TRANSENTERIX INC.
Form 10-Q
August 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC. 20549

FORM 10-Q

(Mark One)

x Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
for the Quarterly Period ended June 30, 2016

or

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

Commission File Number 0-19437

TRANSENTERIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	11-2962080
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
635 Davis Drive, Suite 300, Morrisville, NC	27560
(Address of principal executive offices)	(Zip code)

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

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

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

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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	o

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

115,000,060 shares of the Company’s common stock, par value $0.001 per share, were outstanding as of August 1, 2016.

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,” “in the event that,” “may,” “plans,” “potential,” “predicts,” “should” or “will” or the negative of these ter 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, 2015 filed on March 3, 2016, and other filings we make with the Securities and Exchange Commission. Furthermore, such forward-looking statements speak only as of the date of this report. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations except as required by applicable law. References in this report to “we”, “our”, “us”, or the “Company” refer to TransEnterix, Inc. and the combined enterprise of SafeStitch Medical, Inc., TransEnterix Surgical, Inc., TransEnterix International, Inc., TransEnterix Italia S.r.l, TransEnterix Europe S.Á.R.L and TransEnterix Europe S.Á.R.L, Bertrange, Swiss Branch, Cadempino.

TransEnterix, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2016	2015	June 30, 2016	2015
Operating Expenses				
Research and development	$6,364	$6,579	$14,749	$14,063
Sales and marketing	1,306	373	2,989	748
General and administrative	2,895	1,990	5,134	3,845
Amortization of intangible assets	1,786	126	3,603	251
Change in fair value of contingent consideration	944	—	1,800	—
Inventory write-down related to restructuring	2,565	—	2,565	—
Restructuring and other charges	3,085	—	3,085	—
Goodwill impairment	61,784	—	61,784	—
Total Operating Expenses	80,729	9,068	95,709	18,907
Operating Loss	(80,729)	(9,068)	(95,709)	(18,907)
Other Expense				
Interest expense, net	(489)	(280)	(1,067)	(561)
Other income	95	—	95	—
Total Other Expense, net	(394)	(280)	(972)	(561)
Loss before income taxes	$(81,123)	$(9,348)	$(96,681)	$(19,468)
Income tax benefit	992	—	3,637	—
Net loss	$(80,131)	$(9,348)	$(93,044)	$(19,468)
Other comprehensive loss				
Foreign currency translation (loss) gains	(2,286)	—	1,510	—
Comprehensive loss	$(82,417)	$(9,348)	$(91,534)	$(19,468)
Net loss per share - basic and diluted	$(0.70)	$(0.14)	$(0.85)	$(0.30)
Weighted average common shares outstanding - basic and diluted	114,319	68,105	109,290	65,937

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$64,609	$38,449
Accounts receivable, net	77	76
Inventories	4,247	3,923
Interest receivable	19	6
Other current assets	7,011	6,689
Total Current Assets	75,963	49,143
Restricted cash	289	—
Inventories, net of current portion	—	709
Property and equipment, net	4,743	4,408
Intellectual property, net	42,571	46,898
In-process research and development	16,811	16,511
Goodwill	69,756	130,869
Other long term assets	63	64
Total Assets	$210,196	$248,602
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$2,002	$4,450
Accrued expenses	7,344	7,395
Contingent consideration – current portion	12,500	12,500
Notes payable - current portion	7,658	6,727
Total Current Liabilities	29,504	31,072
Long Term Liabilities		
Contingent consideration – less current portion	12,800	11,000
Net deferred tax liabilities	12,920	16,263
Notes payable - less current portion, net of debt discount	9,080	12,990
Total Liabilities	64,304	71,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2016 and December 31, 2015; 115,000,003 and 100,180,872 shares issued at June 30, 2016 and December 31, 2015, respectively; and 114,928,458 and 100,149,453 shares outstanding at June 30, 2016 and December 31, 2015, respectively	115	100
Additional paid-in capital	423,544	363,280

Accumulated deficit	(275,908)	(182,864)
Treasury stock at cost, 71,545 and 31,419 shares at June 30, 2016 and December 31, 2015, respectively	(203)	(73)
Accumulated other comprehensive loss	(1,656)	(3,166)
Total Stockholders' Equity	145,892	177,277
Total Liabilities and Stockholders' Equity	$210,196	$248,602

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands)

(Unaudited)

	Common Stock Shares	Common Stock Amount	Treasury Stock Shares	Treasury Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance, December 31, 2015	100,180	$ 100	(31)	$ (73)	$ 363,280	$ (182,864)	$ (3,166)	$ 177,277
Stock-based compensation	—	—	—	—	2,477	—	—	2,477
Issuance of common stock, net of issuance costs	14,474	15	—	—	57,622	—	—	57,637
Exercise of stock options and restricted stock units	346	—	—	—	165	—	—	165
Return of common stock to pay withholding taxes on restricted stock	—	—	(41)	(130)	—	—	—	(130)
Other comprehensive gain	—	—	—	—	—	—	1,510	1,510
Net loss	—	—	—	—	—	(93,044)	—	(93,044)
Balance, June 30, 2016	115,000	$ 115	(72)	$ (203)	$ 423,544	$ (275,908)	$ (1,656)	$ 145,892

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2016	2015
Operating Activities		
Net loss	$ (93,044)	$ (19,468)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,052	517
Amortization of intangible assets	3,603	251
Amortization of debt discount and debt issuance costs	99	54
Stock-based compensation	2,477	1,667
Inventory write-down related to restructuring	2,565	—
Non-cash restructuring and other charges	2,551	—
Goodwill impairment	61,784	—
Deferred tax benefit	(3,657)	—
Change in fair value of contingent consideration	1,800	—
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts receivable	—	125
Interest receivable	(13)	—
Inventories	(3,983)	—
Other current and long term assets	(213)	150
Accounts payable	(2,497)	(162)

Accrued expenses	(60)	490
Restricted cash	(290)	250
Net cash and cash equivalents used in operating activities	(27,826)	(16,126)
Investing Activities		
Purchase of property and equipment	(517)	(311)
Net cash and cash equivalents used in investing activities	(517)	(311)
Financing Activities		
Payment of debt	(3,078)	—
Proceeds from issuance of common stock, net of issuance costs	57,637	52,533
Taxes paid related to net share settlement of vesting of restricted stock units	(130)	—
Proceeds from exercise of stock options and warrants	165	250
Net cash and cash equivalents provided by financing activities	54,594	52,783
Effect of exchange rate changes on cash and cash equivalents	(91)	—
Net increase in cash and cash equivalents	26,160	36,346
Cash and cash equivalents, beginning of period	38,449	34,766
Cash and cash equivalents, end of period	$ 64,609	$ 71,112
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 713	$ 375
Supplemental Schedule of Noncash Investing Activities		
Transfer of inventory to property and equipment	$ 1,823	$ —

See accompanying notes to consolidated financial statements.

TransEnterix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Capitalization

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

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

The SurgiBot System is designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. In June 2015, the Company submitted a 510(k) application to the FDA for the SurgiBot System and worked with the FDA to provide additional information as requested. On April 19, 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalence based on the data and information submitted by TransEnterix in the 510(k) submission. As a result, the Company has reprioritized its near-term regulatory efforts to focus on the 510(k) submission for the ALF-X System. Consequently, in May 2016, the Company implemented a restructuring plan. The restructuring plan resulted in: 1) reducing the Company's workforce; 2) abandoning certain equipment; 3) cancelling certain contracts; 4) writing off inventory related to the SurgiBot System; and 5) writing off certain patents. See Note 14 to the consolidated financial statements for further details.

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.

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

acquisition included all of the assets, employees and contracts related to the ALF-X System. See Note 3 for a description of the related transactions.

As used herein, the term “Company” refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, and includes TransEnterix International, TransEnterix Italia, TransEnterix Europe S.Á.R.L, and TransEnterix Europe S.Á.R.L, Bertrange, Swiss Branch, Cadempino after giving effect to the ALF-X Acquisition, the term “SafeStitch” refers to the historic business of SafeStitch Medical, Inc. prior to the Merger, and the term “TransEnterix Surgical” refers to the historic business of TransEnterix Surgical, Inc. prior to the Merger.

The Company operates in one business segment.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying unaudited interim condensed consolidated financial statements in accordance with the instructions to Form 10-Q and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Consequently, the Company has not necessarily included in this Form 10-Q all information and footnotes required for audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements in this Form 10-Q contain all adjustments, consisting only of normal recurring adjustments, except as otherwise indicated, necessary for a fair statement of its financial position, results of operations, and cash flows of the Company for all periods presented. The results reported in these condensed consolidated financial statements should not be regarded as necessarily indicative of results that may be expected for any subsequent period or for the entire year. These unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the Company's audited financial statements and the notes thereto included in the Company's latest Annual Report on Form 10-K. Certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted in the accompanying interim consolidated financial statements. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. 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., TransEnterix Italia S.r.l., TransEnterix Europe S.Á.R.L and TransEnterix Europe S.Á.R.L, Bertrange, Swiss Branch, Cadempino. All inter-company accounts and transactions have been eliminated in consolidation.

