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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC. 20549

FORM 10-Q

(Mark One)

☒ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**

for the Quarterly Period ended September 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 ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	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 ☒

100,142,684 shares of the Company's common stock, par value $0.001 per share, were outstanding as of November 2, 2015.

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," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should" or "will" or the negative of these terms or other comparable 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," "Notes to Consolidated Financial Statements" and "Risk Factors" 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 its direct and indirect subsidiaries, and the combined enterprise of SafeStitch Medical, Inc. and TransEnterix Surgical, Inc.

TransEnterix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Sales	$ —	$ 61	$ —	$ 267
Operating Expenses				
Cost of goods sold	—	202	—	660
Research and development	7,048	9,067	21,111	21,960
Sales and marketing	413	456	1,161	1,323
General and administrative	1,762	1,481	5,607	4,757
Amortization of intangible assets	338	125	589	376
Acquisition related costs	4,003	—	4,003	—
Total Operating Expenses	13,564	11,331	32,471	29,076
Operating Loss	(13,564)	(11,270)	(32,471)	(28,809)
Other Expense				
Interest Expense, net	(436)	(237)	(997)	(764)
Total Other Expense, net	(436)	(237)	(997)	(764)
Loss before income taxes	(14,000)	(11,507)	(33,468)	(29,573)
Income tax benefit	99	—	99	—
Net loss	$(13,901)	$(11,507)	$(33,369)	$(29,573)
Other comprehensive loss				
Foreign currency translation loss	(429)	—	(429)	—
Comprehensive loss	$(14,330)	$(11,507)	$(33,798)	$(29,573)
Net loss per share - basic and diluted	$ (0.16)	$ (0.18)	$ (0.46)	$ (0.52)
Weighted average common shares outstanding - basic and diluted	86,044	63,068	72,713	57,212

See accompanying notes to consolidated financial statements.

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

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 52,893	$ 34,766
Accounts receivable, net	78	133
Inventories	3,435	—
Interest receivable	6	1
Other current assets	5,450	740
Total Current Assets	61,862	35,640
Restricted cash	—	250
Property and equipment, net	4,388	3,120
Intellectual property, net	63,866	2,241
Trade names, net	6	7
In-process research and development	22,197	—
Goodwill	116,054	93,842
Other long term assets	59	11
Total Assets	$ 268,432	$ 135,111
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 4,394	$ 1,768
Accrued expenses	6,160	1,769
Notes payable - current portion	4,780	610
Total Current Liabilities	15,334	4,147
Long Term Liabilities		
Contingent consideration	24,300	—
Long-term deferred tax liabilities	21,218	—
Notes payable - less current portion, net of debt discount	14,884	9,175
Total Liabilities	75,736	13,322
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at September 30, 2015 and December 31, 2014; 100,103,989 and 63,182,806 shares issued at September 30, 2015 and December 31, 2014, respectively; and 100,102,816 and 63,182,806 shares outstanding at September 30, 2015 and December 31, 2014, respectively	100	63
Additional paid-in capital	362,313	257,642
Accumulated deficit	(169,285)	(135,916)
Treasury stock at cost, 1,173 and 0 shares at September 30, 2015 and December 31, 2014, respectively	(3)	—
Accumulated other comprehensive loss	(429)	—
Total Stockholders' Equity	192,696	121,789
Total Liabilities and Stockholders' Equity	$ 268,432	$ 135,111

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands)
(Unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Number of shares	Par value	Number of shares	Amount				
Balance, December 31, 2014	63,183	$ 63	—	$ —	$257,642	$ (135,916)	$ —	$ 121,789
Stock-based compensation	—	—	—	—	2,388	—	—	2,388
Issuance of common stock, net of issuance costs	20,756	21	—	—	58,274	—	—	58,295
Issuance of common stock, acquisition	15,543	15	—	—	43,662	—	—	43,677
Exercise of stock options and restricted stock	622	1	—	—	251	—	—	252
Return of common stock to pay withholding taxes on restricted stock	(1)	—	1	(3)	—	—	—	(3)
Issuance of warrants	—	—	—	—	96	—	—	96
Other comprehensive loss	—	—	—	—	—	—	(429)	(429)
Net loss	—	—	—	—	—	(33,369)	—	(33,369)
Balance, September 30, 2015	100,103	$100	1	$ (3)	$362,313	$ (169,285)	$ (429)	$ 192,696

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30, 2015	2014
Operating Activities		
Net loss	$(33,369)	$(29,573)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	1,391	936
Amortization of debt discount and debt issuance costs	89	57
Stock-based compensation	2,388	2,018
Loss on disposal of property and equipment	34	5
Deferred tax benefit	(99)	—
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	133	150
Interest receivable	(5)	68
Inventories	(250)	434
Other current and long term assets	(248)	(241)
Restricted cash	250	125
Accounts payable	984	1,461
Accrued expenses	4,127	350
Net cash and cash equivalents used in operating activities	(24,575)	(24,210)
Investing Activities		
Proceeds from sale and maturities of investments	—	6,191
Proceeds from sale of property and equipment	—	25
Payments for acquisition	(25,000)	—
Purchase of property and equipment	(728)	(1,626)
Net cash and cash equivalents (used in) provided by investing activities	(25,728)	4,590
Financing Activities		
Payment of debt	—	(2,877)
Proceeds from issuance of common stock, net of issuance costs	58,295	52,433
Proceeds from issuance of debt, net of debt discount	9,886	4,321
Taxes paid related to net share settlement of vesting of restricted stock units	(3)	—
Proceeds from exercise of stock options and warrants	252	73
Net cash and cash equivalents provided by financing activities	68,430	53,950
Effect of exchange rate changes on cash and cash equivalents	—	—
Net increase in cash and cash equivalents	18,127	34,330
Cash and Cash Equivalents, beginning of period	34,766	10,014
Cash and Cash Equivalents, end of period	$ 52,893	$ 44,344
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 598	$ 518
Supplemental Schedule of Noncash Investing and Financing Activities		
Issuance of common stock warrants	$ 96	$ 54
Contingent consideration related to acquisition	$ 24,300	$ —
Issuance of common stock related to acquisition	$ 43,677	$ —

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Notes to Financial Statements

1. Organization and Capitalization

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

The SurgiBot System 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 high definition ("3DHD") vision technology.

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

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

On September 18, 2015, the Company entered into a Membership Interest Purchase Agreement, (the "Purchase Agreement") with SOFAR S.p.A., ("SOFAR") as seller, Vulcanos S.r.l. ("Vulcanos"), as the acquired company, and TransEnterix International, Inc. ("TransEnterix International"), a direct, wholly owned subsidiary of the Company which was incorporated in September 2015, as buyer. The closing of the transactions occurred on September 21, 2015 (the "Closing Date") pursuant to which the Company acquired all of the membership interests of Vulcanos from SOFAR (the "ALF-X Acquisition"), and changed the name of Vulcanos to TransEnterix Italia S.r.l ("TransEnterix Italia"). The acquisition included all of the assets, employees and contracts related to the ALF-X System. See Note 5 for a description of the related transactions.

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

The Company operates in one business segment.

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

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.

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.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has accumulated a deficit of approximately $169.3 million as of September 30, 2015, a net loss of approximately $33.4 million for the nine months ended September 30, 2015, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

Consolidation

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

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.

Inventories

Inventories are stated at the lower of cost or market. Cost is based on the first in, first out method. The Company records reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Identifiable Intangible Assets and Goodwill

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 7 to 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed at September 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 September 30, 2015 or December 31, 2014.

In-Process Research and Development

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

Contingent Consideration

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

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.

Translation of Foreign Currencies

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

The Company's intercompany accounts are denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany receivables that the Company considers to be of a long-term investment nature are recorded as a cumulative translation adjustment in accumulated other comprehensive income or loss as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany receivables from a foreign subsidiary for which the Company anticipates settlement in the foreseeable future are recorded in the consolidated statement of operations. The net gains and losses recorded in the consolidated statements of operations for the three and nine months ended September 30, 2015 were not significant.

Business Acquisitions

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

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

Impact of Recently Issued Accounting Standards

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

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

Reclassifications

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

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

3. 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 2.85% for the year ending December 31, 2015. The Company incurred losses for the three and nine month periods ended September 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 to record a net deferred tax asset associated with the U.S. operations, accordingly. A full valuation allowance has been recorded related to the net deferred tax asset in that jurisdiction. Deferred tax assets and liabilities related to the TransEnterix Italia subsidiary have been recorded on a preliminary basis as a component of purchase accounting as of the acquisition date. The Company is recording an income tax benefit for the quarter ended September 30, 2015 in the amount of $99,000 in connection with the Italian taxing jurisdiction. There is no net deferred tax asset recorded in relation to TransEnterix Italia and accordingly no valuation allowance has been recorded in that jurisdiction.

The Company's effective tax rate for each of the nine month periods ended September 30, 2015 and 2014 was 0.297% and 0%, respectively. At September 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 three and nine months ended September 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. Acquisition of ALF-X Surgical Robotic System

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

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of 15,543,413 shares of the Company's common stock (the "Securities Consideration") and approximately $25 million U.S. Dollars and €27.5 million Euro in cash consideration (the "Cash Consideration"). The Securities Consideration was issued in full at the closing of the ALF-X Acquisition; the Cash Consideration was or will be paid in four tranches, as follows:

(1) $25 million of the Cash Consideration was paid at closing;

(2) The second tranche of the Cash Consideration (the "Second Tranche") of €10 million shall be payable after the achievement of both of the following milestones (i) the earlier of approval from the FDA for the ALF-X System or December 31, 2016, and (ii) the Company having cash on hand of at least $50 million, or successfully completing a financing, raising at least $50 million in gross proceeds; with payment of simple interest at a rate of 9.0% per annum between the achievement of the first milestone event and the payment date;

(3) The third tranche of the Cash Consideration (the "Third Tranche") of €15 million shall be payable upon achievement of trailing revenues from sales or services contracts of the ALF-X System of at least €25 million over a calendar quarter; and

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

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

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

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

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

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

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

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

Common shares issued	15,543
Closing price per share	$ 2.81
	$43,677
Cash consideration	25,000
Contingent consideration	24,300
Total consideration	$92,977

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

Accounts receivable	$ 78
Inventories	3,200
Current deferred tax asset	351
Other current assets	4,180
Property and equipment	1,384
Intellectual property	62,500
In-process research and development	22,300
Goodwill	22,315
Total assets acquired	$116,308
Accounts payable and other liabilities	1,915
Long-term deferred tax liabilities	21,416
Net assets acquired	$ 92,977

The Company allocated $62.5 million of the preliminary purchase price to identifiable intangible assets of intellectual property that met the separability and contractual legal criterion of ASC 805. The intellectual property will be amortized using the straight-line method over 7 years.

