, 2014.

Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SafeStitch LLC, and TransEnterix Surgical, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

Reverse Merger

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

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

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

Reverse Stock Split

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

Identifiable Intangible Assets and Goodwill

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed at June 30, 2015 or December 31, 2014.

Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at December 31st or when events or changes in circumstances indicate evidence of potential impairment exists, using a fair value based test. No impairment existed at June 30, 2015 or December 31, 2014.

Debt Issuance Costs

The Company capitalizes costs associated with the issuance of debt instruments and amortizes these costs to interest expense over the term of the related debt agreement using the effective yield amortization method. Unamortized debt issuance costs will be charged to operations when indebtedness under the related credit facility is repaid prior to maturity.

Business Acquisitions

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

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

3. Income Taxes

Income taxes have been accounted for using the liability method in accordance with ASC 740 Income Taxes . The Company computes its interim provision for income taxes by applying the estimated annual effective tax rate method. The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2015 as the Company incurred losses for the three and six month periods ended June 30, 2015 and is forecasting additional losses through the year, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2015. Due to the Company s history of losses, there is not sufficient evidence at this time to support the conclusion that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the net deferred tax assets have been reduced by a full valuation allowance. Therefore, no federal or state income taxes are expected and none have been recorded at this time.

The Company s effective tax rate for each of the six month periods ended June 30, 2015 and 2014 was 0%. At June 30, 2015, the Company had no unrecognized tax benefits that would affect the Company s effective tax rate.

4. Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options and warrants. In computing diluted net loss per share for the six months ended June 30, 2015 and 2014, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants would be anti-dilutive.

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

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

Restricted cash, consisting of a money market account used as collateral securing a letter of credit under the terms of the corporate office operating lease that commenced in 2010 and expired in April 2015, was $0 and $250,000 as of June 30, 2015 and December 31, 2014, respectively.

The Company held no investments at June 30, 2015 and December 31, 2014 as it sold all its investment securities during 2014. There were no realized gains or losses for the six months ended June 30, 2015 or 2014.

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

	June 30, 2015 (unaudited)	December 31, 2014
	(In thousands)	
Cash	$ 1,851	$ 1,511
Money market	69,261	33,255
Total cash and cash equivalents	71,112	34,766
Total restricted cash	$	$ 250
Total	$ 71,112	$ 35,016

6. Fair Value

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

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

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

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

The following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

	June 30, 2015 (In thousands) (unaudited)			
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total June 30, 2015
Assets measured at fair value				
Cash and Cash Equivalents	$ 71,112	$	$	$ 71,112
Total Assets measured at fair value	$ 71,112	$	$	$ 71,112

	December 31, 2014 (In thousands)			
Description	Quoted Prices in Active Markets for	Significant Other Observable Inputs	Significant Unobservable Inputs	Total December 31, 2014

	Identical Assets (Level 1)	(Level 2)	(Level 3)	
Assets measured at fair value				
Cash and Cash Equivalents	$ 34,766	$	$	$ 34,766
Restricted Cash	250			250
Total Assets measured at fair value	$ 35,016	$	$	$ 35,016

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7. Goodwill and Intangible Assets

The following table presents the carrying value of the components of goodwill and intangible assets at the balance sheet dates:

	June 30, 2015	December 31, 2014
	(In thousands)	
	(unaudited)	
Goodwill	$ 93,842	$ 93,842
Intangible assets:		
Intellectual property	5,000	5,000
Trade names	10	10
Amortization of intangible assets	(3,013)	(2,762)
Total intangible assets	$ 1,997	$ 2,248

8. Accrued Expenses

The following table presents the components of accrued expenses:

	June 30, 2015	December 31, 2014
	(In thousands)	
	(unaudited)	
Compensation and benefits	$ 1,174	$ 1,036
Legal and professional fees	289	145
Consulting and other vendors	271	208
Interest and final payment fee	269	131
Deferred rent	101	46
Taxes	54	189
Other	101	14
Total accrued expenses	$ 2,259	$ 1,769

9. Related-Person Transactions

Synecor, LLC and its shareholders and officers collectively owned approximately 7% and 9% of the Company s common stock at June 30, 2015 and 2014, respectively. Various research and development services are purchased from Synecor LLC and its wholly owned subsidiary Synchrony Labs LLC pursuant to arms length terms approved by

the Audit Committee and totaled approximately $431,000 and $15,000 for the six months ended June 30, 2015 and 2014, respectively.

