

SafeStitch Medical, Inc.
Form 10-Q
November 14, 2013

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 September 30, 2013

or

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

Commission File Number 0-19437

SAFESTITCH MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

11-2962080

(I.R.S. employer identification no.)

635 Davis Drive, Suite 300, Morrisville, NC

(Address of principal executive offices)

27560

(Zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ..

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ..

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

Large accelerated filer .. Accelerated filer .. Non-accelerated filer .. **Smaller reporting company x**

Edgar Filing: SafeStitch Medical, Inc. - Form 10-Q

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

168,396,174 shares of the Company's common stock, par value \$0.001 per share, were outstanding as of November 6, 2013.

SAFESTITCH MEDICAL, INC.

TABLE OF CONTENTS FOR FORM 10-Q

PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements	
	Consolidated Statements of Operations and Comprehensive Loss (unaudited)	3
	Consolidated Balance Sheets (unaudited)	4
	Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit) (unaudited)	5
	Consolidated Statements of Cash Flows (unaudited)	6
	Notes to Consolidated Financial Statements (unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	20
Item 4.	Controls and Procedures	20
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	21
Item 1A.	Risk Factors	21
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	21
Item 3.	Defaults Upon Senior Securities	21
Item 4.	Removed and Reserved	21
Item 5.	Other Information	21
Item 6.	Exhibits	21
	SIGNATURES	22

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

SafeStitch Medical, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Sales	\$ 362	\$ 531	\$ 1,212	\$ 1,741
Operating Expenses				
Cost of goods sold	2,059	1,077	4,096	3,465
Research and development	2,909	1,228	7,855	4,552
Sales and marketing	437	1,025	1,490	2,991
General and administrative	1,279	777	2,665	2,176
Merger expenses	2,891	-	2,891	-
Total Operating Expenses	9,575	4,107	18,997	13,184
Operating Loss	(9,213)	(3,576)	(17,785)	(11,443)
Other (Expense) Income				
Remeasurement of fair value of preferred stock warrant liability	(1,800)	-	(1,800)	-
Interest expense, net	(252)	(94)	(742)	(251)
Total Other (Expense) Income, net	(2,052)	(94)	(2,542)	(251)
Net Loss	\$ (11,265)	\$ (3,670)	\$ (20,327)	\$ (11,694)
Other comprehensive income (loss)	-	-	-	-
Comprehensive loss	\$ (11,265)	\$ (3,670)	\$ (20,327)	\$ (11,694)
Net loss per share - basic and diluted	\$ (0.21)	\$ (0.68)	\$ (0.95)	\$ (2.17)
Weighted average common shares outstanding - basic and diluted	52,921	5,391	21,409	5,391

See accompanying notes to financial statements.

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

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	\$ 23,829	\$ 8,896
Short-term investments	1,104	907
Accounts receivable, net	294	536
Accounts receivable - related party	24	-
Interest receivable	10	16
Inventory, net	766	1,382
Other current assets	1,033	235
Total Current Assets	27,060	11,972
Restricted cash	375	375
Property and equipment, net	1,823	1,767
Intellectual property, net	2,866	3,241
Trade names	10	-
Goodwill	93,670	-
Other long term assets	129	205
Total Assets	\$ 125,933	\$ 17,560
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current Liabilities		
Accounts payable	\$ 2,567	\$ 515
Related party payable	-	6
Accrued expenses	1,078	538
Note payable - current portion	3,795	1,519
Total Current Liabilities	7,440	2,578
Long Term Liabilities		
Preferred stock warrant liability	-	109
Note payable - less current portion	5,604	8,481
Total Liabilities	13,044	11,168
Commitments and Contingencies		
Redeemable Convertible Preferred Stock		
Series A Redeemable Convertible Preferred Stock, \$0.001 par value, 5,734,402 shares authorized; and 5,696,261 shares issued and outstanding at December 31, 2012	-	19,885
Series B Redeemable Convertible Preferred Stock, \$0.001 par value, 11,504,298	-	40,016