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

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

All legal, consulting and other costs related to the acquisition, aggregating approximately $4.0 million, have been expensed as incurred and are included in operating expenses in the Company's consolidated statements of operations. The results of operations for TransEnterix Italia are included in the Company's consolidated statements of operations for the period from the September 21, 2015 acquisition date to September 30, 2015. The Company has no revenues and incurred $262,000 in net losses from September 21, 2015 through September 30, 2015 associated with the operations of TransEnterix Italia.

The following unaudited pro forma information presents the combined results of operations for the three and nine months ended September 30, 2015 and 2014, as if we had completed the ALF-X Acquisitions at the beginning of fiscal 2014. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma consolidated financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs and amortization of intellectual property.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Revenue	$ 77	$ 61	$ 77	$ 267
Net loss	12,597	14,575	38,058	38,869
Net loss per share	$ 0.13	$ 0.19	$ 0.43	$ 0.53

6. 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 September 30, 2015 and December 31, 2014, respectively.

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

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

	September 30, 2015 (In thousands) (unaudited)
Cash	$ 874
Money market	52,019
Total cash and cash equivalents	52,893
Total restricted cash	$ —
Total	$ 52,893

7. Fair Value

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

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

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

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

The carrying values of accounts receivable, inventories, interest receivable, accounts payable, and certain accrued expenses at September 30, 2015 and December 31, 2014, approximate their fair values due to the short-term nature of these items. The Company's notes payable balance also approximates fair value as of September 30, 2015 and December 31, 2014.

The following are the major categories of assets measured at fair value on a recurring basis as of September 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):

	September 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 September 30, 2015
Assets measured at fair value				
Cash and Cash Equivalents	$ 52,893	$ —	$ —	$ 52,893
Total Assets measured at fair value	$ 52,893	$ —	$ —	$ 52,893
Liabilities measured at fair value				
Contingent consideration	$ —	$ —	$ 24,300	$ 24,300
Total liabilities measured at fair value	$ —	$ —	$ 24,300	$ 24,300

	December 31, 2014 (In thousands)			
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total December 31, 2014
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

The Company's financial liabilities consisted of contingent consideration potentially payable to SOFAR related to the ALF-X acquisition in September 2015 (Note 5). This liability is reported as Level 3 as estimated fair value of the contingent consideration related to the acquisition requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome. There was no change in the fair value of the contingent consideration from September 21, 2015, the date of the ALF-X Acquisition, to September 30, 2015.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 as of September 30, 2015:

	Fair Value at September 30, 2015 (In thousands)		Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	$ 24,300	Probability weighted income approach	Milestone dates	2016 to 2017
			Discount rate	7.5% to 9.0%
			Probability of occurrence	100%

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the nine months ended September 30, 2015:

	September 30, 2015 (In thousands) (unaudited)
Beginning balance	$ —
Additions	24,300
Change in fair value	—
Ending balance	$ 24,300

8. Inventories

The components of inventories are as follows:

	September 30, 2015 (In thousands) (unaudited)
Finished goods	$ 3,185
Raw materials	250
Ending balance	$ 3,435

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

Goodwill

Goodwill has been recorded in connection with the Merger, as discussed in Note 15, and the ALF-X Acquisition, as discussed in Note 5. The carrying value of goodwill and the change in the balance for the nine months ended September 30, 2015 is as follows:

	September 30, 2015 (In thousands) (unaudited)
Beginning balance	$ 93,842
Additions	22,315
Foreign currency translation impact	(103)
Ending balance	$ 116,054

The Company has no accumulated impairment losses on goodwill.

In-Process Research and Development

As described in Note 5, on September 21, 2015, the Company acquired all of the assets related to the ALF-X System and recorded $22.3 million of IPR&D. The estimated fair value of the IPR&D was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 50% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The carrying value of the Company's IPR&D assets and the change in the balance for the nine months ended September 30, 2015 is as follows:

	September 30, 2015 (In thousands) (unaudited)
Beginning balance	$ —
Additions	22,300
Foreign currency translation impact	(103)
Ending balance	$ 22,197

Intellectual Property

As described in Note 5, on September 21, 2015, the Company acquired all of the assets related to the ALF-X System and recorded $62.5 million of intellectual property. The estimated fair value of the intellectual property was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 45% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The carrying value of the Company's intellectual property and the change in the balance for the nine months ended September 30, 2015 is as follows:

	September 30, 2015 (In thousands) (unaudited)
Beginning balance	$ 5,000
Additions	62,500
Foreign currency translation impact	(286)
Ending balance	67,214
Amortization of intellectual property	(3,348)
Total intellectual property	$ 63,866

10. Accrued Expenses

The following table presents the components of accrued expenses:

	September 30, 2015 (In thousands) (unaudited)	December 31, 2014
Taxes and other assessments	$ 3,023	$ 189
Compensation and benefits	1,713	1,036
Legal and professional fees	594	145
Consulting and other vendors	324	208
Interest and final payment fee	220	131
Deferred rent	230	46
Other	56	14
Total accrued expenses	$ 6,160	$ 1,769

11. Related-Person Transactions

Synecor, LLC and its shareholders and officers collectively owned approximately 6% and 9% of the Company's common stock at September 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 $434,000 and $15,000 for the nine months ended September 30, 2015 and 2014, respectively.

12. Notes Payable

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

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

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

On September 18, 2015, in connection with entry into the Purchase Agreement with SOFAR S.p.A. (see Note 5 for a description of the related transactions), the Company and the Lenders entered into the Consent and Second Amendment to Amended and Restated Loan Agreement (the "Second Amendment"). The Second Amendment modified the period in which the Company can make interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The interest-only period could be extended to July 1, 2016 if the Company completes an offering of its equity securities above $40,000,000 prior to January 31, 2016. The interest-only period could be further extended to January 1, 2017 upon obtaining 510(k) clearance from the FDA on its SurgiBot System by June 30, 2016. The Second Amendment has a maturity date of July 1, 2018 without the interest-only extensions, December 1, 2018 with the first interest-only extension, and June 1, 2019 with both interest-only extensions.

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

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

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

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

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

In accordance with ASC 470-50 Debt – *Modifications and Extinguishments*, it was determined that the debt refinancings on August 14, 2015 and September 18, 2015 were considered to be debt modifications. Additionally, during the third quarter of 2015, the Company adopted ASU No. 2015-03, "Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs". ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. Accordingly, the Company reclassified its previously recorded net debt issuance costs to a debt discount liability and recorded approximately $210,000 of additional debt discount, consisting of the $90,000 facility fee, the relative fair value of warrants on the issue date of approximately $97,000 and approximate legal fees of $23,000, for these two amendments. In accordance with ASU 2015-03, this adopted guidance was applied retrospectively. The December 31, 2014 balance sheet was adjusted by reducing Other current assets by $49,000, Other long term assets by $51,000, and the Notes payable- less current portion, net of debt discount by $100,000. The debt discount will be amortized over the life of the new debt agreement using the effective interest method into Interest expense, net.

As of September 30, 2015 future principal payments under the Company's notes payable agreements are as follows:

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

13. Warrants

On August 14, 2015, in connection with the First Amendment and the first tranche borrowings, the Company issued 112,903 common stock warrants to the Lenders to purchase shares of the Company's common stock, with an exercise price of $3.10 per share. Additional common stock warrants will be issued if additional tranche term loans are made under the Amended and Restated Loan Agreement, as amended. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and will be amortized using the effective interest method from issuance to the maturity of the note. None of these warrants were exercised during the nine months ended September 30, 2015.

14. Controlled Equity Offering and Public Offering of Common Stock

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

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

On February 20, 2015, the Company entered into a Controlled Equity Offering℠ 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 $25.0 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The Company pays Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the Sales Agreement. Unless otherwise terminated earlier, the 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):

	Nine Months Ended September 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.

15. Closing of 2013 Merger and Financing Transaction

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

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

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

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

In connection with the Merger Agreement and the September 2013 private placement, certain of SafeStitch's and TransEnterix Surgical's former stockholders, comprising approximately 93% of our stock on the effective date of the Merger, entered into Lock-up and Voting Agreements, pursuant to which such persons agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Company's securities held by them (collectively, "Covered Securities") for one year following the September 3, 2013 closing date (the "Merger Closing Date"). The Lock-up and Voting Agreements provide that such persons may sell, transfer or convey: (i) up to 50% of their respective Covered Securities during the period commencing on the one-year anniversary of the Merger Closing Date and ending on the eighteen-month anniversary of the Merger Closing Date; and (ii) up to an aggregate of 75% of their respective Covered Securities during the period commencing on the eighteen-month anniversary of the Merger Closing Date and ending on the two-year anniversary of the Merger Closing Date. The restrictions on transfer contained in the Lock-up and Voting Agreements ceased to apply to the Covered Securities on September 3, 2015.

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

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

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

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

Common shares outstanding at the date of Merger	12,350
Closing price per share	$ 7.60
	$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.

16. Commitments and Contingencies

Contingent Consideration

As discussed in Note 5, in September 2015, the Company completed the ALF-X Acquisition using a combination of cash, stock and potential post-acquisition milestone payments. These milestone payments may be payable in the future, depending on the achievement of certain regulatory and commercial milestones. The maximum amount of the aggregate milestone payments could be €27.5 million. As of September 30, 2015, the fair value of the contingent consideration was $24.3 million.

License and Supply Agreements

As discussed in Note 5, in September 2015, the Company completed the ALF-X Acquisition. As part of this transaction, the Company assumed certain license and supply agreements. Commitments under these agreements amount to approximately $250,000 in 2015, $850,000 in 2016, $950,000 in 2017, $675,000 in 2018 and $3.4 million thereafter until termination in 2027.