Use of Estimates

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

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.

Cash and Cash Equivalents

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.

Fair Value of Financial Instruments

The carrying values of cash equivalents, accounts receivable, interest receivable, accounts payable, and certain accrued expenses at June 30, 2016 and December 31, 2015, approximate their fair values due to the short-term nature of these items. The Company's notes payable balance approximates fair value as of June 30, 2016 and December 31, 2015, as the Company's notes payable were amended and modified in the third quarter of 2015.

2. Summary of Significant Accounting Policies (Continued)

Concentrations and Credit Risk

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

The Company's accounts receivable are derived from net revenue to customers and distributors located throughout the world. The Company evaluates its customers' financial condition and, generally, requires no collateral from its customers. The Company provides reserves for potential credit losses but has not experienced significant losses to date. The Company had one customer who constituted 100% of the Company's net accounts receivable at June 30, 2016 and December 31, 2015.

Accounts Receivable

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

Inventories

Inventories are stated at the lower of cost or market. Cost is based on the first in, first out method. The Company records reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Any inventory on hand at the measurement date in excess of the Company's current requirements based on anticipated levels of sales is classified as long-term on the Company's consolidated balance sheets. The Company's classification of long-term inventory requires it to estimate the portion of on-hand inventory that can be realized over the next 12 months.

Identifiable Intangible Assets and Goodwill

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 7 to 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Intellectual property consists of purchased patent rights and developed research and development acquired as part of a business acquisition. Amortization of the patent rights is recorded using the straight-line method over the estimated useful life of the patents of 10 years. Amortization of the developed research and development is recorded using the straight-line method over the estimated useful life of 7 years. This method approximates the period over which the Company expects to receive the benefit from these assets. See Note 10 for additional information related to the write-off of purchased patents in connection with the restructuring plan executed in May 2016. No impairment existed at December 31, 2015.

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 31 or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value based test. The Company continues to operate in one segment, which is considered to be the sole reporting unit and therefore, goodwill is tested for impairment at the enterprise level. See Note 10 for additional information related to goodwill impairment recorded during the second quarter of 2016. No impairment existed at December 31, 2015.

2. Summary of Significant Accounting Policies (Continued)

In-Process Research and Development

In-process research and development ("IPR&D") assets represent the fair value assigned to technologies that were acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. The IPR&D was acquired on September 21, 2015. No impairment existed at June 30, 2016 and December 31, 2015.

Property and Equipment

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

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

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

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

Impairment of Long-Lived Assets

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

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones

and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration at each reporting date is updated by reflecting the changes in fair value in our statement of operations and comprehensive loss.

Translation of Foreign Currencies

The functional currency of the Company’s foreign subsidiaries is Euros. The assets and liabilities of the Company’s foreign subsidiaries 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.

2. Summary of Significant Accounting Policies (Continued)

The Company's intercompany accounts are denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany receivables that the Company considers to be of a long-term investment nature are recorded as a cumulative translation adjustment in accumulated other comprehensive income or loss as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany receivables from a foreign subsidiary for which the Company anticipates settlement in the foreseeable future are recorded in the consolidated statement of operations and comprehensive loss. The net gains and losses included in net loss in the consolidated statements of operations and comprehensive loss for the six months ended June 30, 2016 and 2015 were not significant.

Business Acquisitions

Business acquisitions are accounted for using the acquisition method of accounting in accordance with 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. Under ASC 805, acquisition related costs (i.e., advisory, legal, valuation and other professional fees) and certain acquisition-related restructuring charges impacting the target company are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

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

Risk and Uncertainties

The Company is subject to a number of risks similar to other similarly-sized companies in the medical device industry. These risks include, without limitation, the historical lack of profitability; the Company's ability to raise additional capital; its ability to successfully integrate the ALF-X System into its business; its ability to successfully develop, clinically test and commercialize its products; the timing and outcome of the regulatory review process for its products; changes in the health care and regulatory environments of the United States, Italy, other countries in the European Union, 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.

Research and Development Costs

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

Stock-Based Compensation

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

2. Summary of Significant Accounting Policies (Continued)

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

The Company records as expense the fair value of stock-based compensation awards, including stock options and restricted stock units. Compensation expense for stock-based compensation was approximately $2,477,000 and $1,667,000 for the six months ended June 30, 2016 and 2015, respectively.

Income Taxes

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

Comprehensive Loss

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

Segments

The Company operates in one business segment—the research, development and sale of medical device robotics to improve minimally invasive surgery. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 56% of the Company's total consolidated assets are located within the U.S. as of June 30, 2016. The remaining assets are mostly located in Europe and are primarily related to the Company's facility in Italy, and include goodwill, intellectual property, in-process research and development, other current assets and inventory of $93.2 million at June 30, 2016, 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 June 30, 2016.

Impact of Recently Issued Accounting Standards

In March 2016, the FASB issued Accounting Standards Update ("ASU") 2016-09, Compensation – Stock Compensation (Topic 718) – Improvements to Employee Share-Based Payment Accounting. Under ASU 2016-09, the tax effects of stock compensation will be recognized as income tax expense or benefit in the income statement and the tax effects of exercised or vested awards will be treated as discrete items in the reporting period in which they occur. Along with other income tax cash flows, excess tax benefits will be classified as operating activities, and cash paid by an employer when directly withholding shares for tax withholding purposes will be classified as financing activities. Entities may make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur. The threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions. For public companies, ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted, however, an entity that elects early adoption must adopt all amendments under

the new standard in the same period. The Company is currently in the process of evaluating the impact of the amended guidance on our consolidated financial statements.

Except as noted above, there have been no significant changes to our assessment of the impact of recently issued accounting standards included in Note 2 of Notes to Consolidated Financial Statements in our Fiscal 2015 Form 10-K.

Reclassifications

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

3. Acquisition of ALF-X Surgical Robotic System

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

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

(1) $25.0 million of the Cash Consideration was paid at closing;

(2) The second tranche of the Cash Consideration (the "Second Tranche") of €10.0 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 $50.0 million in gross proceeds; with payment of simple interest at a rate of 9.0% per annum between the achievement of the first milestone event and the payment date;

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

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

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

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

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

In connection with the ALF-X Acquisition, the Company also entered into a Registration Rights Agreement, dated as of September 21, 2015, with SOFAR, pursuant to which the Company agreed to register the Securities Consideration shares for resale following the end of the lock-up periods described below. The resale Registration Statement has been filed and is effective, pending lapse of the lock-up restrictions.

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.

3. Acquisition of ALF-X Surgical Robotic System (Continued)

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	23,900
Total consideration	$92,577

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

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

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

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

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

All legal, consulting and other costs related to the acquisition, aggregating approximately $4.2 million, have been expensed as incurred and are included in operating expenses in the Company’s consolidated statement of operations and comprehensive loss for the year ended December 31, 2015. The results of operations for TransEnterix Italia are included in the Company’s consolidated statements of operations and comprehensive loss for the period from the September 21, 2015 acquisition date.

4. Cash, Cash Equivalents and Restricted Cash

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

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Cash	$5,511	$ 1,666
Money market	59,098	36,783
Total cash and cash equivalents	$64,609	$ 38,449
Restricted cash	$289	$ —
Total	$64,898	$ —

5. Fair Value

The Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets and liabilities include available for sale securities classified as cash and cash equivalents, restricted cash 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 June 30, 2016 and December 31, 2015, 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 June 30, 2016 and December 31, 2015, as they were modified in the third quarter of 2015.