Edgar Filing: SafeStitch Medical, Inc. - Form 10-Q

shares authorized; and 11,489,972 shares issued and outstanding at December 31, 2012			
Series B-1 Redeemable Convertible Preferred Stock, \$0.001 par value, 48,454,545			
shares authorized; and 45,998,220 shares issued and outstanding at December 31, 2012	-		15,104
Stockholders' Equity (Deficit)			
Series B Convertible Preferred Stock, \$0.01 par value, 25,000,000 shares authorized, 7,569,704.4 shares issued and outstanding at September 30, 2013	30,197		-
Common stock \$0.001 par value, 225,000,000 and 113,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 167,504,447 and 4,674,495 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	168		5
Additional paid-in capital	172,757		1,288
Accumulated deficit	(90,233)		(69,906)
Total Stockholders' Equity (Deficit)	112,889		(68,613)
Total Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)	\$ 125,933	\$	17,560

See accompanying notes to financial statements.

SafeStitch Medical, Inc.
Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)
(Unaudited)

	Preferred Stock		Series B		Series B-1		Preferred Stock		Common Stock	Additional		A
	Series A	Series B	Series B	Series B-1	Series B	Series B-1	Series B	Series B-1		Paid-in	Capital	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance, December 31, 2012	5,696	\$19,885	11,490	\$40,016	45,998	\$15,104	-	-	4,675	\$5	\$1,288	\$-
Accretion of issuance costs	-	-	-	31	-	9	-	-	-	-	(40)	-
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	484	-
Exercise of stock options	-	-	-	-	-	-	-	-	53	-	34	-
Exercise of warrants	-	-	-	-	-	-	-	-	150	-	50	-
Reverse acquisition recapitalization adjustment	(5,696)	(19,885)	(11,490)	(40,047)	(45,998)	(15,113)	-	-	162,895	163	169,032	-
Redemption of TransEnterix shares for cash to non-accredited investors	-	-	-	-	-	-	-	-	(271)	-	-	-
Conversion of preferred stock warrants to common stock warrants	-	-	-	-	-	-	-	-	-	-	1,909	-
Issuance of Preferred Stock	-	-	-	-	-	-	7,570	30,197	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	-	-
Balance, September 30, 2013 (unaudited)	-	\$-	-	\$-	-	\$-	7,570	\$30,197	167,502	\$168	\$172,757	\$-

See accompanying notes to financial statements.

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

	Nine months ended September 30, 2013	2012
Operating Activities		
Net loss	\$ (20,327)	\$ (11,694)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	1,064	1,444
Amortization of debt issuance costs	78	23
Remeasurement of fair value of preferred stock warrant liability	1,800	(19)
Accretion/amortization of bond discount/premium	(1)	1
Stock-based compensation	484	274
Gain on disposal of property and equipment	32	4
Impairment loss on property and equipment	304	-
Changes in operating assets and liabilities:		
Accounts receivable	251	(232)
Interest receivable	6	(62)
Inventory	667	(282)
Other current and long term assets	(527)	(122)
Accounts payable	1,444	(351)
Related party payable	173	(10)
Accrued expenses	505	125
Net cash and cash equivalents used in operating activities	(14,047)	(10,901)
Investing Activities		
Purchase of investments	(1,104)	(4,702)
Proceeds from sale and maturities of investments	907	-
Cash received in acquisition of a business, net of cash paid	305	-
Purchase of property and equipment	(724)	(92)
Proceeds from sale of property and equipment	-	49
Net cash and cash equivalents used in investing activities	(616)	(4,745)
Financing Activities		
Proceeds from issuance of debt	1,998	4,000
Payment of debt	(601)	-
Proceeds from issuance of preferred stock, net of issuance costs	28,199	268
Proceeds from exercise of stock options	-	3
Net cash and cash equivalents provided by financing activities	29,596	4,271
Net increase (decrease) in cash and cash equivalents	14,933	(11,375)
Cash and Cash Equivalents, beginning of period	8,896	14,004
Cash and Cash Equivalents, end of period	\$ 23,829	\$ 2,629
Supplemental Disclosure for Cash Flow Information		
Interest paid	\$ 625	\$ 219

Supplemental Schedule of Noncash Investing and Financing Activities

Issuance of preferred stock warrants and debt issuance costs	\$ 128	\$ 63
Conversion of bridge notes to preferred stock	\$ 1,998	\$ -
Conversion of preferred stock warrants to common stock warrants	\$ 1,909	\$ -

See accompanying notes to financial statements.