17. Segment and Enterprise Wide Disclosures

The Company operates in one business segment—the research, development and sale of medical device robotics to improve minimally invasive surgery. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 57% of the Company's total consolidated assets are located within the U.S. as of September 30, 2015. The remaining assets are mostly located in Europe and are primarily related to the Company's ALF-X facility in Italy, and include goodwill, intellectual property, in-process research and development and inventory of $115.6 million at September 30, 2015, associated with the ALF-X Acquisition in September 2015. Total assets outside of the U.S. excluding goodwill amounted to 35% of total consolidated assets at September 30, 2015. There were no international sales (sales outside the U.S.) during the nine months ended September 30, 2015 and 2014, respectively.

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 pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical challenges associated with current laparoscopic and robotic options. The company is focused on the development and commercialization of the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform, and the commercialization of ALF-X® Surgical Robotic System ("ALF-X System"), a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology. The SurgiBot System has been submitted for clearance to the FDA, and is not yet available for sale in any market. The ALF-X System has been granted a CE Mark in Europe for use in Urology, General Surgery, Gynecology and Thoracic Surgery, but is not available for sale in the U.S.

The SurgiBot System 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 high definition ("3DHD") vision technology.

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

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

Our strategy is to focus our resources on the development and commercialization of the SurgiBot System, and the commercialization the ALF-X System. On June 1, 2015, we submitted our 510(k) application to the FDA for the SurgiBot System.

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 September 30, 2015, we had an accumulated deficit of approximately $169.3 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.

Recent Events - Acquisition of ALF-X Surgical Robotic System

On September 18, 2015, we entered into a Membership Interest Purchase Agreement, (the "Purchase Agreement") with SOFAR S.p.A., ("SOFAR"), Vulcanos S.r.l. ("Vulcanos"), as the acquired company, and TransEnterix International, Inc. ("TransEnterix International"), a wholly owned subsidiary of the Company, as the buyer. The closing of the transactions occurred on September 21, 2015 (the "Closing Date") pursuant to which we acquired all of the membership interests of Vulcanos from SOFAR, and changed the name of Vulcanos to TransEnterix Italia S.r.l ("TransEnterix Italia"). The acquisition included all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery known as the ALF-X System.

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of 15,543,413 shares of our common stock (the "Securities Consideration") and approximately $25 million U.S. Dollars and €27.5 million Euro in cash consideration (the "Cash Consideration"). The Securities Consideration was issued in full at the closing of the ALF-X Acquisition; the Cash Consideration was or will be paid in four tranches, as follows:

(1) $25 million of the Cash Consideration was paid at closing;

(2) The second tranche of the Cash Consideration (the "Second Tranche") of €10 million shall be payable after the achievement of both of the following milestones (i) the earlier of approval from the FDA for the ALF-X System or December 31, 2016, and (ii) the Company having cash on hand of at least $50 million, or successfully completing a financing, raising at least $50 million in gross proceeds; with payment of simple interest at a rate of 9.0% per annum between the achievement of the first milestone event and the payment date;

(3) The third tranche of the Cash Consideration (the "Third Tranche") of €15 million shall be payable upon achievement of trailing revenues from sales or services contracts of the ALF-X System of at least €25 million over a calendar quarter; and

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

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

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

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

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

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

Reverse Stock Split

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

Public 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. 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. 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):

	Nine Months Ended September 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 this 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 and the results of TransEnterix Italia from the acquisition date of September 21, 2015, forward.

Revenue

We derived sales in the past from our manual 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. We anticipate initiating our first commercial sale of the ALF-X System in Europe in the first quarter of 2016, and the first commercial sale of the SurgiBot system in the second quarter of 2016. However, 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, the ALF-X System or any of our other products will be successfully commercialized.

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. As we transition to the commercial phase, our cost of goods sold will include under-absorbed overhead in advance of our first commercial sales.

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 ALF-X System and 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 ALF-X System and SurgiBot System commercialization. We cannot assure you that the SurgiBot System will be cleared by the FDA, or that we will meet our anticipated product launch targets 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, and general corporate expenses. In future periods, we expect general and administrative expenses to increase to support our sales, marketing, research and development efforts.

Acquisition Related Costs

Acquisition related costs are primarily composed of legal, accounting, filing, registration tax and other professional fees related to the acquisition.

Other Expense, Net

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

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

Sales for the three months ended September 30, 2015 decreased to $0 compared to $61,000 for the three months ended September 30, 2014. The $61,000 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 September 30, 2015 decreased to $0 as compared to $202,000 for the three months ended September 30, 2014. The $202,000 decrease was primarily the result of discontinued sales of the SPIDER System on December 31, 2014.

R&D expenses for the three months ended September 30, 2015 decreased to $7.1 million as compared to $9.1 million for the three months ended September 30, 2014. The $2.0 million decrease resulted primarily from decreased contract engineering services, consulting and other outside services of $1.4 million related primarily to product development of our SurgiBot System and decreased supplies of $0.6 million.

Sales and marketing expenses for the three months ended September 30, 2015 decreased to $413,000 compared to $456,000 for the three months ended September 30, 2014. The $43,000 decrease was primarily related to lower stock compensation costs of $18,000 and reduced expenditures for other marketing expenses of $25,000.

General and administrative expenses for the three months ended September 30, 2015 increased to $1.8 million compared to $1.5 million for the three months ended September 30, 2014. The $0.3 million increase was primarily due to increased personnel related expenses of $0.2 million, increased stock compensation costs of $0.1 million, increased other costs of $0.1 million, offset by decreased consulting costs of $0.1 million.

In connection with the acquisition of the ALF-X System, we incurred $4.0 million in acquisition-related expenses in 2015.

Interest expense for the three months ended September 30, 2015 increased to $436,000 compared to $237,000 for the three months ended September 30, 2014 as a result of additional term loans of $4.4 million in September 2014 and $10 million in August 2015.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Sales for the nine months ended September 30, 2015 decreased to $0 compared to $267,000 for the nine months ended September 30, 2014. The $267,000 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 nine months ended September 30, 2015 decreased to $0 as compared to $660,000 for the nine months ended September 30, 2014. The $660,000 decrease was primarily the result of discontinued sales of the SPIDER System on December 31, 2014.

R&D expenses for the nine months ended September 30, 2015 decreased to $21.1 million as compared to $22.0 million for the nine months ended September 30, 2014. The $0.9 million decrease resulted primarily from decreased supplies expense of $1.8 million, decreased contract engineering services, consulting and other outside services of $0.5 million related primarily to product development of our SurgiBot System, offset by increased preclinical lab expenses of $0.8 million, increased personnel related expenses of $0.2 million, and increased other costs of $0.4 million.

Sales and marketing expenses for the nine months ended September 30, 2015 decreased to $1.2 million compared to $1.3 million for the nine months ended September 30, 2014. The $0.1 million decrease was primarily related to lower personnel-related costs of $58,000 and decreased travel-related expenses of $42,000.

General and administrative expenses for the nine months ended September 30, 2015 increased to $5.6 million compared to $4.8 million for the nine months ended September 30, 2014. The $0.8 million increase was primarily due to increased stock compensation costs of $0.6 million, increased personnel related expenses of $0.3 million, increased consulting costs of $0.1 million, offset by decreased public company costs of $0.1 million and decreased other costs of $0.1 million.

In connection with the acquisition of the ALF-X System, we incurred $4.0 million in acquisition related expenses in 2015.

Interest expense for the nine months ended September 30, 2015 increased to $997,000 compared to $764,000 for the nine months ended September 30, 2014 as a result of additional term loans of $4.4 million in September 2014 and $10 million in August 2015.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception we have incurred significant losses and, as of September 30, 2015, we had an accumulated deficit of $169.3 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. Our recurring losses raise substantial doubt about our ability to continue as a going concern. As a result, the Company's independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the years ended December 31, 2014 and 2013 with respect to this uncertainty. We expect to continue to fund research and development, sales and marketing and general and administrative expenses at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash have been proceeds from common and preferred stock offerings, incurrence of debt and the sale of equity securities held as investments.

Our primary liquidity requirements are to fund the expansion of our commercial infrastructure for the ALF-X System outside the U.S., fund milestone payments related to the ALF-X System acquisition, increase our inventory levels for the ALF-X System and SurgiBot System, fund product development, prepare for commercial launch of the SurgiBot System in the U.S., and to provide for general working capital needs. Through September 30, 2015, we have funded our operations principally from 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 do not expect existing cash balances will be sufficient to fund our operations and satisfy our other anticipated cash requirements for 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 $50.0 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 closing of the public offering occurred on June 17, 2015. 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 the Sales Agreement with Cantor, as sales agent, pursuant to which we can sell through Cantor, from time to time, up to $25.0 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 September 30, 2015, we had the ability to raise an additional $43.6 million from the January 2014 Shelf Registration Statement.

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 September 30, 2015, we had cash and cash equivalents of approximately $52.9 million. Our cash and cash equivalents increased by approximately $18.1 million during the nine months ended September 30, 2015, primarily as a result of proceeds from the issuance of common stock, net of issuance costs, of $58.3 million, proceeds from the incurrence of debt of $9.9 million and proceeds from the exercise of options of $252,000, offset by net cash used in operating activities of $24.6 million, payment of $25.0 million in connection with the acquisition of the ALF-X System and purchases of property and equipment of $728,000.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was $24.6 million during the nine months ended September 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 nine months ended September 30, 2015, which consisted primarily of increases in accrued expenses, accounts payable, inventories and other current and long term assets and decreases in restricted cash and accounts receivable.

Net Cash Used in Investing Activities

Net cash used in investing activities was $25.7 million during the nine months ended September 30, 2015. This amount reflected cash payments related to the acquisition of the ALF-X System of $25.0 million and payments for the purchases of property and equipment of $728,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2015 of $68.4 million was primarily related to proceeds from the issuance of common stock, net of issuance costs, of $58.3 million, proceeds from the incurrence of debt of $9.9 million and proceeds from the exercise of options of $252,000.

Operating Capital and Capital Expenditure Requirements

We expect existing cash balances will not 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 sales and marketing, 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.