The following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

	June 30, 2016 (In thousands) (unaudited)			
Description	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Total

	Identical Assets (Level 1)	(Level 2)	(Level 3)	
Assets measured at fair value				
Cash and cash equivalents	$64,609	$ —	$ —	$64,609
Restricted cash	289	—	—	289
Total Assets measured at fair value	$64,898	$ —	$ —	$64,898
Liabilities measured at fair value				
Contingent consideration	$—	$ —	$ 25,300	$25,300
Total liabilities measured at fair value	$—	$ —	$ 25,300	$25,300

5. Fair Value (Continued)

	December 31, 2015 (In thousands)			
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets measured at fair value				
Cash and cash equivalents	$38,449	$ —	$ —	$38,449
Total Assets measured at fair value	$38,449	$ —	$ —	$38,449
Liabilities measured at fair value				
Contingent consideration	$—	$ —	$ 23,500	$23,500
Total liabilities measured at fair value	$—	$ —	$ 23,500	$23,500

The Company's financial liabilities consisted of contingent consideration potentially payable to SOFAR related to the ALF-X acquisition in September 2015 (Note 3). This liability is reported as Level 3 as estimated fair value of the contingent consideration related to the acquisition requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome. The change in fair value of the contingent consideration of $1,800,000 for the six months ended June 30, 2016 was primarily due to the effect of the passage of time on the fair value measurement and the impact of foreign currency exchange rates. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statements of operations and comprehensive loss.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 as of September 21, 2015, December 31, 2015, and June 30, 2016:

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

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the six months ended June 30, 2016:

	Fair Value Measurement at Reporting Date (Level 3) (In thousands) (unaudited)
Balance at December 31, 2015	$ 23,500
Change in fair value	1,800
Balance at June 30, 2016	$ 25,300
Current portion	12,500
Long-term portion	12,800
Balance at June 30, 2016	$ 25,300

6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Gross accounts receivable	$ 77	$ 76
Allowance for uncollectible accounts	—	—
Total accounts receivable, net	$ 77	$ 76

7. Inventories

The components of inventories are as follows:

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Finished goods	$4,247	$ 2,704
Raw materials	—	1,928
Total inventories	$4,247	$ 4,632
Short-term portion	$4,247	$ 3,923
Long-term portion	—	709
Total inventories	$4,247	$ 4,632

As disclosed in Note 14, the Company executed a restructuring plan in May 2016 and wrote down inventory related to the SurgiBot System. The write down of inventory of $2.6 million is included in the accompanying consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2016. There were no such write-downs for the three and six month periods ended June 30, 2015.

8. Other Current Assets

The following table presents the components of other current assets:

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Advances to vendors	$5,007	$ 5,403
Prepaid expenses	1,075	750
Other receivables	929	536
Total	$7,011	$ 6,689

9. Property and Equipment

Property and equipment consisted of the following:

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Machinery and manufacturing equipment	$6,367	$ 5,846
Computer equipment	1,986	1,875
Furniture	384	374
Leasehold improvements	1,717	1,700
Total property and equipment	10,454	9,795
Accumulated depreciation and amortization	(5,711)	(5,387)
Property and equipment, net	$4,743	$ 4,408

As disclosed in Note 14, the Company executed a restructuring plan in May 2016 and disposed of certain long-lived assets, primarily equipment and fixtures related to the SurgiBot System. The disposal of long-lived assets of $1.0 million is included as a component of restructuring and other charges in the accompanying consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2016. There were no such disposals for the three and six months ended June 30, 2015.

Depreciation expense was $1,052,000 and $517,000 for the six months ended June 30, 2016 and 2015, respectively.

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

Goodwill

Goodwill of $93.8 million was recorded in connection with the Merger, as discussed in Note 1, and goodwill of $38.3 million was recorded in connection with the ALF-X Acquisition, as discussed in Note 3. The carrying value of goodwill and the change in the balance for the six months ended June 30, 2016 is as follows:

	Goodwill (In thousands) (unaudited)
Balance at December 31, 2015	$ 130,869
Foreign currency translation impact	671
Impairment loss	(61,784)
Balance at June 30, 2016	$ 69,756

The Company performs an annual impairment test of goodwill at December 31, or more frequently if events or changes in circumstances indicates that the carrying value of the Company’s one reporting unit may not be recoverable. During the second quarter of 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalency, negatively impacting the Company’s market capitalization, and warranting an interim two-step quantitative impairment test. Goodwill is tested for impairment using a two-step approach. In the first step, the fair value of the reporting unit is determined and compared to the reporting unit's carrying value, including goodwill. If the fair value of the reporting unit is less than its carrying value, the second step of the goodwill impairment test is performed to measure the amount of impairment, if any. In the second step, the fair value of the reporting unit is allocated to the assets and liabilities of the reporting unit as if it had been acquired in a business combination and the purchase price was equivalent to the fair value of the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is referred to as the implied fair value of goodwill. The implied fair value of the reporting unit's goodwill is then compared to the actual carrying value of goodwill. If the implied fair value of goodwill is less than the carrying value of goodwill, an impairment loss is recognized for the difference.

The Company determined the fair value of the reporting unit using a discounted cash flow analysis derived from the Company’s long-term plans. The fair value of the reporting unit was corroborated using market prices for TransEnterix, Inc. The inputs used to determine the fair values were classified as Level 3 in the fair value hierarchy. Based on the impairment test, the Company recorded goodwill impairment of $61.8 million during the second quarter of 2016. No impairment was recorded as of December 31, 2015. While the Company has substantially completed all actions necessary in the determination of the implied fair value of goodwill, some of the estimated fair values and allocations are subject to adjustment once the valuations and other computations are completed. The Company will finalize these items and record any required adjustments as it obtains information necessary to complete the analysis, which the Company expects to occur in the third quarter of 2016. Depending on the changes in the Company’s business outlook and other assumptions underlying the fair value measurements of the Company’s reporting unit, the Company may be required to recognize additional goodwill impairments.

In-Process Research and Development

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

The carrying value of the Company's IPR&D assets and the change in the balance for the six months ended June 30, 2016 is as follows:

	In-Process Research and Development
	(In thousands) (unaudited)
Balance at December 31, 2015	$ 16,511
Foreign currency translation impact	300
Balance at June 30, 2016	$ 16,811

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

Intellectual Property

In 2009, the Company purchased certain patents from an affiliated company for $5 million in cash and concurrently terminated a license agreement related to the patents. The patent expiration dates begin in 2027. In addition, as described in Note 3, on September 21, 2015, the Company acquired all of the developed technology related to the ALF-X System and recorded $48.5 million of intellectual property. The estimated fair value of the intellectual property was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 45% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

As disclosed in Note 14, the Company executed a restructuring plan in May 2016 and wrote-off certain intellectual property consisting of patents related to the SurgiBot System. The write-off of intellectual property of $1.6 million is included as a component of restructuring and other charges in the accompanying consolidated statements of operations and comprehensive losses for the three and six months ended June 30, 2016. There were no such write offs for the three and six months ended June 30, 2015.

The components of gross intellectual property, accumulated amortization, and net intellectual property as of June 30, 2016 and December 31, 2015 are as follows:

	June 30, 2016 (In thousands)					December 31, 2015 (In thousands)			
	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation impact	Write-off	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation impact	Net Carrying Amount
Patents	$5,000	$ (3,438)	$ —	$ (1,562)	$—	$5,000	$ (3,259)	$ —	$1,741
Developed technology	48,500	(5,108)	(821)	—	42,571	48,500	(1,672)	(1,671)	45,157
Total intellectual property	$53,500	$ (8,546)	$ (821)	$ (1,562)	$42,571	$53,500	$ (4,931)	$ (1,671)	$46,898

11. 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 6.7% for the year ending December 31, 2016. This rate does not include the impact of any discrete items. The Company incurred losses for the three and six month periods ended June 30, 2016 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, 2016. 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 and 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 deferred tax benefit during the six months ended June 30, 2016 of approximately $3.6 million includes an immaterial adjustment of approximately $1.7 million to the deferred tax liability of TransEnterix Italia which relates to a change in the Italian income tax rate in December 2015.

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 six month periods ended June 30, 2016 and 2015 was 3.8% and 0%, respectively. The effective tax rate for June 30, 2016 includes the tax effect of the Company's goodwill impairment charge, which is being treated as a discrete item for the quarter ending June 30, 2016. At June 30, 2016, the Company had no unrecognized tax benefits that would affect the Company's effective tax rate.

12. Accrued Expenses

The following table presents the components of accrued expenses:

	June 30, 2016	December 31, 2015
	(In thousands) (unaudited)	
Taxes and other assessments	$3,072	$ 3,112
Compensation and benefits	1,814	2,492
Consulting and other vendors	954	553
Interest and final payment fee	743	411
Deferred rent	231	278
Legal and professional fees	205	268
Restructuring charges	199	—
Other	126	281
Total	$7,344	$ 7,395

13. Notes Payable

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

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

On August 14, 2015, the Company entered into the First Amendment to the Amended and Restated Loan Agreement (the “First Amendment”) with the Lenders. The first tranche of the First Amendment increased the Company’s borrowings at August 14, 2015 from $10,000,000 to $20,000,000. The First Amendment allowed for interest-only payments at 7.5% per annum through April 30, 2016 and a maturity date of October 1, 2018.

On September 18, 2015, in connection with entry into the Purchase Agreement with SOFAR S.p.A. (see Note 3 for a description of the related transactions), the Company and the Lenders entered into the Consent and Second Amendment to Amended and Restated Loan Agreement (the “Second Amendment”). The Second Amendment modified

the period in which the Company can make interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The Second Amendment has a maturity date of July 1, 2018.