SafeStitch Medical, Inc.
Notes to Consolidated Financial Statements
(Unaudited)

1. Description of Business

SafeStitch Medical, Inc., a Delaware corporation (“SafeStitch”), was originally incorporated in August 1988 as NCS Ventures Corp., after which SafeStitch’s name was changed to Cellular Technical Services Company, Inc. (“Cellular Technical”). On September 4, 2007, SafeStitch acquired SafeStitch LLC, and, in January 2008, Cellular Technical changed its name to SafeStitch Medical, Inc. On September 3, 2013, SafeStitch consummated a merger with TransEnterix, Inc. (“TransEnterix”) in which a wholly owned subsidiary of the Company merged with TransEnterix, with TransEnterix being the surviving entity (the “Merger”). As such, the term the “Company” refers to the combined enterprise of SafeStitch Medical, Inc. and TransEnterix, the term “SafeStitch” refers to the business of SafeStitch Medical, Inc. prior to the Merger and the term “TransEnterix” refers to the business of TransEnterix, Inc., prior to the Merger. See Note 14 for a description of the Merger and the related transactions. The Merger is being treated as a reverse acquisition for financial accounting and reporting purposes, with SafeStitch as the acquired entity and TransEnterix as the acquirer. As a result, the assets and liabilities and the historical operations that are reflected in the Company’s financial statements filed with the SEC are those of TransEnterix, and the Company’s assets, liabilities and results of operations will be consolidated with the assets, liabilities and results of operations of TransEnterix and SafeStitch effective September 3, 2013. Effective September 3, 2013, the Company is headquartered in Morrisville, North Carolina.

The Company is a medical device company that is focused on the development and commercialization of a robotic assisted surgical system called the SurgiBot System (“SurgiBot”). The SurgiBot utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, at the patient’s bedside. The flexible nature of the SurgiBot allows for multiple instruments to be introduced and deployed through a single space, thereby offering room for visualization and manipulation once in the body. The SurgiBot also integrates three-dimensional, or 3-D, high definition vision technology. The Company has also commercialized the SPIDER® Surgical System, (the “SPIDER System”) a manual laparoscopic system in the United States, Europe and the Middle East. The SPIDER System utilizes flexible instruments and articulating channels controlled directly by the surgeon, allowing for multiple instruments to be introduced via a single small incision. The product is U.S. Food and Drug Administration cleared and has received CE Mark approval. The Company sells its products through a direct sales force and international distributors.

Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity and GERD, and has developed surgical devices, including the SMART Dilator and Bite Blocks, to be utilized in treating obesity, GERD, esophageal strictures and airway problems during endoscopy. SafeStitch also has a 510k cleared and CE Mark approved stapler called the AMID Hernia Fixation Device.

The Company operates in one business segment.

Concurrent with the closing of the Merger on September 3, 2013, the Company completed a private placement of 7,544,704.4 shares of its Series B Convertible Preferred Stock (“Preferred Stock”), par value \$0.01, each share of which is convertible, subject to certain conditions, into ten (10) shares of common stock, par value \$0.001 per share (“Common Stock”) for a purchase price of \$4.00 per share of Preferred Stock, which was paid in cash, cancellation of certain indebtedness of TransEnterix or a combination thereof. The Company issued and sold an additional 25,000 shares of Preferred Stock within the period provided in the Securities Purchase Agreement.