On September 21, 2015, we completed the strategic acquisition from SOFAR S.p.A., of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery known as the ALF-X System. Under the terms of the Purchase Agreement, the Securities Consideration consisted of the issuance of 15,543,413 shares of the Company's common stock and approximately $25 million U.S. Dollars and €27.5 million Euro in Cash Consideration. The Securities Consideration was issued in full at the closing of the ALF-X Acquisition; the Cash Consideration was or will be paid in four tranches, as follows:

(1) $25 million of the Cash Consideration was paid at closing;

(2) The Second Tranche of €10.0 million shall be payable after the achievement of both of the following milestones (i) the earlier of approval from the FDA for the ALF-X System or December 31, 2016, and (ii) the Company having cash on hand of at least $50.0 million, or successfully completing a financing, raising at least $50 million in gross proceeds; with payment of simple interest at a rate of 9.0% per annum between the achievement of the first milestone event and the payment date;

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

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

On January 17, 2012, we entered into a loan and security agreement with the Lenders. The terms of the Original Loan Agreement provided for two term loans in aggregate of $10.0 million comprised of a $4.0 million term loan and a $6.0 million term loan. In connection with the Merger, we assumed and became the borrower under TransEnterix Surgical's Original Loan Agreement, and agreed to amendments to the Original Loan Agreement, dated as of September 3, 2013 and October 31, 2013, respectively. The Original Loan Agreement had a maturity date of January 1, 2016 and a fixed interest rate of 8.75% per annum. As of September 26, 2014, the outstanding principal amount of the Original Loan Agreement was $5.6 million.

On September 26, 2014, we entered into the Amended and Restated Loan Agreement with the Lenders. Under the Amended and Restated Loan Agreement, the Lenders agreed to make certain Amended and Restated Term Loans in an aggregate principal amount of up to $25.0 million. The first tranche of the Amended and Restated Term Loans increased our borrowings at September 26, 2014 from $5.6 million to $10.0 million. The Amended and Restated Term Loans allowed for interest-only payment at 7.5% per annum through October 31, 2015 and a maturity date of April 1, 2018.

On August 14, 2015, we entered into the First Amendment to the Amended and Restated Loan Agreement with the Lenders. The first tranche of the First Amendment increased our borrowings at August 14, 2015 from $10.0 million to $20.0 million. A second tranche of $10.0 million, is available to us upon recognition of at least $10.0 million of trailing six-month revenues from the SurgiBot System and SurgiBot-related products no later than March 31, 2017. The First Amendment allowed for interest-only payments at 7.5% per annum through April 30, 2016 and a maturity date of October 1, 2018.

On September 18, 2015, in connection with entry into the Purchase Agreement with SOFAR S.p.A., we and the Lenders entered into the Consent and Second Amendment to Amended and Restated Loan Agreement. The Second Amendment modified the period in which we can make interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The interest-only period could be extended to July 1, 2016 if we complete an offering of our equity securities above $40.0 million prior to January 31, 2016. The interest-only period could be further extended to January 1, 2017 upon obtaining 510(k) clearance from the FDA on our SurgiBot System by June 30, 2016. The Second Amendment has a maturity date of July 1, 2018 without the interest-only extensions, December 1, 2018 with the first interest-only extension, and June 1, 2019 with both interest-only extensions.

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

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

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

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

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. 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.

On September 3, 2013, we consummated a Private Placement transaction in which we issued and sold shares of our Series B Preferred Stock to finance our operations following the Merger. The Private Placement was done pursuant to a Securities Purchase Agreement with accredited 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 Securities 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.

During August 2013, TransEnterix Surgical issued 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 the Lenders. The Bridge Notes were converted into the Company's Series B Preferred Stock at the effective time of the Merger.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2014 (in millions):

		Payments due by period		
	Total	Less than 1 year	1 to 3 years	3 to 5 years
Long-term debt obligations	$24.4	$ 1.0	$ 23.4	$ —
Contractual obligations	6.1	0.2	2.5	3.4
Operating leases	1.8	0.3	1.5	—
Total contractual obligations	$32.3	$ 1.5	$ 27.4	$ 3.4

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

Contractual obligations represent future cash commitments and expected liabilities under agreements with third parties for licenses and supplies.

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

In September 2015, we completed the ALF-X acquisition. Contingent future cash consideration under this agreement is up to €27.5 million, based on certain tranches. The above table does not reflect these payments, as the timing and amount is indeterminate at this time. As of September 30, 2015, the fair value of the contingent consideration was approximately $24.3 million and is reflected on our consolidated balance sheet.

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.

Goodwill

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.

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 and developed research and development acquired as part of a business combination. Amortization is recorded using the straight-line method over the estimated useful life of seven to ten years. We review our long-lived assets including purchased intellectual property, developed research and development 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 September 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 September 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.

Risks related to the recent acquisition of the ALF-X System business.

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

Our ability to successfully integrate the business of our Italian subsidiary, TransEnterix Italia, which relates to the manufacture, development and commercialization of the ALF-X System with our existing business will depend, in part, on our ability to realize the anticipated benefits and cost savings from the expanded market opportunity presented by the acquisition of the technology and the establishment of international operations. To realize these anticipated benefits and cost savings, we must successfully integrate TransEnterix Italia with our other operations and combine our respective operations, technologies and personnel, which is particularly challenging given the geographic and cultural differences between the personnel and facilities based in North Carolina and Italy. If we are not able to achieve these objectives within a reasonable time frame, or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected.

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

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

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

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

The attention of our senior management could be distracted by the activities to integrate TransEnterix Italia into the TransEnterix business.

We have a small management team, and have recruited a number of executives to assist in the commercialization of the ALF-X System business. Factors that could distract management's attention from the core business of TransEnterix include integration of our financial reporting and information services, attention to the changes in the business as we adapt the TransEnterix Italia business to our U.S. publicly traded business model, integration of new executives into the management team and coordination and integration of our fundamental business. Any inability to successfully meet these challenges could have a material adverse effect on our business and results of operations.

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

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

- challenges associated with managing geographically diverse operations, which require an effective organizational structure and appropriate business processes, procedures and controls;
- the increased cost of doing business in foreign jurisdictions, including compliance with international and U.S. laws and regulations that apply to our international operations;
- currency exchange and interest rate fluctuations and the resulting effect on our revenue and expenses, and the cost and risk of entering into hedging transactions, if we chose to do so in the future;
- potentially adverse tax consequences;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- compliance with additional regulations and government authorities in a highly regulated business; and
- general economic and political conditions in Italy.

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

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

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

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

Risks Related to Our Business

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

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. Substantial doubt exists about our ability to continue as a going concern as a result of recurring losses and an accumulated deficit. We continue to incur research and development and general and administrative expenses related to our operations. Our net loss for the nine months ended September 30, 2015 was $33.4 million, and our accumulated deficit as of September 30, 2015 was $169.3 million. We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will not be sufficient to meet our anticipated cash needs for the next 12 months.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products and product candidates. 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”). As of September 30, 2015, we had $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 and the recently acquired ALF-X System, 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 and ALF-X System development activities;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals for both SurgiBot System and the ALF-X System;
- the costs associated with establishing a sales force and commercialization capabilities;
- the costs associated with the expansion of our manufacturing capabilities;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, products and technologies;
- the economic and other terms and timing of our existing licensing arrangement and any collaboration, licensing or other arrangements into which we may enter in the future;
- our need and ability to hire additional management, scientific, medical and sales and marketing personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, quality systems and information technology systems; and
- our ability to maintain, expand and defend the scope of our intellectual property portfolio.

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

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

We are highly dependent on the success of our products, especially the SurgiBot System and the ALF-X System. We cannot give any assurance that the FDA will grant regulatory clearance for the SurgiBot System or the ALF-X System, nor can we give any assurance that the SurgiBot System, the ALF-X 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, including the SurgiBot System and the ALF-X System, that will compete with other medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other medical devices and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical device companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than we do. Some of the medical device companies we expect to compete with include Applied Medical, 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;
- the cost of our products in relation to alternative devices;
- the timing and scope of regulatory clearances or approvals;
- whether our competitors substantially reduce the cost of ownership of an alternative device;
- our ability to protect and defend intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any approved products to the market;
- the availability of adequate coverage and reimbursement by third-party payors for the procedures in which our products are used;
- the effectiveness of our sales and marketing efforts; and
- acceptance of future products by physicians and other health care providers.

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

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

We are party with the Lenders to, and jointly and severally liable with certain of our U.S. subsidiaries for, $20.0 million of outstanding debt under term loans issued under the Amended and Restated Loan Agreement, as amended (the "Loan Agreement"). Under the Loan Agreement, the maximum borrowing potential is up to $30.0 million. We are entitled to make interest-only payments until January 31, 2016, which interest-only period is extended if we close an equity financing at a designated net proceeds level and obtain 510(k) clearance from the FDA on the SurgiBot System by June 30, 2016. The maturity date of the outstanding term loan is July 1, 2018, without the interest-only extensions and until June 1, 2019 with both interest-only extensions. Our resulting substantial level of indebtedness and other financial obligations increase the possibility that we may be unable to pay, when due, the principal of, interest on, or other amounts due in respect of, our indebtedness.

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

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

Our product development activities could be delayed or stopped.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations ("Form 483"), warning letters, non-warning letters incorporating inspectional observations;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory clearances or approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- refusal to clear or approve pending applications or premarket notifications; and
- import and export restrictions.

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

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

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

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales

from that product in the United States. The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

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

If 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.

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.

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

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

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

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

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

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

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

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

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. In the United States, we, or one of our subsidiaries, have or licensed 7 issued patents and over 40 pending patent applications. Many of these relate to the SPIDER System, the SurgiBot System, the ALF-X System, instruments useful with those systems, or alternatives to those systems. We have also filed patent applications abroad for the SurgiBot System, ALF-X System and the SPIDER System. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

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

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

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

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

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

Some of the patents and patent applications in our patent portfolio related to the ALF-X System are licensed to TransEnterix Italia under a license agreement with the European Union. Presently, we rely on such licensed technology for our ALF-X System products and may license additional technology from the European Union or other third parties in the future. The EU license agreement gives us rights for the commercial exploitation of the patents resulting from the patents, patent applications and know-how, subject to certain provisions of the license agreement. Failure to comply with these provisions could result in the loss of our rights under the EU license agreement. Our inability to rely on these patents and patent applications which are the basis of certain aspects of our ALF-X System technology would have an adverse effect on our business.