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

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

13. Notes Payable (Continued)

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

Further, under the Second Amendment, the Lenders consented to the formation of TransEnterix International, the entry of the Company into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. The Company agreed to pledge 100% of the common stock of TransEnterix International as additional security for the borrowings under the Amended and Restated Loan Agreement, as amended. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Amended and Restated Loan Agreement. This provision for the transfer of designated amount was amended on November 13, 2015 with the Third Amendment to the Amended and Restated Loan Agreement. On April 19, 2016, the Company and its U.S. subsidiaries entered into the Consent and Fourth Amendment to the Loan Agreement (the "Fourth Amendment") pursuant to which TransEnterix International, joined the Loan Agreement and the existing promissory notes as a co-borrower thereunder and pledged, as collateral for the obligations under the Loan Agreement, substantially all of its non-intellectual property assets, including up to 65% of the equity interests owned by TransEnterix International in TransEnterix Europe S.Á.R.L, a wholly owned subsidiary of TransEnterix International.

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

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

In connection with the issuance of the notes payable and its amendments, TransEnterix Surgical incurred approximately $371,000 in debt issuance costs paid to lenders and third parties and $280,000 in debt issuance costs related to issuance of warrants to the lenders. The unamortized balance of $185,000 as of June 30, 2016 will be amortized using the effective interest method.

14. Restructuring

On April 19, 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalence based on the data submitted in the 510(k) submission. As a result, the Company has reprioritized its efforts to focus on the commercialization of and regulatory clearance for the ALF-X System. Consequently, in May 2016, the Company implemented a restructuring plan. Under the restructuring plan, the Company reduced headcount, discontinued efforts on the SurgiBot System, and cancelled certain contracts. The restructuring charges amounted to $5.7 million, of which $2.6 million was included as inventory write down related to restructuring and $3.1 million was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, during the second quarter of 2016.

The restructuring and other charges of $3.1 million included: (i) $0.5 million to be paid in cash, of which $0.4 million related to employee severance costs and $0.1 million related to cancellation of certain contracts; and (ii) $2.6 million for other non-cash charges, of which $1.0 million related to the disposal of long-lived assets for the abandonment of certain equipment and tooling directly relating to the SurgiBot System and $1.6 million related to the write-off of intellectual property for certain patents also relating to the SurgiBot System. The Company does not anticipate additional restructuring charges in 2016. The total future payments under the restructuring plan as of June 30, 2016 included in accrued expenses in the consolidated balance sheet as of June 30, 2016 are $199,000.

15. Public Offerings of Common Stock

On February 20, 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "2015 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), as sales agent, pursuant to which the Company sold 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 were 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. Sales under the 2015 Sales Agreement have been fully sold as of February 9, 2016, with cumulative shares of 7,724,488, gross proceeds of $25.0 million and net proceeds of $24.0 million.

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 March 3, 2016, the Company filed an amendment to the November 2014 Shelf Registration Statement increasing the amount available from $100.0 million to $150.0 million.

On February 9, 2016, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "2016 Sales Agreement") with Cantor, as sales agent, pursuant to which the Company can sell through Cantor, from time to time, up to $43.56 million in shares of common stock in an at-the-market offering. All sales of shares have been and will continue to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The Company pays Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2016 Sales Agreement. Unless otherwise terminated earlier, the 2016 Sales Agreement continues until all shares available under the Sales Agreement have been sold.

The following table summarizes the total sales under the 2015 Sales Agreement and 2016 Sales Agreement for the periods indicated (in thousands, except per share amounts):

	2015 Sales Agreement		2016 Sales Agreement
	Six Months Ended	Year Ended December 31, 2015	Six Months Ended

	June 30, 2016		June 30, 2016
Total shares of common stock sold	5,710.2	2,014.3	8,763.4
Average price per share	$3.23	$ 3.25	$ 4.70
Gross proceeds	$18,454	$ 6,546	$ 41,156
Commissions earned by Cantor	$553	$ 197	$ 1,235
Other issuance costs	$—	$ 259	$ 185

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.

16. Stock-Based Compensation

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

The Plan was approved by the majority of the SafeStitch's stockholders on November 13, 2007. The Plan was amended on June 19, 2012 to increase the number of shares of common stock available for issuance to 1,000,000 and was amended on October 29, 2013 to (a) increase the number of shares of common stock authorized for issuance under the 2007 Plan from 1,000,000 shares of common stock to 4,940,000 shares of common stock; and (b) increase the per-person award limitations for options or stock appreciation rights from 200,000 to 1,000,000 shares and for restricted stock, deferred stock, performance shares and/or other stock-based awards from 100,000 to 500,000 shares. The Plan was amended on May 7, 2015 to (a) increase the number of shares reserved for issuance under the Plan to 11,940,000 shares; (b) extend the term of the Plan until May 7, 2025; and (c) make other changes and updates to the Plan. The Plan was amended on June 8, 2016 to (a) approve an increase in the number of shares reserved for issuance under the Plan to 18,940,000 shares and (b) establish maximum equity award limits for initial awards and annual awards to non-employee directors. Under the Plan, which is administered by the Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock and/or deferred stock to employees, officers, directors, consultants and vendors. The exercise price of stock options or stock appreciation rights may not be less than the fair market value of the Company's shares at the date of grant. Additionally, no stock options or stock appreciation rights granted under the Plan may have a term exceeding ten years.

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

17. Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options and warrants and conversion of preferred stock. In computing diluted net loss per share for the six months ended June 30, 2016 and 2015, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants and conversion of preferred stock would be anti-dilutive.

18. Related Person Transactions

Synergy Life Science Partners, L.P. and Synecor, LLC collectively owned approximately 5% and 7% of the Company's common stock at June 30, 2016 and 2015, respectively. A member of the Company's Board of Directors is managing partner of Synergy Life Science Partners, L.P. and an executive officer of Synecor, LLC. Various research and development services were purchased by the Company from Synecor LLC and its wholly owned subsidiary Synchrony Labs LLC pursuant to arms' length terms approved by the Audit Committee and totaled approximately $5,000 and $431,000 for the six months ended June 30, 2016 and 2015, respectively.

On September 18, 2015, TransEnterix Italia entered into a six month service agreement for administrative expenses and rent with SOFAR, a shareholder that owned approximately 14% and 0% of the Company's common stock at June 30, 2016 and 2015, respectively. Expenses under this agreement were approximately $162,000 and $0 for the six months ended June 30, 2016 and 2015, respectively.

19. Commitments and Contingencies

Contingent Consideration

As discussed in Note 3, in September 2015, the Company completed the ALF-X Acquisition using a combination of cash, stock and potential post-acquisition milestone payments. These milestone payments may be payable in the future, depending on the achievement of certain regulatory and commercial milestones. The maximum amount of the aggregate milestone payments could be €27.5 million. As of June 30, 2016, the fair value of the contingent consideration was $25.3 million.

19. Commitments and Contingencies (Continued)

Operating Leases

On November 2, 2009, TransEnterix Surgical entered into an operating lease for its corporate offices for a period of five years commencing in April 2010. On June 12, 2014, the Company entered into a lease amendment extending the term of the lease for a period of 3 years and 2 months commencing on May 1, 2015 and expiring on June 30, 2018, with an option to renew for an additional three years. On October 25, 2013, the Company entered into an operating lease for its warehouse for a period of four years and four months commencing in January 2014, with an option to renew for an additional six years. On May 12, 2016, TransEnterix Italia S.r.l entered into an operating lease for its corporate offices for a period of six years and three months commencing in May 2016.

Rent expense was approximately $345,000 and $298,000 for the six months ended June 30, 2016 and 2015, respectively.

The Company’s approximate future minimum payments for its operating lease obligations that have initial or remaining noncancelable terms in excess of one year as of December 31, 2015 are as follow:

Years ending December 31,	(In thousands)
2016	$ 592
2017	710
2018	579
2019	289
2020	289
Thereafter	457
Total	$ 2,916

Legal Proceedings

On June 2, 2016, a stockholder filed a putative class action complaint, Ashok V. Bankley, individually and on behalf of all others similarly situated vs. TransEnterix, Inc., Todd M. Pope and Joseph P. Slattery, in the United States District Court for the Eastern District of North Carolina (Case No. 5:16-cv-00313-D) (the “Bankley Action”), against TransEnterix, Inc. (the “Company”) and two of its executive officers on behalf of all persons who purchased or otherwise acquired the Company’s common stock between February 10, 2016 and May 10, 2016. The complaint in the Bankley Action alleges that the defendants made false and misleading public statements related to the Company's SurgiBot System and its 510(k) application in violation of certain federal securities laws. The complaint in the Bankley Action seeks class certification for a class consisting of all persons who purchased or otherwise acquired the Company’s common stock between February 10, 2016 and May 10, 2016, unspecified monetary damages, costs, and attorneys’ fees. On June 9, 2016, a different stockholder filed another putative class action complaint, Thomas Ravey, individually and on behalf of all others similarly situated vs. TransEnterix, Inc., Todd M. Pope and Joseph P. Slattery, in the United States District Court for the Middle District of North Carolina (Case No. 1:16-cv-599) (the “Ravey Action”). The Ravey Action asserted substantially similar claims against the same defendants and seeks substantially

similar relief as the Bankley Action. On August 4, 2016, the plaintiff in the Ravey Action voluntarily dismissed the Ravey Action. On August 4, 2016, the defendants filed a motion to dismiss the Bankley Action for failure to state a claim under the securities laws.