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, our ability to raise additional

capital, our ability to successfully develop, clinically test and commercialize our products, the timing and outcome of the regulatory review process for our products, changes in the health care and regulatory environments of the United States and other countries in which we intend to operate, our ability to attract and retain key management, marketing and scientific personnel, competition from new entrants, our ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights, our ability to successfully transition from a research and development company to a marketing, sales and distribution concern, and our ability to identify and pursue development of additional products.

2. Summary of Significant Accounting Policies

Basis of presentation

The Company has prepared the accompanying unaudited consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission. The consolidated financial statements are unaudited and should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012 and the Company's Form 8-K filed with the Securities and Exchange Commission Securities Act of 1933 filed September 6, 2013. The accompanying unaudited interim consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of the Company's management, necessary for a fair statement of the Company's consolidated financial position, results of operations and cash flows for the periods presented. These principles require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The principal estimates relate to accounts receivable reserves, inventory valuation, stock-based compensation, accrued expenses, income tax valuation and purchase price accounting related to the acquisition of SafeStitch. Actual results could differ from those estimates. The year-end balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying unaudited consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred operating losses and negative cash flows from operations, which raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

For a description of our critical accounting policies and estimates, please refer to the “Critical Accounting Policies and Estimates” section of the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section contained in our Form 8-K filed with the Securities and Exchange Commission Securities Act of 1933 filed September 6, 2013 and the Company’s Annual Report on Form 10-K for the year ended December 31, 2012. There have been no material changes in any of our accounting policies since December 31, 2012, however the Company has adopted the following new accounting policies related to the Merger.

Identifiable Intangible Assets and Goodwill

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

Indefinite-lived intangible assets, such as goodwill are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists, using a fair value based test.

Debt Issuance Costs

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

Business Acquisitions

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification (“ASC”) 805, “Business Combinations.” ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, “Fair Value Measurements,” as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price, which may be different than the amount of consideration assumed in the pro forma financial statements. Under ASC 805, acquisition related costs (i.e., advisory, legal, valuation and other professional fees) and certain acquisition-related restructuring charges impacting the target company are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired. Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for

impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

Impact of Recently Issued Accounting Standards

New accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company’s result of operations, financial position or cash flow.

3. Income Taxes

Income taxes have been accounted for using the liability method in accordance with FASB ASC 740. The Company computes its interim provision for income taxes by applying the estimated annual effective tax rate method. The Company estimates an annual effective tax rate of 0% for the year ended December 31, 2013 as the Company incurred losses for the nine month period ended September 30, 2013 and is forecasting additional losses through the 4th quarter, resulting in an estimated net loss for both financial statement and tax purposes for the year ended December 31, 2013. Due to the Company’s history of losses, there is not sufficient evidence at this time to support the conclusion that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the net deferred tax assets have been reduced by a full valuation allowance. Therefore, no federal or state income taxes are expected and none have been recorded at this time.

The Company’s effective tax rate for each of the nine month periods ended September 30, 2013 and 2012 was 0%. At September 30, 2013, the Company had no unrecognized tax benefits that would affect the Company’s effective tax rate.

4. Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss available to common stockholders per common share is computed by dividing net loss by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. The Company's potential dilutive common shares, which consist of shares issuable upon the exercise of stock options, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

5. Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include money market funds. Cash equivalents are carried at fair market value. At September 30, 2013, the Company had \$375,000 of restricted cash in a certificate of deposit securing a line of credit. Related unrealized gains and losses were not material as of September 30, 2013 and December 31, 2012. There have been no unrealized gains or losses reclassified to accumulated other comprehensive income.