10. Notes Payable

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

On September 26, 2014, the Company entered into the Amended and Restated Loan Agreement with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders agreed to make certain term loans (the Term Loans) in an aggregate principal amount of up to $25,000,000. The first tranche increased the Company s borrowings at September 26, 2014 from $5,604,000 to $10,000,000. Two additional tranches are to be made available as follows. The second tranche of $5,000,000 is available at any time prior to one year after the closing date as the Company filed a 510(k) application for its SurgiBot System, and completed an offering of its equity securities above $35 million. The third tranche of $10,000,000, will be made available to the Company at any time prior to two years after the closing date upon recognition of at least $10,000,000 of trailing six-month revenues from the SurgiBot System and SurgiBot-related products. The Company is entitled to make interest-only payments for 12 months from the closing date, which interest-only period is extended to 18 months if the Company receives 510(k) clearance for its SurgiBot System at any time before October 31, 2015. The maturity date of the Term Loans is April 1, 2018 without the interest-only extension and October 1, 2018 with the interest-only extension.

The Term Loans bear interest at a fixed rate equal to 7.50% per annum.

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11. Controlled Equity Offering and Public Offering of Common Stock

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

Subsequent to quarter-end on July 10, 2015, the underwriters exercised a portion of their option to acquire an additional 2,075,000 shares at the public offering price of $3.00 per share for aggregate additional gross proceeds of $6.2 million. Net proceeds after issuance costs were $5.8 million. The purchase of the option shares closed on July 15, 2015. Total proceeds (including the option) were $52.2 million, net of issuance costs of $4.0 million. The common stock was offered and sold pursuant to the Shelf Registration Statement filed in November 2014 (the November 2014 Shelf Registration Statement), which was declared effective on December 19, 2014. The November 2014 Shelf Registration Statement allowed the Company to raise up to $100.0 million through the sale of debt securities, common stock, preferred stock, warrants, or any combination thereof.

On February 20, 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which the Company can sell through Cantor, from time to time, up to $25 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The Company pays Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the Sales Agreement. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold.

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

	Six Months Ended June 30, 2015 (Unaudited)
Total shares of common stock sold	2,014.3
Average price per share	$ 3.25
Gross proceeds	$ 6,546
Commissions earned by Cantor	$ 197
Other issuance costs	$ 259

On April 14, 2014, the Company sold 12,500,000 shares of common stock at a public offering price of $4.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. Certain of the Company s existing stockholders that are affiliated with certain of the Company s directors purchased $10.0 million of common stock in the public offering. The closing of the public offering occurred on April 21, 2014. The Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of Common Stock to cover over-allotments. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of $4.00 per share for aggregate additional gross proceeds of $6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were $52.4 million, net of issuance costs of $4.0 million. The common stock was offered and sold

pursuant to the Shelf Registration Statement filed in January 2014 (the January 2014 Shelf Registration Statement), which was declared effective on April 2, 2014. The January 2014 Shelf Registration Statement allowed the Company to raise up to $100.0 million through the sale of debt securities, common stock, preferred stock, warrants, or any combination thereof.

12. Stock-Based Compensation

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

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

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

13. Closing of Merger and Financing Transaction

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

Pursuant to the Merger Agreement, each share of TransEnterix Surgical s capital stock issued and outstanding immediately preceding the Merger was converted into the right to receive 1.1533 shares of the Company s common stock, par value $0.001 per share, other than those shares of TransEnterix Surgical s common stock held by non-accredited investors, which shares were instead converted into the right to receive an amount in cash per share of SafeStitch common stock equal to $1.08, without interest, which was the volume-weighted average price of a share of common stock on the OTCBB for the 60-trading day period ended on August 30, 2013 (one business day prior to the effective date of the Merger). Upon the closing of the Merger, and in accordance with the terms of the Merger Agreement, the Company issued an aggregate of 21,109,949 shares of the Company s common stock as Merger consideration and paid $293,000 to unaccredited investors in lieu of common stock. Additionally, pursuant to the Merger Agreement, upon consummation of the Merger, the Company assumed all of TransEnterix Surgical s options, whether vested or unvested, and warrants issued and outstanding immediately prior to the Merger at the same Exchange Ratio.

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

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

approximately $100,000. Each share of Series B Preferred Stock was converted into two shares of our common stock, par value $0.001 per share, on December 6, 2013.

In connection with the Merger Agreement and the September 2013 private placement, certain of SafeStitch s and TransEnterix Surgical s former stockholders, comprising approximately 93% of our stock on the effective date of the Merger, entered into Lock-up and Voting Agreements, pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company s securities held by them (collectively, Covered Securities) for one year following the September 3, 2013 closing date (the Closing Date). The Lock-up and Voting Agreements provide that such persons may sell, transfer or convey: (i) up to 50% of their respective Covered Securities during the period commencing on the one-year anniversary of the Closing Date and ending on the eighteen-month anniversary of the Closing Date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on the eighteen-month anniversary of the Closing Date and ending on the two-year anniversary of the Closing Date. The restrictions on transfer contained in the Lock-up and Voting Agreements cease to apply to the Covered Securities following the second anniversary of the Closing Date.