On July 8, 2016, a stockholder filed a putative derivative complaint, Otto Pikal v. Todd M. Pope, et al., in the General Court of Justice, Superior Court Division, Wake County, North Carolina (case number 16CV008930), on behalf of the Company against certain of our current officers and directors. The complaint alleges, among other things, that the defendants breached their fiduciary duties by disseminating false and misleading information to the Company's shareholders relating to the Company's SurgiBot System and its 510(k) application in violation of certain federal securities laws and by failing to ensure that the Company maintained adequate internal controls. The complaint seeks, among other things, unspecified monetary damages and an order directing the Company to take steps to improve its corporate governance and to protect the Company and its stockholders from future wrongdoing such as that alleged in the complaint. The defendants have not been served with the suit, and the time for defendants to respond to the complaint has not yet expired.

On April 25, 2016, Intuitive Surgical, Inc. and its French subsidiary, Intuitive Surgical SAS (collectively, "Intuitive"), brought a request for unilateral measures of enquiry in front of the President of the Commercial Court of Toulon (France) (the "President") against two employees of TransEnterix International, Inc. alleging that the company, through these two employees, engaged in acts of unfair competition. On May 3, 2016, the President rendered an order granting Intuitive's request for unilateral measures of enquiry with respect to its allegations (the "Order"). On June 28, 2016, TransEnterix International filed a writ challenging the Order and

requesting that it be withdrawn by the President. The parties are awaiting the President's decision with respect to TransEnterix International's challenge and withdrawal request, which is expected to occur in September 2016.

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

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

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

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. In June 2015, the Company submitted a 510(k) application to the FDA for the SurgiBot System and worked with the FDA to provide additional information as requested. On April 19, 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalence based on the data and information submitted by TransEnterix in the 510(k) submission. The Company is in the process of obtaining additional information from the FDA to determine the level of effort and investment necessary to obtain clearance for the SurgiBot System.

Our current strategy is to focus our resources on the commercialization of and regulatory clearance for the ALF-X System. After recent interactions with the FDA, we believe that a new 510(k) application would need to be submitted in order to obtain clearance for the SurgiBot System. Based on this belief, we have evaluated the operational and financial feasibility of pursuing two 510(k) applications in parallel and have elected to primarily focus our near term efforts on the 510(k) submission for the ALF-X System and we have delayed any decision related to pursuit of regulatory clearance for the SurgiBot System until after we have completed our discussions with the FDA.

Consequently, in May 2016, the Company implemented a restructuring plan. The restructuring plan resulted in: 1) reducing the Company's workforce; 2) abandoning certain equipment; 3) cancelling certain contracts; 4) writing off inventory related to the SurgiBot System; and 5) writing off certain patents.

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

Since inception, we have been unprofitable. As of June 30, 2016 we had an accumulated deficit of $275.9 million.

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

We operate in one business segment.

Recent Events

Controlled Equity Offering

On February 9, 2016, we entered into a Controlled Equity Offering[SM] Sales Agreement (the "2016 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") under which we can offer and sell, through Cantor, up to approximately $43.6 million in shares of common stock in an at-the market offering (the "2016 ATM Offering"). On February 20, 2015, we had entered into a Controlled Equity Offering[SM] Sales Agreement (the "2015 Sales Agreement") with Cantor, as sales agent, pursuant to which we offered and sold,

through Cantor, $25.0 million in shares of common stock in an at-the-market offering from February 2015 through February 2016 (the "2015 ATM Offering"). All sales of shares were made pursuant to an effective shelf registration statement on Form S-3 filed with the Securities and Exchange Commission (the "SEC"). We pay Cantor a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2015 Sales Agreement and the 2016 Sales Agreement.

The following table summarizes the total sales under the 2015 Sales Agreement and 2016 Sales Agreement for the periods indicated (in thousands, except per share amounts):

	2015 Sales Agreement Six Months Ended June 30, 2016	2015 Sales Agreement Year Ended December 31, 2015	2016 Sales Agreement Six Months Ended June 30, 2016
Total shares of common stock sold	5,710.2	2,014.3	8,763.4
Average price per share	$3.23	$ 3.25	$ 4.70
Gross proceeds	$18,454	$ 6,546	$ 41,156
Commissions earned by Cantor	$553	$ 197	$ 1,235
Other issuance costs	$—	$ 259	$ 185

2015 Events

Public Offering

On June 11, 2015, we sold 16,666,667 shares of common stock at a public offering price of $3.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 2,500,000 shares of common stock to cover over-allotments. The common stock was offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-199998) registering an aggregate of $100.0 million of our designated securities. The closing of the public offering occurred on June 17, 2015. On July 10, 2015, the underwriters exercised a portion of their over-allotment option to acquire an additional 2,075,000 shares at the public offering price of $3.00 per share for aggregate additional gross proceeds of $6.2 million. The purchase of the over-allotment shares closed on July 15, 2015. Total proceeds were $52.2 million, net of issuance costs of $4.0 million.

ALF-X Acquisition and Related Transactions

Membership Interest Purchase Agreement

On September 21, 2015, the Company announced that it had entered into a Membership Interest Purchase Agreement, dated September 18, 2015 (the "Purchase Agreement") with SOFAR S.p.A., (the "Seller"), Vulcanos S.r.l., as the acquired company, and TransEnterix International, Inc., a wholly owned subsidiary of the Company (the "Buyer"). The closing of the transactions contemplated by the Purchase Agreement occurred on September 21, 2015 (the "Closing Date")

pursuant to which the Buyer acquired all of the membership interests of the acquired company from the Seller, and changed the name of the acquired company to TransEnterix Italia S.r.l ("TransEnterix Italia"). On the Closing Date, pursuant to the Purchase Agreement, the Company completed the strategic acquisition from SOFAR S.p.A. of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery known as TELELAP ALF-X (the "ALF-X Acquisition").

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

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

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

Registration Rights and Lock-Up Agreements

In connection with the ALF-X Acquisition, we also entered into a Registration Rights Agreement, dated as of September 21, 2015, with the Seller, pursuant to which we agreed to register the Securities Consideration shares for resale following the end of the lock-up periods described below. The resale Registration Statement has been filed and is effective, pending lapse of the lock-up restrictions.

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

Amendment to Loan Agreement

In connection with entry into the Purchase Agreement, we sought the consent of Silicon Valley Bank (“SVB”), as a Lender, and Oxford Finance LLC (“Oxford”), as Lender and Collateral Agent under our existing Amended and Restated Loan and Security Agreement, dated as of September 26, 2014, as amended by the First Amendment, dated August 14, 2015 (collectively, the “Loan Agreement”), and entered into the Consent and Second Amendment to Amended and Restated Loan Agreement (the “Second Amendment”). Under the Second Amendment, the Lenders and Collateral Agent consented to the formation of the Buyer, the entry of the Company and Buyer entering into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. We agreed to pledge 100% of the common stock of the Buyer as additional security for the borrowings under the Loan Agreement. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Loan Agreement. Further, the Second Amendment modified the period in which we could make interest-only payments on the term loans until January 31, 2016. On April 19, 2016, the Company and its U.S. subsidiaries entered into the Consent and Fourth Amendment to the Loan Agreement (the “Fourth Amendment”) pursuant to which TransEnterix International, joined the Loan Agreement and the existing promissory notes as a co-borrower thereunder and pledged, as collateral for the obligations under the Loan Agreement, substantially all of its non-intellectual property assets, including up to 65% of the equity interests owned by TransEnterix International in TransEnterix Europe S.á.r.l., a wholly owned subsidiary of TransEnterix International.

2013 Merger Transaction

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

Results of Operations

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

Research and Development

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

R&D expenses for the three months ended June 30, 2016 decreased to $6.4 million as compared to $6.6 million for the three months ended June 30, 2015. The $0.2 million decrease resulted primarily from decreased SurgiBot System contract engineering services of $2.0 million, decreased supplies expense of $0.5 million, offset by increased preclinical lab expense of $0.3 million, increased other expenses of $0.3 million and expenses incurred for development of the ALF-X System acquired in September 2015 of $1.7 million.

The R&D expenses of $1.7 million related to product development of the ALF-X System in 2016 consisted primarily of personnel related costs $0.6 million, supplies expense of $0.5 million, contract engineering services, consulting and other outside services of $0.4 million, and other costs of $0.2 million.