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

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our

employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

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

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

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

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

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

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

As of September 30, 2015, the net carrying value of our goodwill and other intangible assets totaled approximately $202.1 million, which was 75% of total assets. In accordance with generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and share price declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

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

In the June 2015 public offering, and the acquisition of the ALF-X System assets from SOFAR (the "Acquisition Transaction"), we issued a significant number of new shares of common stock to increase our outstanding shares of common stock to over 100,000,000 shares. The issuance of these shares caused existing stockholders at the time of the public offering and Acquisition Transaction to experience immediate and significant dilution in their percentage ownership of our outstanding common stock.

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

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

During the two year period ended September 30, 2015, the market price of our common stock fluctuated from a high of $14.00 per share to a low of $1.25 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

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

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

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

Trading of our common stock is currently conducted on the NYSE MKT. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all. As of September 30, 2015, approximately 45.8% 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 September 30, 2015, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 29.5% 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 Acquisition Transaction, we entered into a lock-up agreement and registration rights agreement with SOFAR.

In connection with the Acquisition Transaction, we entered into a Registration Rights Agreement, dated as of September 21, 2015, with SOFAR, pursuant to which the Company agreed to register the 15,543,413 shares of the Company's common stock issued as part of the transaction consideration (the "Securities Consideration") for resale following the end of the lock-up periods described below.

In connection with the Acquisition Transaction, SOFAR entered into a Lock-Up Agreement pursuant to which it agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Securities Consideration for one year following the Closing Date. The Lock-up Agreement provides that SOFAR may sell, transfer or convey: (i) no more than 50% of the Securities Consideration during the period commencing on the one-year anniversary of the Closing Date and ending on the eighteen-month anniversary of the Closing Date; and (ii) no more than 75% of the Securities Consideration during the period commencing on the eighteen-month anniversary of the Closing Date and ending on the two-year anniversary of the Closing Date. The restrictions on transfer contained in the Lock-up Agreement cease to apply to the Securities Consideration following the second anniversary of the Closing Date, or earlier upon certain other conditions. Once such lock-up restrictions end, it is possible that SOFAR will sell shares of our common stock in underwritten or private placement transactions.

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

On September 21, 2015, the Company completed the strategic acquisition of the ALF-X System business through the Acquisition Transaction. Under the terms of the Purchase Agreement, the Securities Consideration issued to SOFAR consisted of 15,543,413 shares of the Company's common stock. The issuance of the Securities Consideration was effected as a private placement of securities deemed exempt from registration under Section 4(a)(2) of the Securities Act, and Rule 506 of Regulation D promulgated thereunder, regarding transactions by an issuer not involving a public offering. SOFAR represented to us that it was an accredited investor and was acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that it could bear the risks of the investment and could hold the securities for an indefinite period of time. SOFAR received written disclosures that the Securities Consideration was not registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration. The Company entered into a Registration Rights Agreement with SOFAR in connection with the Acquisition Transaction.

The following table summarizes the Company's purchases of its common stock for the quarter ended September 30, 2015:

Period	Total Number of Shares Purchased (1)	Purchase Price
July 1-31, 2015	—	
August 1-31, 2015	—	
September 1-30, 2015	1,173	$3,003

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Description
2.1	Membership Interest Purchase Agreement, dated September 18, 2015, by and among SOFAR S.p.A., Vulcanos S.r.l., the Company and TransEnterix International, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed September 21, 2015).
4.1	Form of Warrant to Purchase Common Stock for warrants issued to the Lenders (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed September 30, 2014).
10.1	Consent and Second Amendment to Amended and Restated Loan Agreement, dated September 18, 2015, by and among the Company, its subsidiaries TransEnterix Surgical, Inc. and SafeStitch LLC (collectively, the "Borrowers"), and SVB, as Lender, and Oxford, as Lender and Collateral Agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed September 21, 2015).
10.2	Amended and Restated Loan Agreement, dated September 26, 2014, among the Borrowers and the Lenders and Collateral Agent, as amended by the First Amendment thereto, dated August 14, 2015 (incorporated by reference, respectively, to the Company's Current Report on Form 8-K, filed September 30, 2014 (Loan Agreement) and the Company's Current Report on Form 8-K, filed August 17, 2015 (First Amendment)).
10.3	Registration Rights Agreement, dated September 21, 2015, by and between the Company and SOFAR S.p.A. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed September 21, 2015).
10.4	Lock-Up Agreement , dated September 21, 2015, by and between the Company and SOFAR S.p.A. (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed September 21, 2015).
10.5 * +	Licence Contract between the European Union and Vulcanos s.r.l. (now known as TransEnterix Italia S.r.l.), dated September 18, 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.

\+ Confidential treatment has been requested for certain portions of this agreement pursuant to an application for confidential treatment filed with the Securities and Exchange Commission on November 9, 2015. Such provisions have been filed separately with the Commission.

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: November 9, 2015

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

Date: November 9, 2015

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

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH "*" AND BRACKETS AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

LICENCE CONTRACT

BETWEEN

THE EUROPEAN UNION

AND

VULCANOS s.r.l.

[**********]

The European Union, hereinafter referred to as the "Union", represented by the European Commission, hereinafter referred to as "the Commission", represented for the purpose of signing this contract by Mr. Vladimir Šucha, Director-General of the Joint Research Centre (hereinafter referred to as "the JRC"),

on the one part,

Vulcanos s.r.l., having its seat at via Firenze, 40, Trezzano Rosa (Milan), Italy, registered under the number MI-2072973 at the Entrepreneur Register of Milan, VAT number 09162250964, hereinafter referred to as the "Licensee", represented for the purpose of signing this contract by Mr. Andrea Biffi in his capacity as sole director, duly authorized to enter into this agreement pursuant to the by-laws of the company (hereinafter referred to as "VULCANOS" or "the Licensee")

on the other part,

both parties hereinafter referred to collectively as "the Parties" or individually as "a Party",

WHEREAS

VULCANOS is an Italian company totally held by SOFAR S.p.A. (hereinafter referred to as "SOFAR"), having its seat at via Firenze, 40, Trezzano Rosa (Milan), Italy, registered under the number MI-852745 at the Entrepreneur Register of Milan, VAT number 03428610152.

On 7th January 1998, the Commission adopted a Decision concerning the European Technology Transfer Initiative whereby it seeks to promote the transfer of Joint Research Centre technologies to companies/organisations in the Member States, to provide access of companies to JRC research results and to validate the expertise and the installations of the JRC.

In this context, the JRC seeks to promote the commercialisation of its technologies through the creation of new enterprises and via the transfer of technology to existing companies.

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Pursuant to Commission Decision of 12 September 2001 SEC (2001) 1397 Article 13 the Union has the mandate to exploit technologies resulting from the programmes and activities under its responsibility, grant licences thereto and promote technology transfer.

The Commission and SOFAR had already collaborated during the period of 25 months from the 12 July 2002 to the 12 August 2004 on the basis of the Collaboration Agreement [**********], a letter of intent signed on the 12 December 2003, the Collaboration and Option Agreement [**********] from 9 September 2004 as amended by the Amendment N° 1 to the Collaboration and Option Agreement of 8 September 2006, and SOFAR duly paid all the sums for services and for the Licence Option fee established by the above-mentioned Agreements on the basis of the work progress.

SOFAR on one hand provided engineering services, software development, equipment supply and manufacturing support for the full development and testing of the tele-medical system designed and patented by the JRC.

On the other hand, the JRC directed the development works and transferred know-how to SOFAR personnel on the JRC-owned software for robotics motion control -named GENERIS- and on robotics manipulators design and development.

The Union is the owner of the patents, copyright and any intellectual property rights on the Product listed in Annex A to this Agreement over which it has the power of disposal.

SOFAR was owner of the trademark ALF-X, over which the Union has no rights or powers.

SOFAR had a diversity of competencies in the health care and pharmaceutical industries and was interested in expanding its area of expertise and market in the field of medical devices by developing and commercialising tele-medical robotics systems.

The scientific results obtained through the JRC SOFAR collaboration were highly innovative with potential applications in other fields.

SOFAR was interested to extend this cooperation with the JRC in order to jointly carry out application development of the technology established by the JRC in view to enable SOFAR's commercial exploitation of the technology owned by the Union.

On the above basis, the Union and SOFAR entered on the 17.11.2008 into a License Agreement to manufacture, further develop and extend the functionalities of the Product in the Field of Use, to distribute it, to use and to offer, sell or sub-licence in the Territory, to which the Commission agrees in order to ensure the effective commercialisation of the Technology.

On December 2011, SOFAR obtained the CE Trademark certification.

In March 2014, SOFAR started negotiations with the Union to amend the license Agreement. After negotiations, SOFAR and the Union agreed to terminate the previous licence agreement and make the Union and VULCANOS enter into this license agreement under the following terms and conditions. SOFAR was of the view that it had exposed heavy costs in the further development of the technology and the Union was of the view that allowing a new licensee to launch its activities under new terms and conditions would better favour the societal impact and reach of the technology.

THE PARTIES HAVE AGREED AS FOLLOWS:

ARTICLE 1 - Definitions

The following terms will have the meaning given hereunder:

1.1 **Effective date -** date of signature of this Agreement by the last Party, save as provided in Article 23.

1.2 **Technology -** all know-how, data, scientific or technical information related to methods and apparatus for tele-medical assisted procedures as further identified in the Patents.

1.3 **Product -** any and all products which make use of the Technology and fall within the Field of Use. In the context of this Agreement, the Product is identified as a tele-medical system of robotic manipulator arms displaying the design and features claimed in the patents listed in Annex A and B. This system is designed with the know-how of the JRC and runs the JRC software Technology mentioned in Annex A and B as the software control platform. The aforementioned system does not comprise specific surgical instruments to be adapted to the manipulator arms and other accessories not covered by the claims of the patents listed in Annex A and B. The system may be composed of at least two and up to five manipulator arms.

1.4 **Field of Use -** medical procedures including minimally invasive robotic surgery and diagnostic procedures, installed in private and public hospitals, universities, medical training centres and research organizations.

1.5 **Know-how -** all the technical information, knowledge and expertise which the Union owns and administers on the Effective date that are transmitted to the Licensee by any means including technical assistance, namely the confidential know-how developed in the course of this project including any software code that is essential to the application of the Technology.