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

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

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

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

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

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

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

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

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

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

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

14. Subsequent Events

There are no other subsequent events besides the public offering option exercise discussed in Note 11.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

We are a medical device company that is focused on the development and future commercialization of a robotic-assisted surgical system called the SurgiBot System (the SurgiBot System). The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. The flexible nature of the SurgiBot System allows for multiple instruments to be introduced and deployed through a single site, thereby offering room for visualization and manipulation once inside the body. The SurgiBot System also allows for three-dimensional (3-D) high definition vision technology. We have commercialized the SPIDER ® Surgical System, (the SPIDER System) a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilized flexible instruments and articulating channels that are controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single site. The SPIDER System was cleared by the U.S. Food and Drug Administration (FDA). We also manufactured multiple instruments that could be deployed using the SPIDER System, and which are being adapted for use with the SurgiBot System. In April 2014, we launched the Flex Ligating Shears (FLS) which is an advanced energy device used with the existing SPIDER Surgical System. The FLS device is designed to deliver controlled energy to effectively ligate and divide tissue. We intend to offer a similar device in the future for the SurgiBot System. We have chosen to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014 when we discontinued sales.

During the second quarter of 2014, we ceased internal development of the SafeStitch Gastroplasty Device and are currently evaluating strategic alternatives for the former SafeStitch products.

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

Our strategy is to focus our resources on the development and commercialization of the SurgiBot System. We are planning to make the product available, subject to our obtaining the requisite regulatory and government clearances. On June 1, 2015, we submitted our 510(k) application to the FDA for the SurgiBot System.

We believe that:

- there are a number of hospitals and an increasing number of ambulatory surgery centers in the U.S. and internationally that could benefit from the addition of robotic-assisted minimally invasive surgery at a lower cost of entry than existing robotic-assisted surgery systems;

surgeons can benefit from the ease of use, 3-D visualization and precision of robotic-assisted surgery while remaining patient-side within the sterile field, consistent with current laparoscopic surgery procedures; and

patients will continue to seek a minimally invasive option, offering minimal scarring and fewer incisions, for many common general abdominal surgeries.

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

Since inception, we have been unprofitable. As of June 30, 2015, we had an accumulated deficit of approximately $155.4 million.

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

We operate in one business segment.

Reverse Stock Split

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

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Public Offerings

On June 11, 2015, we sold 16,666,667 shares of common stock at a public offering price of $3.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. Net proceeds after issuance costs were $46.4 million. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,500,000 shares of common stock. The common stock was offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-199998) registering an aggregate of $100 million of our designated securities (the November 2014 Shelf Registration Statement). The November 2014 Shelf Registration Statement was declared effective by the SEC on December 19, 2014. The closing of the public offering occurred on June 17, 2015. Subsequent to quarter-end on July 10, 2015, the underwriters exercised a portion of their option and acquired an additional 2,075,000 shares at the public offering price of $3.00 per share for aggregate additional gross proceeds of $6.2 million. Net proceeds after issuance costs were $5.8 million. The purchase of the option shares closed on July 15, 2015. Total proceeds (including the option) were $52.2 million, net of issuance costs of $4.0 million.

On February 20, 2015, we entered into a Controlled Equity Offering[SM] Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which we can sell through Cantor, from time to time, up to $25 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to the November 2014 Shelf Registration Statement S-3 filed with the SEC (File No.333-199998). We pay Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the Sales Agreement. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold.

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

	Six Months Ended June 30, 2015 (Unaudited)
Total shares of common stock sold	2,014.3
Average price per share	$ 3.25
Gross proceeds	$ 6,546
Commissions earned by Cantor	$ 197
Other issuance costs	$ 259

On April 14, 2014, we sold 12,500,000 shares of common stock at a public offering price of $4.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of common stock to cover over-allotments. Certain of our existing stockholders that are affiliated with certain of our directors purchased $10 million of common stock in the public offering. The common stock was offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-193235) registering an aggregate of $100 million of our designated securities (the January 2014 Shelf Registration Statement). The January 2014 Shelf Registration Statement was declared effective by the SEC on April 2, 2014. The closing of the public offering occurred on April 21, 2014. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of $4.00 per share for aggregate additional gross proceeds of $6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were $52.4 million, net of issuance costs

of $4.0 million.

In connection with the public offering, our common stock was eligible to be listed on the NYSE MKT and began trading on such exchange on April 15, 2014.

Results of Operations

Our results of operations include the acquired SafeStitch operations from the Merger date, September 3, 2013, forward.

Revenue

We derived sales from the SPIDER System and other distributed products through limited direct sales in the United States and international distributors. We discontinued sales of the SPIDER System on December 31, 2014. The Company recorded revenue when persuasive evidence of an arrangement existed, delivery occurred which is typically at shipping point, the fee was fixed or determinable and collectability was reasonably assured. Shipping and handling costs billed to customers were included in revenue.