R&D expenses for the six months ended June 30, 2016 increased to $14.7 million as compared to $14.1 million for the six months ended June 30, 2015. The $0.6 million increase resulted primarily from increased expenses incurred for development of the ALF-X System acquired in September 2015 of $3.0 million, increased personnel related costs of $0.5 million, increased other costs of $0.8 million, increased preclinical lab expense of $0.5 million, increased stock compensation costs of $0.3 million, offset by decreased SurgiBot System contract engineering services, consulting and other outside services of $3.1 million, and decreased supplies expense of $1.4 million. The R&D expenses of $3.0 million related to product development of the ALF-X System in 2016 consisted primarily of supplies expense of $1.1 million, personnel related costs $1.0 million, contract engineering services, consulting and other outside services of $0.6 million and other costs of $0.3 million.

Sales and Marketing

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshows, marketing clinical studies and consulting expenses. We expect sales and marketing expenses to increase significantly in 2016 in support of our ALF-X System product launch.

Sales and marketing expenses for the three months ended June 30, 2016 increased to $1.3 million compared to $0.4 million for the three months ended June 30, 2015. The $0.9 million increase was primarily related to increased personnel related costs of $0.4 million, increased tradeshow costs of $0.1 million, increased travel related expenses of $0.1 million, and increased consulting costs of $0.1 million. In addition, sales and marketing expenses related to the ALF-X System in 2016 were $0.2 million.

Sales and marketing expenses for the six months ended June 30, 2016 increased to $3.0 million compared to $0.7 million for the six months ended June 30, 2015. The $2.3 million increase was primarily related to increased personnel related costs of $0.8 million, increased stock compensation costs of $0.2 million, increased tradeshow costs of $0.3 million, increased travel related expenses of $0.2 million, increased consulting costs of $0.2 million, and increased other costs of $0.2 million. In addition, sales and marketing expenses related to the ALF-X System in 2016 were $0.4 million.

General and Administrative

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

General and administrative expenses for the three months ended June 30, 2016 increased to $2.9 million compared to $2.0 million for the three months ended June 30, 2015. The $0.9 million increase was primarily due to increased legal, accounting, and investor relation fees and other public company costs of $0.3 million and $0.6 million in general and administrative expenses related to the ALF-X System in 2016.

General and administrative expenses for the six months ended June 30, 2016 increased to $5.1 million compared to $3.8 million for the six months ended June 30, 2015. The $1.3 million increase was primarily due to increased personnel costs of $0.2 million, increased stock compensation costs of $0.2 million, increased legal, accounting, and investor relation fees and other public company costs of $0.5 million, and $0.7 million in general and administrative expenses related to the ALF-X System in 2016, offset by decreases in other expenses of $0.3 million.

Amortization of Intangible Assets

Amortization of intangible assets for the three months ended June 30, 2016 increased to $1.8 million compared to $0.1 million for the three months ended June 30, 2015. The $1.7 million increase was primarily the result of amortization of developed technology related to the acquisition of the ALF-X System on September 21, 2015.

Amortization of intangible assets for the six months ended June 30, 2016 increased to $3.6 million compared to $0.3 million for the six months ended June 30, 2015. The $3.3 million increase was primarily the result of amortization of developed technology related to the acquisition of the ALF-X System on September 21, 2015.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration in connection with the ALF-X Acquisition was $0.9 million for the three months ended June 30, 2016 primarily related to the effect of the passage of time on the fair value measurement and the impact of foreign currency exchange rates.

The change in fair value of contingent consideration in connection with the ALF-X Acquisition was $1.8 million for the six months ended June 30, 2016 primarily related to the effect of the passage of time on the fair value measurement and the impact of foreign currency exchange rates.

Inventory write-down related to restructuring

On April 19, 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalence based on the data submitted in the 510(k) submission. As a result, we reprioritized our near-term regulatory efforts to the 510(k) submission for the ALF-X System. Consequently, in May 2016, the Company implemented a restructuring plan. Under this plan, we recorded a $2.6 million write-down of inventory related to the SurgiBot System.

Restructuring and other charges

Under the restructuring plan executed in May 2016, we recorded $3.1 million in restructuring and other charges. The restructuring charges included: (i) $0.5 million to be paid in cash, of which $0.4 million related to employee severance costs and $0.1 million related to cancellation of certain contracts; and (ii) $2.6 million for other non-cash charges, of which $1.0 million related to the write-off of long-lived assets for the abandonment of certain equipment and tooling and $1.6 million related to the write-off of intellectual property for certain patents.

Goodwill impairment

The Company performs an annual impairment test of goodwill at December 31, or more frequently if events or changes in circumstances indicates that the carrying value of our one reporting unit may not be recoverable. During the second quarter of 2016, we were notified by the FDA that the SurgiBot System did not meet the criteria for substantial equivalency, negatively impacting our market capitalization, and warranting an interim two-step quantitative impairment test. Based on the impairment test, we recorded goodwill impairment of $61.8 million during the second quarter of 2016. While the Company has substantially completed all actions necessary in the determination of the implied fair value of goodwill, some of the estimated fair values and allocations are subject to adjustment once the valuations and other computations are completed. The Company will finalize these items and record any required adjustments as it obtains information necessary to complete the analysis, which the Company expects to occur in the third quarter of 2016.

Other Expense, Net

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

Other expense for the three months ended June 30, 2016 increased to $0.4 million compared to $0.3 million for the three months ended June 30, 2015. The $0.1 million increase was primarily related to the increase in notes payable of approximately $10.0 million in August 2015.

Other expense for the six months ended June 30, 2016 increased to $1.0 million compared to $0.6 million for the six months ended June 30, 2015. The $0.4 million increase was primarily related to the increase in notes payable of approximately $10.0 million in August 2015.

Income Tax Benefit

Income tax benefit consists primarily of taxes related to the amortization of purchase accounting intangibles in connection with the Italian taxing jurisdiction for TransEnterix Italia as a result of the acquisition of the ALF-X System. We recognized $1.0 million and $3.6 million of income tax benefit for the three and six months ended June 30, 2016, respectively.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception we have incurred significant losses and, as of June 30, 2016, we had an accumulated deficit of $275.9 million. We have not yet achieved profitability and we cannot assure investors that we will achieve profitability with our existing capital resources. We expect research and development, sales and marketing and general and administrative expenses will continue at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash to date have been proceeds from public offerings of common stock, private placements of common and preferred stock, incurrence of debt and the sale of equity securities held as investments.

We currently have two effective shelf registration statements on file with the SEC, each of which were initially filed to register up to $100.0 million of debt securities, common stock, preferred stock, or warrants, or any combination thereof for future financing transactions. In March 2016, the November 2014 shelf registration statement was increased by $50.0 million. From April 2014 through June 2016, we have raised $178.8 million in gross proceeds and approximately $168.4 million in net proceeds under such shelf registration statements through public offerings of our securities as described above. As of June 30, 2016 we had $71.2 million available for future financings under such shelf registration statements, including approximately $2.4 million available under the 2016 ATM Offering.

At June 30, 2016, we had cash and cash equivalents of approximately $64.6 million.

Consolidated Cash Flow Data

	Six months ended June 30, 2016	Six months ended June 30, 2015
(in thousands)		
Net cash provided by (used in)		
Operating activities	$(27,826)	$(16,126)
Investing activities	(517)	(311)
Financing activities	54,594	52,783
Effect of exchange rate changes on cash and cash equivalents	(91)	—
Net increase in cash and cash equivalents	$26,160	$36,346

Operating Activities

For the six months ended June 30, 2016, cash used in operating activities of $27.8 million consisted of net loss of $93.0 million and cash used for working capital of $7.1 million, offset by non-cash items of $72.3 million. The non-cash items primarily consisted of $61.8 million goodwill impairment, $2.6 million inventory write-down related

to restructuring, $2.6 million non-cash restructuring and other charges, $2.5 million of stock-based compensation expense, $1.0 million of depreciation, $3.7 million of amortization, and $1.8 million change in fair value of contingent consideration, offset by $3.7 million deferred income tax benefit. The decrease in cash from changes in working capital included $4.0 million increase in inventories, $2.5 million decrease in accounts payable, $0.3 million increase in restricted cash, and $0.2 million increase in other current and long term assets, and decrease in accrued expenses of $0.1 million.

Investing Activities

For the six months ended June 30, 2016, net cash used in investing activities was $0.5 million. This amount reflected the purchases of property and equipment.

Financing Activities

For the six months ended June 30, 2016, net cash provided by financing activities was $54.6 million. This amount was primarily related to $57.6 million in proceeds from the issuance of common stock, net of issuance costs, partially offset by $3.1 million in payments of debt.

Operating Capital and Capital Expenditure Requirements

We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will be sufficient to meet our anticipated cash needs through at least the next 12 months. We intend to spend substantial amounts on commercial activities, on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property, and on contingent consideration payments in connection with the acquisition of the ALF-X System. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, including the ongoing at-the-market offering, debt financings and other funding transactions. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will need to pursue a plan to license or sell our assets, cease operations and/or seek bankruptcy protection.