1.6 **Sub-licence -** any licence granted to any third party by the Licensee with the aim to commercially exploit the Product in the Field of Use and the Territory.

1.7 **Net sales -** for a given year, the sum of sale invoices issued by VULCANOS during that year, related to the sales or commercialisation of the identified Product, net of credit notes. Net sales is further defined in Article 13 in case of operative leasing or other forms of making available of the Product on the market.

1.8 **Sale price -** the price indicated on an sale invoice relating to the sale or commercialization of the Product issued by VULCANOS, net of any discounts, rebates, transportation, insurance costs, sales taxes and custom duties. Sale price is further defined in Article 13 in case of operative leasing or other forms of making available of the Product on the market.

1.9 **Territory** - the territories, as designated in the patent registrations or applications; at the moment of signature of this Agreement, this covers a number of countries in Europe (Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Holland, Poland, Portugal, Sweden and Turkey), the USA, Canada, Japan, Mexico, Brazil, Russia, India, Korea and China.

1.10 **Intellectual property rights -** all industrial and intellectual property rights as listed in Annex A and B, such as, but not limited to, copyrights, rights on patents, patent applications, utility models, trademarks (whether Benelux, Community, international or foreign ones), trade names, designs and models, in particular:

A) **Patents -** the patents, patent applications listed in Annex A and B to this Agreement including the inventions described and claimed therein as well as any divisional, continuations, continuations-in-part, reissues thereof, improvements and derivative work patents.

B) **Copyright** - the copyright on the software listed in Annex A and B to this Agreement.

1.11 **Invention -** the Technology covered by the Patents.

1.12 **Developments and Derivative Works -** the results deriving from research and development activities related to the Technology and based on the Technology.

1.13 **Confidential Information -** the confidential information exchanged between the Commission and the Licensee before or during the execution of this Agreement.

1.14 **[**********
**********].**

1.15 **Related entity -** a legal entity which is linked to another or associated with another in the sense of Article 11 of the Belgian Company Code or of equivalent provisions under European law. In this sense, company A will be related to company B if company B controls company A or vice-versa, if they form a consortium or if they are controlled by a same legal entity or form part of the same group of companies.

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ARTICLE 2 - Subject of the Agreement

2.1 The Union hereby grants the Licensee a personal, exclusive and non-transferrable licence, limited to the Territory and Field of Use under the Union's ownership on the Product, entitling the Licensee to manufacture, further develop and extend the functionalities of the Product, to distribute it, to use and to offer, sell or sub-licence in the Territory, subject to Article 5.

2.2 This Agreement only applies to the activities described herein. Any new product, service (not related to the sale of the Product), or new ways of commercial exploitation related to or originating from the licensed Technology will be negotiated and subject to a written amendment to the present Agreement.

2.3 Notwithstanding Article 2.1, the Parties acknowledge that the Licensee wishes to commercially exploit the Product in the Field of Use in all countries worldwide. The commercial exploitation of the Product in the countries outside the Territory will be under the sole responsibility of the Licensee. If VULCANOS wishes to commercialise the Product outside the Territory, it shall pay for each Product sold outside the Territory [**********] it would pay for Products sold in the Territory, to compensate for the use of the Intellectual Property Rights in the Territory.

2.4 Subject to Article 2.3, the Union undertakes not to supply any Know-how and/or technical support related to the Product to third parties, directly or indirectly, for the purpose of commercializing the Product in the Field of Use in countries outside the Territory.

ARTICLE 3 - Duration, Renewal and Termination

3.1 The Agreement enters into force on the Effective Date and lasts until the expiration date of the last of all Patents existing on the Effective Date in the Territory, except (1) if it is terminated earlier by mutual consent of the Parties on the basis of Article 3.2. or for breach on the basis of Article 3.3. or (2) if it is extended after the expiry of the Patents because VULCANOS still wishes to make use of the Software and/or of the Know-How, in conformity in such case with the procedure of Article 3.6.

3.2 This Agreement may be terminated at any time by written mutual agreement between the Parties.

3.3 In the event of non-performance by the Licensee of any of his obligations arising out of this Agreement and without prejudice to the consequences provided under the law applicable to this Agreement, the Commission may automatically terminate the Agreement without any legal formality, upon notice by registered letter to the Licensee at the address mentioned in Article 19, requiring performance or remedial within thirty days. The consequences of such termination shall be governed by the law specified in Article 18.

3.4 In the event of termination of this Agreement either by mutual consent or for breach by the Licensee, without prejudice to any other measures provided for in the Agreement, the Licensee shall:

a) discontinue the use of the Invention or any other activity covered under Article 2;

b) waive any claim for consequential damages, including any loss of anticipated profits;

c) take all appropriate measures to minimize costs, prevent damage, and cancel his commitments; and

d) only in case of termination by mutual consent, not be obliged to pay the Commission any royalties or sums provided for in Article 13 of this Agreement from the date of termination of the Agreement. Remuneration due at the date of termination of this Agreement but not yet paid shall in any case remain payable.

3.5 Termination of this Agreement shall cause termination of any sub-licence granted under Article 5 prior to the termination date, except if agreed otherwise.

3.6 In the event of expiry of this Agreement due to the expiration of the Patents, the Licensee will be entitled to continue the manufacture and commercialization of the Product in the Field of Use, as any other third party may do with patents which enter the public domain. If VULCANOS still wishes to make use of the Software and/or of the Know-How, VULCANOS shall inform the Union in advance and the Parties will negotiate in good faith the terms of a new licence covering the Software and the Know-How. If no such licence is signed, VULCANOS shall cease using the Software and the Know-How.

ARTICLE 4 - Maintaining the Patents in force

4.1 The Union is entitled to request the Licensee to provide advice and cooperation in any prosecution, filing, and maintenance of the Patents.

4.2 During the term of this Agreement, the Union shall communicate to the Licensee all Developments relating to the Patents or to the Products, which shall automatically be included as part of the Product at [********** **********].

4.3 The Union shall not be obliged to maintain the Patents in force. If the Union decides not to maintain the Patents in force or to discontinue the registration in any given country, it shall inform the Licensee in writing at least three (3) months before the due date required for the formalities necessary to maintain the Patents in force, and the Licensee shall be entitled to take over the Patents on reasonable terms to be negotiated.

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ARTICLE 5 - Sub-licensing

5.1 Subject to the provisions in Article 2, the Licensee is entitled to grant sub-licences to a third party and in such cases will notify the Union accordingly, at least two (2) months in advance of its signature. The non-respect of the above obligation may lead to an immediate termination of the Agreement. In any event, the Licensee shall remain responsible for all acts and omissions of such third parties or sub-licensees as though they were by the Licensee. Sub-license agreements shall not contain any clauses which are contrary to this Agreement. The Union shall receive copies of sublicense agreements concluded by the Licensee within one (1) month of their signature.

5.2 Any sale or commercialisation of the Product by a sublicensee is considered, in terms of payment of royalties to the Union, in the same way as a sale or commercialisation directly by VULCANOS, as further provided in Article 13.

ARTICLE 6 - Licensee's obligations

6.1 The Licensee shall:

a) within three (3) months of signature of this Agreement, [**********
**********];

b) [**********] by doing no less than all best efforts, pro-actively market and promote the Products in the Territory; it is understood by the Licensee that it is, for the Union, of major importance that the Licensee makes all necessary efforts to ensure that, as soon as possible, the Product is put on the market in the European Union and is actually installed and available to a good number of hospitals and patients in the European Union;

c) make its best efforts to obtain FDA approval in the shortest possible time and notify the Union accordingly;

d) manufacture, distribute, use and offer for sale, sell or sub-licence in the Territory the Product, under the conditions mentioned in Articles 2 and 5;

e) pay the minimum amounts of royalties as provided in Article 13. It is understood that paying such minimum amounts of royalties does not discharge the Licensee from its obligation to, in addition to paying the minimum amounts of royalties, pro-actively market and promote the Products and it does not allow the Licensee to decide to "freeze" the Technology and/or concentrate its efforts only on a competing technology;

f) acquire appropriate use rights to the software elements being subject to open source or proprietary licenses and any corresponding rights as set forth in the Copyright definition under Article 1.10.B.

6.2 The Know-how and all Information supplied to the Licensee by the Union shall remain the property of the Union. The Licensee shall undertake to respect its confidential nature and to ensure that his staff and third parties, including distributors, sub-licensees and sub-contractors, who may be concerned in the manufacture and commercialisation of the Product, do likewise. The obligations of confidentiality will cease to apply if and when the Know-how and Information become publicly known through no fault of the Licensee.

6.3 Licensee shall refer clearly that the Product is DEVELOPED UNDER A LICENCE OF THE EUROPEAN COMMISSION JOINT RESEARCH CENTRE on any promotional material including its website.

ARTICLE 7 - Technical support

7.1 The Union is under no obligation to provide the Licensee with any additional service or technical support regarding the know-how, training, co-development of the software, advice and all technical documents in its possession.

ARTICLE 8 - Liability

8.1 The Union makes no representation as to the patentability and or breadth of the Patents. Furthermore, the Union makes no representation as to patents now held or which other parties in the Field of Use or outside the Field of Use will hold for a particular purpose. The Union also makes no express or implied warranties of merchantability or fitness for a particular purpose of the Product. The Union declares that it has no knowledge of any deficiencies impairing the validity of the Patents or of any technical defects in the Invention protected by these Patents. The Union assumes no liability in respect to any infringement of any patent or other right of third parties due to the Licensee's activities under this Agreement.

8.2 The Union disclaims all warranties, expressed or implied, relating to the Patents, the Product or the use thereof by the Licensee or by third parties, except for damages caused by its willful conduct or gross negligence. The Union will not be liable for any loss of use, interruption of business or consequential damages of any kind, including but not limited to loss of profits, loss of contracts, goodwill or anticipated savings, even if the Union has been advised, knew or should have known of the possibility of such damages.

8.3 If the extent of protection of the Patents should be limited by a legal or administrative decision in such a way that third parties can freely manufacture and sell/exploit the Product without infringing the Patents, or if one or more of the Patents are revoked following an action brought by a third party, or if the Licensee, following a decision by the Union not to bring an action for infringement as provided for in this agreement, can prove a substantial decrease in turnover of the Product, the Licensee shall be entitled either:

a) to reduce accordingly the remuneration to the extent agreed with the Union, in order to avoid any distortion of the market for Product, or

b) to terminate this Agreement as of a date to be agreed jointly.