Cost of Goods Sold

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

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Research and Development

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

Sales and Marketing

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshows, marketing studies and consulting expenses. In 2015, we expect sales and marketing expenses to increase modestly as we begin the early stages of commercialization. We expect sales and marketing expenses to increase significantly in 2016 in support of our anticipated SurgiBot System product launch. We cannot assure you that the SurgiBot System will be cleared by the FDA, or that we will meet our anticipated product launch target in 2016.

General and Administrative

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

Other Expense, Net

Other expense is primarily composed of interest expense on notes payable.

Comparison of the Three Months Ended June 30, 2015 and 2014

Sales for the three months ended June 30, 2015 decreased to $0 compared to $113,000 for the three months ended June 30, 2014. The $113,000 decrease was primarily the result of our decision to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014. We discontinued sales of the SPIDER System on December 31, 2014.

Cost of goods sold for the three months ended June 30, 2015 decreased to $0 as compared to $238,000 for the three months ended June 30, 2014. The $238,000 decrease was primarily the result of discontinued sales of the SPIDER System on December 31, 2014.

R&D expenses for the three months ended June 30, 2015 decreased to $6.6 million as compared to $7.9 million for the three months ended June 30, 2014. The $1.3 million decrease resulted primarily from decreased supplies of $1.5 million, decreased personnel related expenses of $132,000, and decreased other expenses of $15,000 offset by increased contract engineering services, consulting and other outside services of $347,000 related primarily to product development of our SurgiBot System.

Sales and marketing expenses for the three months ended June 30, 2015 decreased to $373,000 compared to $461,000 for the three months ended June 30, 2014. The $88,000 decrease was primarily related to lower personnel-related costs of $23,000, decreased stock compensation costs of $23,000, decreased travel-related expenses of $17,000 and reduced expenditures for other marketing expenses of $25,000.

General and administrative expenses for the three months ended June 30, 2015 increased to $2.1 million compared to $1.9 million for the three months ended June 30, 2014. The $200,000 increase was primarily due to increased stock compensation costs of $139,000, increased consulting costs of $116,000, increased other costs of $64,000, offset by decreased public company costs of $119,000.

Interest expense for the three months ended June 30, 2015 increased to $280,000 compared to $206,000 for the three months ended June 30, 2014.

Comparison of the Six Months Ended June 30, 2015 and 2014

Sales for the six months ended June 30, 2015 decreased to $0 compared to $206,000 for the six months ended June 30, 2014. The $206,000 decrease was primarily the result of our decision to focus resources on the SurgiBot System development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System remained on the market for existing customers through December 31, 2014. We discontinued sales of the SPIDER System on December 31, 2014.

Cost of goods sold for the six months ended June 30, 2015 decreased to $0 as compared to $458,000 for the six months ended June 30, 2014. The $458,000 decrease was primarily the result of discontinued sales of the SPIDER System on December 31, 2014.

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R&D expenses for the six months ended June 30, 2015 increased to $14.1 million as compared to $12.9 million for the six months ended June 30, 2014. The $1.2 million increase resulted primarily from increased contract engineering services, consulting and other outside services of $1.2 million related primarily to product development of our SurgiBot System, increased costs of preclinical labs of $766,000, increased personnel related expenses of $258,000 as we increased the headcount, offset by decreased supplies expense of $1.0 million and decreased other expenses of $24,000.

Sales and marketing expenses for the six months ended June 30, 2015 decreased to $748,000 compared to $867,000 for the six months ended June 30, 2014. The $119,000 decrease was primarily related to lower personnel-related costs of $49,000, decreased travel-related expenses of $46,000 and reduced expenditures for other marketing expenses of $24,000.

General and administrative expenses for the six months ended June 30, 2015 increased to $4.1 million compared to $3.5 million for the six months ended June 30, 2014. The $600,000 increase was primarily due to increased stock compensation costs of $527,000, increased consulting costs of $213,000, increased other costs of $53,000, offset by decreased public company costs of $193,000.

Interest expense for the six months ended June 30, 2015 increased to $561,000 compared to $527,000 for the six months ended June 30, 2014.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception we have incurred significant losses and, as of June 30, 2015, we had an accumulated deficit of $155.4 million and have not generated significant revenue or positive cash flows from operations. We have not yet achieved profitability and we cannot assure investors that we will achieve profitability with our existing capital resources. We expect to continue to fund research and development, sales and marketing and general and administrative expenses at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash have been proceeds from public offerings of common stock, private placements of common and preferred stock, incurrence of debt and the sale of equity securities held as investments. We expect existing cash balances will be sufficient to fund our operations and satisfy our other anticipated cash requirements for at least the next 12 months.