Cash and cash equivalents held by our foreign subsidiary totaled $0.3 million at June 30, 2016. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiary. If these funds are needed in the U.S., we believe that the potential U.S. tax impact to repatriate these funds would be immaterial.

Loan Agreement

In connection with the Merger, in September we assumed and became the borrower under TransEnterix Surgical's then outstanding credit facility (the "Loan Agreement"). We have entered into a number of amendment and restatements of the Loan Agreement since that time, including the Consent and Second Amendment (the "Second Amendment") in connection with the ALF-X Acquisition in September 2015. Under the Loan Agreement, as amended, our borrowing capacity is $20.0 million, all of which is borrowed under term loans. We have had periods of interest-only payments during the Loan Agreement, as amended. Under the Second Amendment we made interest-only payments at 7.5% per annum on the term loans until January 31, 2016. The Second Amendment has a maturity date of July 1, 2018.

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

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

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

The Loan Agreement, as amended and restated (the "Amended and Restated Loan Agreement"), is secured by a security interest in all assets of the Company and its current and future U.S. subsidiaries, including a security interest in intellectual property proceeds, but excluding a current security interest in intellectual property. The Amended and Restated Loan Agreement contains customary representations (tested on a continual basis) and covenants that, subject to exceptions, restrict our ability to do the following things: declare dividends or redeem or repurchase equity

interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business.

Further, under the Second Amendment, the Lenders consented to the formation of TransEnterix International, the entry of the Company into the Purchase Agreement and other transaction documents, and the name change of TransEnterix Italia. We agreed to pledge 100% of the common stock of TransEnterix International as additional security for the borrowings under the Amended and Restated Loan Agreement, as amended. The Second Amendment added a provision permitting the Company to transfer designated amounts to TransEnterix Italia during the term of the Amended and Restated Loan Agreement. This provision for the transfer of designated amount was amended on November 13, 2015 with the Third Amendment to the Amended and Restated Loan Agreement. The Fourth Amendment pursuant to which TransEnterix International joined the Loan Agreement and the existing promissory notes as a co-borrower thereunder and pledged, as collateral for the obligations under the Loan Agreement, substantially all of its non-intellectual property assets, including up to 65% of the equity interests owned by TransEnterix International in TransEnterix Europe S.á.r.l., a wholly owned subsidiary of International was entered into on April 19, 2016.

Off-Balance Sheet Arrangements

As of June 30, 2016, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth above under the headings “Results of Operations” and “Liquidity and Capital Resources” have been prepared in accordance with U.S. GAAP and should be read in conjunction with our financial statements and notes thereto appearing in the Annual Report on Form 10-K for the year ended December 31, 2015, filed by the Company with the SEC on March 3, 2016. 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, business acquisitions, in-process research and development, contingent consideration, stock-based compensation, and inventory. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note 2 in the Notes to the Financial Statements in the Annual Report on Form 10-K for the year ended December 31, 2015, filed by the Company with the SEC on March 3, 2016. 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, business acquisitions, in-process research and development, contingent consideration, stock-based compensation, and inventory.

Identifiable Intangible Assets and Goodwill

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

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists by performing either a qualitative evaluation or a two-step quantitative test. The qualitative evaluation is an assessment of factors, including industry, market and general economic conditions, market value, and future projections to determine whether it is more likely than not that the fair value of a reporting unit is less than 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 using a two-step approach. In the first step, the fair value of the reporting unit is determined and compared to the reporting unit's carrying value, including goodwill. If the fair value of the reporting unit is less than its carrying value, the second step of the goodwill impairment test is performed to measure the amount of impairment, if any. In the second step, the fair value of the reporting unit is allocated to the assets and liabilities of the reporting unit as if it had been acquired in a business combination and the purchase price was equivalent to the fair value of the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is referred to as the implied fair value of goodwill. The implied fair value of the reporting unit's goodwill is then compared to the actual carrying value of

goodwill. If the implied fair value of goodwill is less than the carrying value of goodwill, an impairment loss is recognized for the difference.

We performed a qualitative assessment during the annual impairment review for fiscal 2015 as of December 31, 2015 and concluded that it is not more likely than not that the fair value of our single reporting unit is less than its carrying amount. Therefore, the two-step goodwill impairment test for the reporting unit was not necessary in fiscal 2015. During the second quarter of 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalency, negatively impacting the Company's market capitalization, and warranting an interim two-step quantitative impairment test. We determined the fair value of our reporting unit using a discounted cash flow analysis derived from the Company's long-term plans. The fair value of the reporting unit was corroborated using market prices for TransEnterix, Inc. The inputs used to determine the fair values were classified as Level 3 in the fair value hierarchy. Based on the impairment test, we recorded goodwill impairment of $61.8 million during the second quarter of 2016. While we have substantially completed all actions necessary in the determination of the implied fair value of goodwill, some of the estimated fair values and allocations are subject to adjustment once the valuations and other computations are completed. We will finalize these items and record any required adjustments as we obtain the information necessary to complete the analysis, which we

expect to occur in the third quarter of 2016. Depending on the changes in our business outlook and other assumptions underlying the fair value measurements of our reporting unit, we may be required to recognize additional goodwill impairments.

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.

In-Process Research and Development

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

Contingent Consideration

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

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 us has been determined based upon the simplified method, because we do not have sufficient historical information regarding our 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.

Inventory

Inventory, which includes material, labor and overhead costs, is stated at cost, and determined on a first-in, first-out basis, not in excess of market value. We record reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. At

the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Recent Accounting Pronouncements

See “Note 2. Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015, filed by the Company with the SEC on March 3, 2016, 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

General

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

Interest Rates

The primary objective for our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing excess cash in money market funds and Treasury securities. As of June 30, 2016, approximately 100% of the investment portfolio was in cash equivalents with very short term maturities and therefore not subject to any significant interest rate fluctuations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2016. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2016, 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

On June 2, 2016, a stockholder filed a putative class action complaint, Ashok V. Bankley, individually and on behalf of all others similarly situated vs. TransEnterix, Inc., Todd M. Pope and Joseph P. Slattery, in the United States District Court for the Eastern District of North Carolina (Case No. 5:16-cv-00313-D) (the “Bankley Action”), against TransEnterix, Inc. (the “Company”) and two of its executive officers on behalf of all persons who purchased or otherwise acquired the Company’s common stock between February 10, 2016 and May 10, 2016. The complaint in the Bankley Action alleges that the defendants made false and misleading public statements related to the Company's SurgiBot System and its 510(k) application in violation of certain federal securities laws. The complaint in the Bankley Action seeks class certification for a class consisting of all persons who purchased or otherwise acquired the Company’s common stock between February 10, 2016 and May 10, 2016, unspecified monetary damages, costs, and attorneys’ fees. On June 9, 2016, a different stockholder filed another putative class action complaint, Thomas Ravey, individually and on behalf of all others similarly situated vs. TransEnterix, Inc., Todd M. Pope and Joseph P. Slattery, in the United States District Court for the Middle District of North Carolina (Case No. 1:16-cv-599) (the “Ravey Action”). The Ravey Action asserted substantially similar claims against the same defendants and seeks substantially similar relief as the Bankley Action. On August 4, 2016, the plaintiff in

the Ravey Action voluntarily dismissed the Ravey Action. On August 4, 2016, the defendants filed a motion to dismiss the Bankley Action for failure to state a claim under the securities laws.

On July 8, 2016, a stockholder filed a putative derivative complaint, Otto Pikal v. Todd M. Pope, et al., in the General Court of Justice, Superior Court Division, Wake County, North Carolina (case number 16CV008930), on behalf of the Company against certain of our current officers and directors. The complaint alleges, among other things, that the defendants breached their fiduciary duties by disseminating false and misleading information to the Company's shareholders relating to the Company's SurgiBot System and its 510(k) application in violation of certain federal securities laws and by failing to ensure that the Company maintained adequate internal controls. The complaint seeks, among other things, unspecified monetary damages and an order directing the Company to take steps to improve its corporate governance and to protect the Company and its stockholders from future wrongdoing such as that alleged in the complaint. The defendants have not been served with the suit, and the time for defendants to respond to the complaint has not yet expired.

On April 25, 2016, Intuitive Surgical, Inc. and its French subsidiary, Intuitive Surgical SAS (collectively, "Intuitive"), brought a request for unilateral measures of enquiry in front of the President of the Commercial Court of Toulon (France) (the "President") against two employees of TransEnterix International, Inc. alleging that the company, through these two employees, engaged in acts of unfair competition. On May 3, 2016, the President rendered an order granting Intuitive's request for unilateral measures of enquiry with respect to its allegations (the "Order"). On June 28, 2016, TransEnterix International filed a writ challenging the Order and requesting that it be withdrawn by the President. The parties are awaiting the President's decision with respect to TransEnterix International's challenge and withdrawal request, which is expected to occur in September 2016.