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

	September 30, 2013 (In thousands) (unaudited)	December 31, 2012
Cash	\$ 1,181	\$ 729
Money market	\$ 22,648	\$ 8,167
Total cash and cash equivalents	\$ 23,829	\$ 8,896
Restricted cash	\$ 375	\$ 375
Total	\$ 24,204	\$ 9,271

6. Fair Value

The Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets include available for sale securities classified as cash equivalents and preferred stock warrant liability. ASC 820-10 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 following are the major categories of assets and liabilities measured at fair value on a recurring basis as of December 31, 2012, and September 30, 2013 (unaudited), using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

Description	December 31, 2012 (In thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable (Level 2)	Other Inputs (Level 3)	Significant Unobservable Total December 31, 2012
Assets measured at fair value				
Cash and Cash Equivalents	\$ 8,896	\$ -	\$ -	\$ 8,896
Restricted Cash	375	-	-	375
Short term investments	-	907	-	907
Total Assets measured at fair value	\$ 9,271	\$ 907	\$ -	\$ 10,178
Liabilities measured at fair value				
Preferred Stock Warrant Liability	\$ -	\$ -	\$ (109)	\$ (109)
Total Liabilities measured at fair value	\$ -	\$ -	\$ (109)	\$ (109)

Description	September 30, 2013 (unaudited) (In thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable (Level 2)	Other Inputs (Level 3)	Significant Unobservable Total September 30, 2013
Assets measured at fair value				
Cash and Cash Equivalents	\$ 23,829	\$ -	\$ -	\$ 23,829
Restricted Cash	375	-	-	375
Short term investments	-	\$ 1,104	-	\$ 1,104
Total Assets measured at fair value	\$ 24,204	\$ 1,104	\$ -	\$ 25,308

7. Investments

Investments consist of short-term corporate bonds carried at amortized cost using the effective interest method. The Company classifies its corporate bonds as held-to-maturity based upon management's positive intention and ability to hold these securities until their maturity dates. The aggregate fair values of investment securities along with unrealized gains and losses determined on an individual investment security basis are as follows:

	(In thousands)			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
September 30, 2013				
Corporate bonds	\$ 1,105	\$ -	\$ (1)	\$ 1,104
December 31, 2012				
Corporate bonds	\$ 907	\$ -	\$ -	\$ 907

8. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	September 30, 2013 (In thousands) (unaudited)	December 31, 2012
Gross accounts receivable	\$ 326	\$ 586
Allowance for uncollectible accounts	(32)	(50)
Total accounts receivable, net	\$ 294	\$ 536

9. Inventories

The following table presents the components of inventories:

	September 30, 2013 (In thousands) (unaudited)	December 31, 2012
Finished goods	\$ 701	\$ 708
Raw materials	691	784
Work in process	173	-
Reserve for excess and obsolete inventory	(799)	(110)
Total inventories	\$ 766	\$ 1,382

10. Goodwill and Intangible Assets

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

	September 30, 2013 (In thousands) (unaudited)	December 31, 2012
Goodwill	\$ 93,670	\$ -
Intangible assets:		
Intellectual property	\$ 5,000	\$ 5,000
Tradenames	10	-
Amortization of intangible assets	(2,134)	(1,759)
Total intangible assets	\$ 2,876	\$ 3,241

11. Accrued Expenses

The following table presents the components of accrued expenses:

	September 30, 2013 (In thousands) (unaudited)	December 31, 2012
--	--	----------------------

Edgar Filing: SafeStitch Medical, Inc. - Form 10-Q

Vacation	\$	230	\$	66
Bonus		315		-
Vendors		146		76
Legal and professional fees		70		53
Interest		69		43
Corporate credit card		65		47
Salaries and commissions		52		41
Rent		50		82
Consulting		-		67
Other		81		63
Total accrued expenses	\$	1,078	\$	538

12. Debt

In connection with the Merger, the Company assumed and became the borrower under TransEnterix's outstanding credit facility pursuant to the terms of the Loan and Security Agreement, dated as of January 17, 2012, (the "Loan Agreement"), among TransEnterix, Silicon Valley Bank, as collateral agent (the "Collateral Agent"), and Silicon Valley Bank and Oxford Finance, LLC, as lenders (the "Lenders"). The Second Amendment to Loan Agreement, dated as of September 3, 2013, amends the Loan and Security Agreement among the Collateral Agent, the lenders party thereto, and SafeStitch (as so amended, the "Amended Loan Agreement"). The Amended Loan Agreement evidences a term loan, which will mature on January 1, 2016 (the "Term Loan"). The following table presents the components of long-term debt:

	September 30, 2013 (In thousands) (unaudited)
Total long-term debt	9,399
Less: Current portion of long-term debt	3,795
Total long-term debt, net of current portion	\$ 5,604

The Term Loan bears interest at a fixed rate equal to 8.75%.