In November 2014, we filed a Shelf Registration Statement with the SEC which was declared effective on December 19, 2014. The November 2014 Shelf Registration Statement allows us to raise up to $100.0 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof. In January 2014, we filed a Shelf Registration Statement with the SEC which was declared effective on April 2, 2014. The January 2014 Shelf Registration Statement allows us to raise up to $100.0 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof.

On June 11, 2015, we sold 16,666,667 shares of common stock at a public offering price of $3.00 per share for aggregate gross proceeds of $50 million in an underwritten firm commitment public offering. Net proceeds after issuance costs were $46.4 million. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,500,000 shares of common stock. The closing of the public offering occurred on June 17, 2015. Subsequent to quarter-end on July 10, 2015, the underwriters exercised a portion of their option to acquire an additional 2,075,000 shares at the public offering price of $3.00 per share for aggregate additional gross proceeds of $6.2 million. Net proceeds after issuance costs were $5.8 million. The purchase of the option shares closed on July 15,

2015. Total proceeds (including the option) from the offering were $52.2 million, net of issuance costs of $4.0 million. The common stock was offered and sold pursuant to the November 2014 Shelf Registration Statement.

On February 20, 2015, we entered into a Controlled Equity Offering SM Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which we can sell through Cantor, from time to time, up to $25 million in shares of common stock in an at-the-market offering. We pay Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the Sales Agreement. We sold 2,014,274 shares of common stock at an average price per share of $3.25. Net proceeds after issuance costs were $6.1 million. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. All sales of shares have been and will continue to be made pursuant to the effective November 2014 Shelf Registration Statement.

Following these offerings, including the option exercise, we had the ability to raise an additional $37.3 million from the November 2014 Shelf Registration Statement.

On April 14, 2014, we sold 12,500,000 shares of common stock at a public offering price of $4.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of common stock to cover over-allotments. Certain of our existing stockholders that are affiliated with certain of our directors purchased $10.0 million of common stock in the public offering. The closing of the public offering occurred on April 21, 2014. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of $4.00 per share for aggregate additional gross proceeds of $6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds from the offering were $52.4 million, net of issuance costs of $4.0 million. The common stock was offered and sold pursuant to the January 2014 Shelf Registration Statement.

As of June 30, 2015, we had the ability to raise an additional $43.6 million from the January 2014 Shelf Registration Statement.

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In connection with our public offering in April 2014, our common stock was eligible to be listed on the NYSE MKT and began trading on such exchange on April 15, 2014.

At June 30, 2015, we had cash and cash equivalents of approximately $71.1 million. Our cash and cash equivalents increased by approximately $36.3 million during the six months ended June 30, 2015, primarily as a result proceeds from the issuance of common stock, net of issuance costs, of $52.5 million, and proceeds from the exercise of options of $250,000, offset by net cash used in operating activities of $16.1 million, and purchases of property and equipment of $311,000.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was $16.1 million during the six months ended June 30, 2015. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation and amortization and stock-based compensation, plus the net change in operating assets and liabilities for the six months ended June 30, 2015, which consisted primarily of increases in accrued expenses and decreases in restricted cash, accounts payable, other current and long term assets, and accounts receivable.

Net Cash Provided by Investing Activities

Net cash used in investing activities was $311,000 during the six months ended June 30, 2015. This amount reflected cash paid for the purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2015 of $52.8 million was primarily related to proceeds from the issuance of common stock, net of issuance costs, of $52.5 million, and proceeds from the exercise of options of $250,000.

Operating Capital and Capital Expenditure Requirements

We expect existing cash balances will be sufficient to fund our operations and satisfy our other anticipated cash requirements for at least the next 12 months. Following the closing of the public offerings (including the option), we currently have the ability to raise an additional $80.9 million from the January 2014 and November 2014 Shelf Registration Statements. The timing and terms of any additional financing transactions, whether pursuant to the Shelf Registration Statements or otherwise, have not yet been determined. We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, debt financings and other funding transactions. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we may be required to reduce the scope of our planned product development and marketing efforts or may need to pursue a plan to license or sell our assets, or cease operations.

During August 2013, TransEnterix Surgical issued promissory notes (the Bridge Notes) in the aggregate principal amount of $2.0 million. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured

by any collateral and were subordinated in right of payment to the term loan evidenced by the loan and security agreement between TransEnterix Surgical, Inc. and Silicon Valley Bank and Oxford Finance LLC, as lenders (the Lenders). The Bridge Notes were converted into the Company s Series B Preferred Stock at the effective time of the Merger.