Based on the limited nature of the plaintiffs' allegations, the stage of the proceedings, and because significant legal issues have yet to be raised or decided, we have determined that the amount of any possible loss or range of possible loss in connection with the above matters is not reasonably estimable.

Item 1A Risk Factors.

Reference is made to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2015, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are supplemented and updated by the following risk factors.

We are currently highly dependent on the success of a single product, the ALF-X System. We cannot give any assurance that the ALF-X System can be successfully commercialized or that it will receive regulatory clearance in the U.S.

We are currently highly dependent on the commercial success of the ALF-X System, which is currently CE marked but not FDA cleared. We began our selling efforts for the ALF-X System in the fourth quarter of 2015. We cannot assure you that we will be able to successfully commercialize the ALF-X System, or that the FDA will grant regulatory clearance for the ALF X System, for a number of reasons, including, without limitation, failure in our sales and marketing efforts, the potential introduction by our competitors of more clinically effective or cost-effective alternatives or changes in requirements which could impact our ability to obtain clearance in a timely manner, or at all. Any failure to successfully commercialize the ALF-X System 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 us. These regulatory authorities may also clear a product for fewer or more limited uses than we request. In addition, the FDA or other non-U.S. regulatory authorities may not approve or clear the labeling claims necessary or desirable for the successful commercialization of our products.

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

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

The surgical robotics industry is increasingly competitive, which can negatively impact our commercial opportunities.

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 commercializing the ALF-X System in Europe which accepts a CE Mark, the Middle East and selected countries in Asia and face significant competition in such markets. Many of our competitors, including Intuitive Surgical, have significantly greater financial, manufacturing, marketing and product development resources than we do. Some of the medical device companies we compete with or expect to compete with include Intuitive Surgical, Applied Medical, Titan Medical, Medtronic plc, Verb Surgical 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 anticipate that the highly competitive surgical robotics environment can lead our competitors to attempts to slow or derail our commercial progress. We are using our best efforts to enter the commercial markets effectively and efficiently while maintaining compliance with all regulatory and legal requirements. The actions of our competitors may distract our management team from its focus on our commercial operations and lead to increased costs of commercialization, which could have a negative impact on our financial position. On April 25, 2016, Intuitive Surgical, Inc. and its French subsidiary, Intuitive Surgical SAS, brought a request for unilateral measures of enquiry in front of the President of the Commercial Court of Toulon (France) against two employees of TransEnterix International, Inc. alleging that the company, through these two employees, engaged in acts of unfair competition. Although we believe such allegations are without merit, the defense against such actions may be expensive and may distract our management team from its focus on our commercial operations.

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.

In June 2015 the Company submitted a 510(k) application to the FDA for the SurgiBot System and worked with the FDA to provide additional information as requested. On April 19, 2016, the FDA informed the Company that the SurgiBot System did not meet the substantial equivalence test based on the 510(k) application. The Company is continuing to communicate with the FDA to determine the level of effort and investment necessary to obtain clearance for the SurgiBot System, and is also currently developing its U.S. regulatory path forward for the ALF-X System. 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. We can provide no assurance, even if our products are reviewed under the 510(k) premarket notification process that the FDA will review our application 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 we 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 ALF-X System or 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 a Class III PMA device;
- 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.

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

We have a limited operating history. We are not profitable and have incurred losses since our inception. Our net loss for quarter ended June 30, 2016 was $80.1 million, and our accumulated deficit as of June 30, 2016 was $275.9 million. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products and product candidates. We will continue to incur research and development and general and administrative expenses related to our operations, and expect to increase our sales and marketing expenses as we increase our sales and marketing activities for the ALF-X System in Europe and other jurisdictions where CE marking provides authorization for commercial activities, and pursue our regulatory strategy in the U.S. 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.

In the second quarter of 2016 we recorded a significant charge to earnings related to our evaluation of the recoverability of identifiable intangibles, other long-lived assets, and product inventory related to our SurgiBot System.

We assess the recoverability of identifiable intangibles with finite lives and other long-lived assets, such as equipment, for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable

in accordance with the provisions of FASB ASC 360, “Property, Plant and Equipment”. In accordance with FASB ASC 350, “Intangibles-Goodwill and Other,” goodwill and intangible assets with indefinite lives from acquisitions are evaluated annually, or more frequently, if events or circumstances indicate there may be an impairment, to determine whether any portion of the remaining balance of goodwill and indefinite lived intangibles may not be recoverable. Factors that may be considered a change in circumstances indicating that the carrying value of our goodwill or other intangible assets may not be recoverable include a decline in our stock price and market capitalization, future cash flows or external economic or industry changes. We may be required to record a significant charge to earnings in our financial statements during the period in which any impairment of our goodwill or other intangible assets is determined, which could adversely impact our results of operations.

On April 19, 2016, the FDA notified the Company that the SurgiBot System did not meet the criteria for substantial equivalence based on the data submitted in the 510(k) submission. As a result, we reprioritized our efforts on the commercialization of and regulatory clearance for the ALF-X System. Consequently, in May 2016, we implemented a restructuring plan. The restructuring changes amounted to $5.7 million, of which $2.6 million was included as inventory write-off related to restructuring and $3.1 million was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, during the second quarter of 2016. The restructuring and other charges of $3.1 million included: (i) $0.5 million to be paid in cash, of which $0.4 million related to employee severance costs and $0.1 million related to cancellation of certain contracts; and (ii) $2.6 million for other non-cash charges, of which $1.0 million related to the write-off of long-lived assets for the abandonment of certain equipment and tooling directly relating to the SurgiBot System and $1.6 million related to the write-off of intellectual property for certain patents also relating to the SurgiBot System.

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

The international expansion of our business 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 outside of the U.S.

The risks that we face in our international operations may continue to intensify as we further develop and expand our 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.

Our SurgiBot product development activities could be delayed or stopped.

We are currently communicating with the FDA to determine the level of effort and investment necessary to pursue clearance for the SurgiBot System. Until the SurgiBot decision is made, we are not engaged in SurgiBot System development activities and we have delayed any decisions related to pursuit of regulatory clearance for the SurgiBot System until after we have completed our discussions with the FDA. We do not know whether or how this delay

could impact negatively future SurgiBot product development efforts, or if it will cause us to incur additional expenses. Any such increased expenses could adversely impact our results of operations.

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.

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

We will need to effectively manage our operational, sales and marketing, development and other resources in order to successfully pursue our commercialization and research and development efforts for our existing and future products. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel. If we are not successful in retaining and recruiting highly qualified personnel, our business may be harmed as a result.

Our stock price has been volatile and may experience additional fluctuation in the future.

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock. During the two year period ended June 30, 2016, the market price of our common stock fluctuated from a high of $6.10 per share to a low of

$1.03 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 favorable or unfavorable news regarding us, including our product development efforts and regulatory clearance activities;
- the achievement of commercial sales of our products;
- the announcement of new products or product enhancements by us or our competitors;
- the impact of litigation, including class action litigation, on us;
- 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 surgical robotics;
- 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.

We have been named as a defendant in a class action lawsuit with claims of violations of the federal securities laws.

We have been named as a defendant in a class action lawsuit alleging claims under the federal securities laws. See the description in Item 1 above. Based on the limited nature of the plaintiff's allegations, the stage of the proceedings, and because significant legal issues have yet to be raised or decided, we have determined that the amount of any possible loss or range of possible loss in connection with the above matter is not reasonably estimable. Our management believes the alleged claims are without merit, but if we are not successful in our defense of this action, we could be liable for significant damages. The class action lawsuit may also divert our attention from our ordinary business operations, and we may incur expenses associated with the defense. Accordingly, the ultimate resolution of the matter could have a material adverse effect on our business, results of operations, financial condition and liquidity and, consequently, could negatively impact the trading price of our common stock.

Item 2 Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3 Defaults Upon Senior Securities.
None.

Item 4 Mine Safety Disclosures.
Not applicable.

Item 5 Other Information.
None.

Item 6. Exhibits.

Exhibit No.	Description
10.1	Consent and Fourth Amendment to Amended and Restated Loan and Security Agreement, dated April 19, 2016, by and among TransEnterix, Inc., TransEnterix Surgical, Inc., SafeStitch LLC and TransEnterix International, Inc., as Borrower, and Oxford Finance LLC, as Lender and Collateral Agent, and Silicon Valley Bank, as Lender (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed with the SEC on May 10, 2016).
10.2	Amendment to the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 10, 2016).
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 or furnished herewith.

SIGNATURES

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

TransEnterix, Inc.

Date: August 5, 2016 By: /s/ Todd M. Pope
Todd M. Pope
President and Chief Executive Officer

Date: August 5, 2016 By: /s/ Joseph P. Slattery
Joseph P. Slattery
Executive Vice President and Chief Financial Officer