In neither of the aforementioned cases shall any remuneration already paid be refunded. Remuneration due but not yet paid shall remain payable.

ARTICLE 9 - Infringements by third parties

The Parties shall inform each other of any infringement of the Intellectual property rights coming to their knowledge and support the other Party in any action, which said Party brings against a third party for such infringement. The Union shall have the possibility to decide whether or not to bring an action for infringement against the infringer. In the event the Union decides not to bring an action for infringement against the infringer, it will, within one (1) month of becoming aware of the infringement, notify the Licensee, who will be entitled to do so directly.

ARTICLE 10 - Action for infringement brought by third parties

If actions for infringement are brought against the Licensee as a result of the manufacture of the Product, the costs incurred for its defence and payment of damages shall be borne by the Licensee. If an action for infringement is brought against the Licensee, he shall notify the Union and enable it to intervene in the action. The Union may undertake to provide the Licensee with any assistance considered to be appropriate for its defence. If the Licensee should be found guilty or constrained to acquire a licence to exploit the infringed Invention, the Parties shall consult each other in order to determine whether the terms of this Agreement should be revised or the Agreement be terminated.

ARTICLE 11 - Developments and Derivative Works

11.1 The Licensee shall inform the Commission in writing of all Developments and Derivative Works made to the Product, at least once a year.

11.2 The Union shall be released from all liability arising from failure to comply with legal or statutory obligations in respect of marking of the Product.

11.3 Developments made shall be owned by the Party that developed them but will only be exploited while duly respecting all pre-existing Intellectual property rights of the Party which developed the pre-existing Technology.

11.4 If further Developments to the Product made and owned by the Commission are patentable by the Commission, the Licensee shall be free to accept or refuse an exclusive licence on those patents within three (3) months from their filing. This right of use shall cover work, orders or research undertaken by third parties for the Union's account. In the latter scenario, the possibility of licence remains open to further economic operators.

11.5 Any other Developments outside the scope of this Agreement but linked to the Invention made by the Union will not automatically be transferred to the Licensee. Should the Licensee be interested in acquiring the Development made by the Union, a specific contract will have to be negotiated independently of this Agreement.

ARTICLE 12 - Designation of Personnel

12.1 Each Party designates for its performance the personnel necessary for the proper execution of the tasks devolving upon it. In the event of the personnel being designated by name in this Agreement, each Party shall have the right, with the prior approval of the other Party to replace them by others possessing equivalent qualifications.

ARTICLE 13 - Royalties

13.1 In consideration for the granting of the licence, the Licensee shall pay royalties to the Union for the exploitation of the Technology, the Software and the Patents, in accordance with the mechanisms and principles described in the following paragraphs.

13.2 **[**] royalty-free Products**. Without prejudice to Article 13.4., the Licensee has the right to sell the first [**********] Products on a royalty-free basis, in consideration for the investments made prior to the Effective Date by SOFAR, which was initially granted an exclusive license on the Patents and which has asked that its license be terminated and that a new license be granted to VULCANOS, in which SOFAR has, on the Effective Date, financial interests.

13.3 **Royalty-bearing Products**. Following sale of the first [********] Products, the Licensee undertakes to pay the Union an annual royalty fee calculated on the Sales price of the Product, as follows:

- [**]on Sales price from the [**********] Products. It is agreed that (1) the first [*********] of Products made through any distributor, while triggering royalties, will not be considered in the calculation of this target ([**********]) and (2), for this calculation, any sales of Products outside the Territory only count as [********] (e.g. [**] Products sold outside the Territory count as [**]Products);

- [***] on Sales price from the [**********]Products. It is agreed that (1) the first [***]sales of Products made through any distributor, while triggering royalties, will not be considered in the calculation of this target ([**********]) and (2), for this calculation, any sales of Products outside the Territory only count as [********] (e.g. [**]Products sold outside the Territory count as [**]Products);

[****] on Sales price from the [****] Product onwards.

13.4 **Minimum royalties**. The Licensee shall pay to the Union the following minimum royalties, regardless of the number of Products actually sold and/or commercialised and notwithstanding the mechanism of 30 royalty-free Products:

- in 2015: [**********] EUR;

- in 2016: [**********] EUR;

- in 2017: [**********] EUR;

- in 2018 and every year thereafter until the termination of the Agreement: [**********] EUR.

However, the Licensee is entitled to off-set such minimum royalty payments from the annual royalty payments due from sales of the Product established in Article 13.3.

The minimum annual royalty is due entirely for each year started even in the case where the Agreement is terminated at the initiative of the Licensee as foreseen in Article 3. It is due at the end of each corresponding calendar year (e.g. [*******] EUR by December 31, 2017), being understood that the Union shall send an invoice corresponding to the amount to be paid.

13.5 **Calculation of royalties**. The amount taken as a basis to calculate the Sales price and royalties due by the Licensee is the amount of **Net sales on a yearly basis**, starting on the anniversary date of the Effective Date, as such Net sales are reflected via the Sale price.

Except for the first year of the Agreement, calculations are made on a calendar basis (i.e. from January 1 to December 31).

If the Products are not sold via a transfer of ownership to the buyer but rather made available via **operative leasing** (*noleggio*, with the right to acquire the ownership of the Product at the end of the leasing period against payment of a nominal amount),
the amount to take into account shall be [**********
****
****
****
**********]. It is understood that if the customer pays through the operative leasing immediately the entire price, VULCANOS shall pay the Union the whole amount of the royalties at the end of the relating year.

If the Products are neither sold nor made available via leasing but via **renting** (temporary right to use the Product against payment of a periodical fee, for a determined or undetermined period of time, with no contractual mechanism foreseen to acquire the ownership of the Product at the end of the contractual period), or if the Products are made available via **any other**
form of commercialisation of the Products, the amount to take into account shall be [**********
****
****
****
**********]. It is

understood that if the customer pays through the renting immediately the entire price, VULCANOS shall pay to the Union the whole amount of the royalties at the end of relating year.

Where necessary, the amount will be established by comparison with similar market situations where the Product has actually been sold to customers.

It is understood that no royalties will be due for [**********] decided in good faith by VULCANOS.

In case of revenues generated via **sublicenses** granted by the Licensee, the amounts to be taken into account for the calculation of the royalties due to the Union will be based on the turnover of the sublicensee related to the sale and commercialization of the Product.

In case of revenues generated by sales via a **distributor**, since the royalties payable to the Union per Product are likely to be inferior when the Product is sold to a final customer via a distributor, the following principles shall apply:

[**********]; and

[**********].

For the avoidance of doubt and as per article 2.3., for **Products sold outside the Territory**, VULCANOS shall pay [***] of the royalties it would pay for Products sold in the Territory, to compensate for the use of the Intellectual Property Rights in the Territory.

13.6 The payment shall be made in Euro, all costs of the payment being borne by the Licensee. Late or non-payment by the Licensee's customers has no influence on the amount of the royalties due. All payments will be made to a bank account of the Union to be advised by the Commission.

Each statement will, as is the case, bear the following references:

- 'payment due under Article 13 of the contract [**********] period of reference from ….to ….'

13.7 The Licensee shall submit to the Commission, by the 31st January of each year, a report for the preceding calendar year detailing the Net sales during that calendar year, including the first 30 Products royalty-free and the Sales price per Product.

Said report shall enclose a list of the customers and their country of residence, the number of each invoice, the date and the related amount so invoiced. The report shall also specify if the Products were made available via a sales contract, a leasing contract or otherwise. The report shall show the quantity, description and price of the Products sold and be sufficiently detailed to ascertain payments due under this Agreement, including mechanisms used to come to the amount of royalties due in function of the number of machines previously sold on a royalty-free basis and the different percentages used in function of the number of machines previously sold (calculated cumulatively) and taking into consideration the minimum royalties which have already been paid for the corresponding year.

The Licensee shall keep separate records relating to the Sales of the Product showing the quantity, description and price of the Products sold and being sufficiently detailed to ascertain payments due under this Agreement. The Commission shall have the right, once a year, to inspect and determine the correctness of the bookkeeping and its consistency with the general bookkeeping of the Licensee either by its own services or through a licensed auditor. The costs for such an audit shall be borne by the Union, but in case of discovery of discrepancies of more than 5%, they shall be borne by the Licensee.

Payments due under the present Article shall be made within thirty (30) days of receipt of the Commission's invoice.

ARTICLE 14 - Intellectual property rights

14.1 Intellectual property rights related to the Product as described in Annex B are the exclusive property of the Union. The Licensee shall not at any time and under any circumstances use the copyright, save to exercise the rights granted by this Agreement, to grant licences on the Product within the scope of this Agreement and save any use expressly authorised by the Union.

The Licensee shall only use any logo of the Communities, the Commission, the JRC or any of JRC's research institutes subject to prior written consent of the Union.

14.2 The Licensee acknowledges the Intellectual property rights on the Product as described in Annex B to belong to the Union and shall not acquire any Intellectual property right on the Product with the exception of the rights granted by this Agreement.

14.3 The Union declares that it is not aware of any legal deficiencies of the Product. The Union particularly declares that it is aware of neither any third party's prior rights to use, nor of a dependency of the licensed Patents on third party's rights. Without prejudice to Article 14(2), the Union assumes no liability for possible deficiencies mentioned above.

ARTICLE 15 - Indemnification

15.1 Subject to Article 15(2), the Licensee shall defend at its own expenses any claim, suit or proceeding brought against the Licensee, insofar as it arises from the Licensee's use of

the Product and shall indemnify and hold the Union harmless for all claims, damages, costs and expenses awarded to the Licensee or third parties against the Union arising from any such claim, suit or proceeding.

15.2 In the event any claim, suit or proceeding is brought against the Licensee based on a claim that any portion of the Product constitutes an infringement of patent or copyright, or other intellectual property rights of any third party arising under the applicable law, the Union shall have the right, at its option, to assume the defence of such action or to cooperate with the Licensee in assuming such defence.

15.3 The Union shall have no liability, if the alleged infringement is based on a modification of the Product by anyone other than the Union, including the Licensee, or on use of the Product other than in accordance with the Union's specifications and documentation.