On September 3, 2013, we consummated a private placement (the Private Placement) transaction in which we issued and sold shares of our Series B Convertible Preferred Stock, par value $0.01 per share (the Series B Preferred Stock) to finance our operations following the merger. The Private Placement was done pursuant to a Securities Purchase Agreement (the Purchase Agreement) with accredited investors (the Investors), the majority of which were considered related parties as existing investors in SafeStitch and TransEnterix Surgical, pursuant to which the Investors agreed to purchase an aggregate of 7,544,704.4 shares of the Series B Preferred Stock, each share of which was convertible, subject to certain conditions, into two shares of common stock, for a purchase price of $4.00 per share of Series B Preferred Stock, which was paid in cash, cancellation of certain indebtedness of TransEnterix Surgical or a combination thereof. In accordance with the Purchase Agreement, we issued and sold an additional 25,000 shares of Series B Preferred Stock on September 17, 2013. Proceeds from the issuance of the Series B Preferred Stock, net of issuance costs, were $28.2 million.

In connection with the Merger, we assumed and became the borrower under TransEnterix Surgical s outstanding credit facility (the Original Loan Agreement). On September 26, 2014, we entered into an amended and restated loan and security agreement (the Amended and Restated Loan Agreement) with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders have agreed to make certain term loans (the Term Loans) in an aggregate principal amount of up to $25.0 million, with the first tranche adding to the outstanding principal amount of the existing term loan, which was $5.6 million, borrowed by the Company from the Lenders under the Original Loan Agreement, for an aggregate of $10.0 million in borrowings as of September 26, 2014. Two additional tranches are to be made available as follows. The second tranche of $5.0 million is available at any time prior to one year after the closing date as we filed a 510(k) application for the SurgiBot System, and completed an offering of equity securities above $35.0 million. The third tranche of $10.0 million, will be made available to us at any time prior to two years after the closing date upon recognition of at least $10.0 million of trailing six-month revenues from the SurgiBot System and SurgiBot-related products. We are entitled to make interest-only payments for 12 months from the closing date, which interest-only period is extended to 18 months if we receive 510(k) clearance for the SurgiBot system at any time before October 31, 2015. The maturity date of the Term Loans is April 1, 2018 without the interest-only extension and October 1, 2018 with the interest-only extension.

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The Term Loans bear interest at a fixed rate equal to 7.50% per annum, subject to adjustment at funding for subsequent tranches on an increase in LIBOR above a designated rate. The Term Loans will be required to be prepaid if the Term Loans are accelerated following an event of default. In addition, we are permitted to prepay the Term Loans in full at any time upon 10 days written notice to the Lenders. Upon the earliest to occur of the maturity date, acceleration of the term loans, or prepayment of Term Loans, we are required to make a final payment equal to 5.45% of the original principal amount of each Term Loan without the interest-only extension or 6.75% with the interest-only extension (the Final Payment Fee). Any prepayment, whether mandatory or voluntary, must include the Final Payment Fee, interest at the default rate (which is the rate otherwise applicable plus 5%) with respect to any amounts past due, and the Lenders expenses and all other obligations that are due and payable to the Lenders.

In connection with the entry into the Amended and Restated Loan Agreement, we became obligated to make a payment equal to the accrued portion of the 3.33% final payment fee due under the Original Amended Loan Agreement plus a facility fee payment of $75,000. In addition, in connection with the first tranche borrowings, we issued warrants to the Lenders to purchase shares of our common stock. Additional common stock warrants will be issued if additional tranche Term Loans are made under the Amended and Restated Loan Agreement. The warrants expire seven years from their respective issue date.

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

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth above under the headings Results of Operations and Liquidity and Capital Resources have been prepared in accordance with U.S. GAAP and should be read in conjunction with our consolidated financial statements and notes thereto appearing in the Annual Report on Form 10-K for the year ended December 31, 2014, filed by the Company with the SEC on February 20, 2015. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our critical accounting policies and estimates, including identifiable intangible assets and goodwill, stock-based compensation, and intellectual property and long-lived assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note 2 in the Notes to the Consolidated Financial Statements in the Annual Report on Form 10-K for the year ended December 31, 2014, filed by the Company with the SEC on February 20, 2015. Actual results may differ from these estimates under different assumptions and conditions.

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

Identifiable Intangible Assets and Goodwill

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

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

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Accounting for Stock-Based Compensation

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

Intellectual Property and Long-Lived Assets

Intellectual property consists of purchased patent rights. Amortization is recorded using the straight-line method over the estimated useful life of the patents of ten years. We review our long-lived assets including purchased intellectual property and property and equipment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine the recoverability of our long-lived assets, we evaluate the probability that future estimated undiscounted net cash flows will be less than the carrying amount of the assets. If such estimated cash flows are less than the carrying amount of the long-lived assets, then such assets are written down to their fair value. Our estimates of anticipated cash flows and the remaining estimated useful lives of long-lived assets could be reduced in the future, resulting in a reduction to the carrying amount of long-lived assets.

Recent Accounting Pronouncements

See Note 2. Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2014, filed by the Company with the SEC on February 20, 2015, for a full description of recent accounting pronouncements including the respective expected dates of adoption and effects on Consolidated Balance Sheets and Consolidated Statements of Operations and Comprehensive Loss.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2015. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required

disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our principal executive officer and principal financial officer concluded that, as of such a date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company s internal control over financial reporting during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

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We have a history of operating losses, and we may not be able to achieve or sustain profitability.

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. We continue to incur research and development and general and administrative expenses related to our operations. Our net loss for the six months ended June 30, 2015 was $19.5 million, and our accumulated deficit as of June 30, 2015 was $155.4 million. We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will be sufficient to meet our anticipated cash needs for at least the next 12 months.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products and product candidates. If our products fail in development or do not gain regulatory clearance or approval, or if our products do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that, if needed, we will seek capital from other sources, such as equity offerings. 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 beyond the next 12 months. We have filed shelf registration statements which have been declared effective by the Securities and Exchange Commission (SEC). Following the offerings, we currently have $80.9 million available for future financings. However, we cannot assure you that we will be successful in obtaining such additional financing on terms acceptable to the Company or at all.

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

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

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

- the costs of our SurgiBot System development activities;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals;
- 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 future clinical testing;

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

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

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

the effect of competing technological and market developments;

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

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

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

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

If we cannot achieve sufficient margins for our SurgiBot System, we may not be able to grow our revenues sufficiently to sustain our business.

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

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

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address minimally invasive and robotic-assisted surgery, including new entrants in the competitive market. We are currently developing and commercializing medical devices 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, Medtronic plc, Intuitive Surgical, Johnson & Johnson, and a number of minimally invasive surgical device, robotic surgical device manufacturers and providers of products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many other universities and private and public research institutions are or may become active in research involving surgical devices for minimally invasive and robotic-assisted surgery.

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

- the efficacy, safety and reliability of our products;

the speed at which we develop our products;

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

our ability to design and successfully execute appropriate clinical trials;

the cost of our products in relation to alternative devices;

the timing and scope of regulatory clearances or approvals;

whether our competitors substantially reduce the cost of ownership of an alternative device;

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

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

the availability of adequate coverage and reimbursement by third-party payors for the procedures in which our products are used;

the effectiveness of our sales and marketing efforts; and

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

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

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

We are party with the Lenders to, and jointly and severally liable with our subsidiaries for, $10.0 million of outstanding debt under a Term Loan under the Amended and Restated Loan Agreement. Under the Amended and Restated Loan Agreement, the maximum borrowing potential is up to $25.0 million. The Company is entitled to make interest-only payments for 12 months, until September 2015. The maturity date of the outstanding Term Loan is April 1, 2018. Our resulting substantial level of indebtedness and other financial obligations increase the possibility that we may be unable to pay, when due, the principal of, interest on, or other amounts due in respect of, our indebtedness.

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

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

Our product development activities could be delayed or stopped.

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

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

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

We are engaged in the research and development of minimally invasive surgical devices, robotic surgical devices, and medical devices 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, our products are prone to the risks of failure inherent in medical device product development. In particular, any of our products may fail to show desired efficacy and safety traits. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results at earlier points. The occurrence of any such events would have a material adverse effect on our business.

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

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

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

In the future, we may need to conduct clinical trials to support approval of new products, and any future clinical trial activities that we undertake will be subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies intended to support a 510(k) or Premarket Approval (PMA) must be conducted in compliance with the FDA s Good Clinical Practice regulations and similar requirements in foreign jurisdictions. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and Notified Bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of associated product submissions and, ultimately, our ability to commercialize products requiring submission of clinical data. It is also possible that patients enrolled in a clinical trial will experience adverse side effects that are not currently part of the product candidate s safety profile, which could cause us to delay or abandon development of such product.

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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.

The product development and design, testing, manufacturing, labeling, approval, clearance, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our products in the United States until we receive a clearance letter under the 510(k) process or approval of a PMA from the FDA, depending on the nature of the device. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews a premarket notification in 90 days, there is no guarantee that our future products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, even if a device is reviewed under the 510(k) premarket notification process, that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. In the past the Company has been successful in receiving 510(k) clearance within the 90 day review period, but it can take longer (six to eighteen months) to obtain 510(k) clearance for a Class II device. If the FDA fails to provide clearance for a product candidate, such as the SurgiBot System, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product.

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

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

other non-U.S. regulatory authorities may not approve our processes or facilities or those of any of our third-party manufacturers, thereby restricting export; or

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

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

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

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

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

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

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters, non-warning letters incorporating inspectional observations;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory clearances or approvals;

total or partial suspension of production;

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

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

import and export restrictions.