15.4 The Licensee shall use due diligence in order to prevent the infringement of any Intellectual property rights during its marketing and distribution activities. In the event that the distribution activities of the Licensee lead to an infringement of the Intellectual property rights, the Licensee shall be fully liable to the Union for any damages resulting from such infringement.

15.5 The Union shall have, in addition to any other remedies available to it, the right to injunctive relief to enjoin breaches of this Agreement.

ARTICLE 16 - Confidentiality obligations

16.1 Irrespective of the provisions of laws relating to know-how, patents and other intellectual property rights, the Licensee undertakes during the term of this Agreement and thereafter to keep secret all facts, Confidential Information, knowledge, documents or other matters communicated to him or which come into its possession during the performance of this Agreement.

16.2 The access rights of the Commission and the Licensee to the Confidential Information shall be limited to the scope of this Agreement.

All the Confidential Information that shall consist of technical details, business and manufacturing secrets and in particular research, development, production and market data as well as other business information and any other information is communicated under strict confidence. Neither the Commission nor the Licensee shall disclose to any third parties any Technology or other Confidential Information received by them.

16.3 The Union and the Licensee may only pass on the Confidential Information to their employees if such Confidential Information is required for evaluation. The Union and the Licensee must ensure that such employees having access to the Confidential Information are committed to confidentiality in the same way they have committed themselves and that they will not divulge Confidential Information and/or Know-how to any third party even after completion of their assignment.

Licensee warrants that its employees, consultants and contractors are bound by confidentiality.

16.4 The Parties have the joint understanding that valuable confidential Know-how might be exchanged or created in the course of the performance of this Agreement and that the commercial value of such confidential Know-how is fundamentally put at stake if any divulgation of such Know-how occurs.

16.5 Any loss or damage, caused to one of the Parties and arising out of the breach of this Article shall be borne exclusively by the Party responsible for such breach; the breaching Party shall be responsible for making compensation thereof and shall indemnify and hold harmless the other Party in respect of any such loss, damage or injury, including but not limited to reasonable attorneys' fees.

16.6 At the termination of this Agreement, the Commission and the Licensee shall return all Confidential Information to the disclosing Party, or destroy the same, as instructed by the disclosing Party, without retaining any copies of the documents. However, this clause shall not require the return of Confidential Information recorded in laboratory notebooks kept in the ordinary course of business, nor of records required by law to be maintained.

ARTICLE 17 - Taxes and governmental charges, permits

17.1 All turnover taxes and indirect or direct taxes, which have to be paid for the royalty payments, shall be borne by the Licensee.

17.2 Pursuant to Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities, the Union is, in respect of its financial interests in this Agreement, exempt from all duties and taxes, including value-added tax.

17.3 The necessary steps for obtaining all permits and licences required for the implementation of this Agreement under the laws and regulations in force at the place where the services are to be provided shall be the exclusive responsibility of the Licensee.

If the Licensee is unable, whether or not by reason of its own default, to obtain any permit or licence as referred to above, it shall forthwith inform the Commission, who, after consultation with the Licensee and with due regard to the effect of this situation upon the work, shall decide whether all or any part of it is to be discontinued.

ARTICLE 18 - Law and Jurisdiction

18.1 This Agreement shall be governed by and construed in accordance with the law of the European Union, complemented where necessary by the substantive laws of Belgium.

18.2 Any dispute between the Parties resulting from the interpretation or application of this Agreement which it has not been possible to settle amicably shall be submitted to the jurisdiction of the General Court of the European Union in Luxembourg.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH "*" AND BRACKETS AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

ARTICLE 19 - Administrative provisions

19.1 Any communication with reference to the performance of this Agreement, all notifications of payment and any relevant correspondence shall be made in writing and addressed to the following addresses:

For the UNION:

European Commission, Joint Research Centre
Intellectual Property and Technology Transfer
To the attention of the [**********]
[**********]
[**********]
[********]

For the LICENSEE:

Vulcanos S.r.l.
[**********]
[**********]
[*****]
[**********]
[**********]

19.2 The Agreement reference is [**********]. It shall be quoted in all correspondence with the Union.

ARTICLE 20 - Non-transferability

20.1 Without prejudice to the provisions of Article 5 on sub-licensing, the Licensee may not assign this Agreement to any third party without the prior written consent of the Union.

20.2 It is however understood that any changes in the shareholding structure of VULCANOS (resulting e.g. from finding one or several new partners, be they industrial or purely financial) will be allowed and will not need the prior written consent of the Union.

ARTICLE 21 - Miscellaneous provisions

21.1 This Agreement, including the Annexes attached hereto, is the entire Agreement among the Parties relating to the subject matter hereof and may only be modified by a written amendment signed by the authorised representatives of each Party. In case of conflict between a provision in an Annex and a provision in this Agreement, the provision in this Agreement will prevail.

21.2 If any term or provision of this Agreement shall be found to be illegal or unenforceable then, notwithstanding that term, all other terms of this Agreement shall remain in full force and effect.

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ARTICLE 22 - Annexes

The following are appended to and are an integral part of this Agreement:

Annex A	Description of the Product
Annex B	Portfolio of relevant Union's Patents
Annex C	Licensee's Market & Business Plan (to be appended later)

ARTICLE 23 - Condition precedent

This Agreement shall be effective subject to the condition precedent of the execution of the public notarial deed, relating to the transfer of the 100% of the shares of VULCANOS to TransEnterix International, Inc., a U.S. company duly incorporated, such deed to be executed by SOFAR and by TransEnterix International, Inc. The name of TransEnterix International, Inc. is to be considered a Confidential Information not to be disclosed to any third party before the execution of the public notarial deed and even after save as the disclosure will be required by the law or agreed by the Parties.

Should the condition precedent not materialise within 60 calendar days from the signature of this Agreement, the Agreement will become null and void.

ARTICLE 24 - Parent guarantee letter

VULCANOS shall, at the latest within 90 calendar days from the execution of this Agreement, submit a parent company guarantee letter to the Union, valid under Belgian law and duly signed by TransEnterix, Inc., a U.S. company duly incorporated or, with the Union's prior consent, by another legal entity presented by VULCANOS and having at least an equivalent financial solidity and good reputation. The name of TransEnterix, Inc. is to be considered a Confidential Information not to be disclosed to any third party before the execution of the public notarial deed and even after save as the disclosure will be required by the law or agreed by the Parties. The draft of the parent guarantee letter is attached as ANNEX D to this Agreement.

Should such guarantee letter not be provided with 90 days from the execution of this Agreement, VULCANOS will be in breach of its contractual obligations, with all contractual and legal consequences attached thereto, including as the case may be regarding possible damages for the Union in accordance with the applicable law.

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Done in Brussels,
In two originals in the English language

For the LICENSEE,
Date: 16 September, 2015
Andrea Biffi
Sole Director
VULCANOS s.r.l.

For the UNION,
Date: 18 September, 2015
Vladimir Šucha
Director-General
Joint Research Centre

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Annex A to the Agreement [**********]

Description of the Product

The Product consists of:

- [*****] patents altogether describing a tele-medical robotics system with [**********];
- the source code of the JRC- GENERIS software motion control system platform.

Patents description:

[**********]

[**********].

[**********]
[**********].

[**********]
[**********].

Description of the JRC-GENERIS software motion control system ([********]):

[**********].

[**********].

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Annex B to the Agreement [*************************]

Portfolio of the relevant Communities Patents and Software

[***]	**[*********]** [**********] [********** *********** *********** **********]	[**]	[************* ************** ************* ************]	[********** ************ ************ *************]	[************ ************** ************** ************* ********]
[***]	**[*********]** [**********] [********** *********** *********** **********]	[**]	[************* ************** ************* ************]	[********** ************ ************ *************]	[************ ************** ************** ************* ********]
[***]	**[*********]** [**********] [********** *********** *********** **********]	[**]	[************* ************** ************* ************]	[********** ************ ************ *************]	[************ ************** ************** ************* ********]
[****]**			[************ *********** ************* *******]		

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[**********]

[**********]

[**********]

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Annex D to the Agreement [**********]

Irrevocable Parent Company Guarantee

On Parent Company's head letter

, 2015

European Commission
Joint Research Centre (JRC)
Mr. Vladimir ŠUCHA, Director-General
SDME 06162
1049 Brussels
Belgium

- by registered letter anticipated by e-mail
@ec.europa.eu-

Re: Contract n. JRC - irrevocable parent company guarantee

Dear Sirs,

With reference to the contract n. (the "Contract") signed between the Union and Vulcanos s.r.l. on September , 2015, the undersigned with registered office in at , no personally and irrevocably guarantee with all its assets the fulfillment of the obligations of the Licensee, as defined in and provided by the Contract.

More in particular, the undersigned:

a) guarantees the due performance of the payment by the Licensee of all royalties due to the Union (minimum royalties and any other royalties) pursuant to the Contract, as and when such royalties become due;

b) agrees to be jointly and severally liable for the due respect of the above payment obligation, should the Licensee fail to perform in accordance with its payment obligations, including if such failure originates from insolvency, liquidation, bankruptcy, administration or any equivalent form of dissolution, composition or incapacity of the Licensee.

This guarantee is valid until the expiration of the Contract and in any case until all the obligations provided by the Contract will be duly fulfilled by the Licensee.

This guarantee shall be governed by and construed in accordance with the law of the European Union, complemented where necessary by the substantive laws of Belgium.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH "*" AND BRACKETS AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Any dispute resulting from the interpretation or application of this guarantee which it has not been possible to settle amicably shall be submitted to the jurisdiction of the General Court of the European Union in Luxembourg.

Best regards,

Name of the Company

Name of the Person who signed
Title and reference to authorization
(board resolution - by-laws)

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Todd M. Pope, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TransEnterix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Joseph P. Slattery, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TransEnterix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd M. Pope, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and 18 U.S.C. Section 1350, that the Quarterly Report on Form 10-Q of TransEnterix, Inc. (the "Company") for the quarterly period ended September 30, 2015 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2015

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

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Exchange Act, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph P. Slattery, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and 18 U.S.C. Section 1350, that the Quarterly Report on Form 10-Q of TransEnterix, Inc. (the "Company") for the quarterly period ended September 30, 2015 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2015

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

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Exchange Act, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.