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

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

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

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

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

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

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

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

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

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

The FDA and similar foreign governmental authorities such as the competent authorities of the EEA countries have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their

own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

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

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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

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

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

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

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

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

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

Most significantly, in March 2010, President Obama signed into law both the Patient Protection and Affordable Care Act (the Affordable Care Act) and the reconciliation law known as Health Care and Education Reconciliation Act (the Reconciliation Act , and, with the Affordable Care Act, the 2010 Health Care Reform Legislation). The Supreme Court of the United States upheld fundamental aspects of the 2010 Health Care Reform Legislation in June 2012 and again

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

Beyond coverage and reimbursement changes, the 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. Although there are current bills in Congress to repeal this excise tax, it remains current law. This excise tax will likely increase our expenses in the future.

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

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

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

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

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

timing of market introduction of competitive products;

safety and efficacy of our products;

physician training in the use of our products;

prevalence and severity of any side effects;

potential advantages or disadvantages over alternative treatments;

strength of marketing and distribution support; and

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

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

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

We will need to effectively manage our managerial, operational, financial, development, marketing and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future products. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our senior management, particularly Todd M. Pope 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.

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

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

We previously operated manufacturing facilities for production of the SPIDER System and maintained manufacturing facilities for the AMID HFD product (both products were discontinued in 2014). In the future, we may choose to use a third-party manufacturer for our other products. In addition, certain product component parts are likely to 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.

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

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

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

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

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

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

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

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. In the United States, we have 6 issued patents and over 30 pending patent applications. Many of these relate to the SPIDER System, the SurgiBot System, instruments useful with those systems, or alternatives to those systems. We have also filed patent applications abroad for both the Spider System and the SurgiBot System. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

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

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

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

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

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

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

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

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

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

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

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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 June 30, 2015, the net carrying value of our goodwill and other intangible assets totaled approximately $93.8 million, which was 55% of total assets. In accordance with generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

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

As a result of the Merger, we issued new shares of common stock to certain former TransEnterix Surgical stockholders, representing approximately 65% of the total outstanding voting power of all our stockholders immediately following the closing of the Merger. The issuance of these shares caused existing stockholders at the time of the Merger to experience immediate and significant dilution in their percentage ownership of our outstanding common stock. In addition, the private placement issuance of our Series B Preferred Stock in September 2013 caused substantial dilution to our stockholders, as each share of Series B Preferred Stock was converted into ten shares of our common stock on December 6, 2013, and our stockholders experienced additional dilution in our April 2014 common stock public offering, our February to May 2015 at-the-market offerings and our June 2015 common stock public offering. Collectively in such offerings we raised approximately $119 million.

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

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

During the two year period ended June 30, 2015, the market price of our common stock fluctuated from a high of $14.00 per share to a low of $0.36 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;

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

developments in the medical device industry;

the results of product liability or intellectual property lawsuits;

future issuances of common stock or other securities;

the addition or departure of key personnel;

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

general market conditions and other factors, including factors unrelated to our operating performance.

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

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

Trading of our common stock is currently conducted on the NYSE MKT. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts and the media s coverage of us, if at all. As of June 30, 2015, approximately 37% of the issued and outstanding shares of our common stock were held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

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

As of June 30, 2015, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 37% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

In connection with the Merger, we entered into a voting and lock-up agreement with certain of our stockholders pursuant to which such stockholders agreed to vote to approve certain corporate actions following the Merger.

In connection with the Merger and the related private placement transaction, stockholders holding an aggregate of 93% of our common stock on the effective date of the Merger, and members of our Board of Directors, entered into lock-up and voting agreements (each, a Voting Agreement), pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company s securities held by them (collectively, Covered Securities) for designated periods following the Merger closing date. As of June 30, 2015, 25% of the Covered Securities remain subject to the lock-up until September 3, 2015, the second anniversary of the Merger closing date. In accordance with a Registration Rights Agreement dated September 3, 2013, we registered, for the account of such holders the Covered Securities that were released from the transfer restrictions of the Voting Agreement on September 3, 2014 and will be obligated to register the remainder in September 2015. Sales of our common stock by such selling stockholders could have a negative impact on the trading price of our common stock and increase the volatility of our common stock trading price.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

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Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Description
10.1	Underwriting Agreement, dated June 11,2 015, by and between the Registrant and Stifel, Nicolaus & Company, Incorporated and RBC Capital Markets, LLC (incorporated by reference to Exhibit 1.1 to the Registrant s Current Report on Form 8-K filed with the SEC on June 12, 2015).
10.2	TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, effective as of May 7, 2015 (incorporated by reference from Exhibit 10.1. to the Company s Registration Statement on Form S-8, File No. 333-203950 filed with the Securities and Exchange Commission on May 7, 2015).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)*
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TransEnterix, Inc.

Date: August 6, 2015

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

Date: August 6, 2015

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