Commencing August 2013, the Amended Loan Agreement provides for the amortization of principal (in the form of level monthly payments of principal and interest). The Term Loan will be required to be prepaid if the Term Loan is accelerated following an event of default. In addition, the Company is permitted to prepay the Term Loan in full at any time upon 10 days' written notice to the Lenders. Upon the earliest to occur of the maturity date, acceleration of the Term Loan, or prepayment of the Term Loan, the Company is required to make a final payment equal to the original principal amount of the Term Loan multiplied by 3.33% (the "Final Payment Fee"). Any prepayment, whether mandatory or voluntary, must include the Final Payment Fee, interest at the default rate (which is the rate otherwise applicable plus 5%) with respect to any amounts past due, the Collateral Agent's and the Lenders' expenses, and all other obligations that are due and payable to the Collateral Agent and the Lenders.

The Amended Loan Agreement is secured by a security interest in substantially all assets of the Company and any future subsidiaries, other than intellectual property. The Amended Loan Agreement contains customary representations (tested on a continual basis) 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; fail to appoint a chief executive officer, chief financial officer, and chief technology officer upon vacancy; undergo a change in control; add or change business locations; and engage in businesses that are not related to the Company's existing business.

13. Warrants

On March 22, 2013, SafeStitch entered into a stock purchase agreement (the "2013 Stock Purchase Agreement") with approximately 17 investors (the "2013 PIPE Investors") pursuant to which the 2013 PIPE Investors agreed to purchase an aggregate of approximately 12,100,000 shares of common stock at a price of \$0.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of PIPE Warrants to purchase approximately 6,050,000 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$0.33 per share and five year expiration. Among the Investors purchasing Shares were related parties who purchased 6.4 million shares and received 3.2 million warrants. During the three months ended

September 30, 2013, 200,000 warrants were exercised.

On January 17, 2012, TransEnterix entered into the SVB-Oxford Loan and Security Agreement with Silicon Valley Bank (“SVB”) and Oxford Finance LLC (“Oxford”). Pursuant to this agreement, TransEnterix issued warrants to SVB and Oxford on January 17, 2012 and December 21, 2012, respectively, to purchase shares of capital stock. Following the Merger, these warrants were assumed by the Company and are now exercisable for an aggregate of approximately 1,397,937 shares of Common Stock.

14. Closing of Merger and Financing Transaction

On September 3, 2013, the Company consummated the Merger in which a wholly owned subsidiary of the Company merged with TransEnterix, pursuant to the Merger Agreement. Under the terms of the Merger Agreement, TransEnterix remained as the surviving corporation and as a wholly-owned subsidiary of the Company.

Upon the closing of the Merger, and in accordance with the terms of the Merger Agreement, the Company issued an aggregate of 105,549,746 shares of the Company's common stock as Merger consideration and paid \$293,000 to unaccredited investors in lieu of common stock.

During July 2013, TransEnterix issued promissory notes (the "Bridge Notes") in the aggregate principal amount of \$2.0 million, as contemplated by the Merger Agreement. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, among Oxford, SVB and TransEnterix. The Bridge Notes were converted into Series B preferred stock at the effective time of the Merger.

Concurrent with the closing of the Merger, and in accordance with the terms of a Securities Purchase Agreement, the Company issued 7,544,704.4 shares of Preferred Stock, each share of which is convertible, subject to certain conditions, into ten (10) shares of Common Stock, for a purchase price of \$4.00 per share of Preferred Stock, which was paid in cash, cancellation of certain Bridge Notes of TransEnterix or a combination thereof. Pursuant to the Securities Purchase Agreement, the Company issued and sold an additional 25,000 shares of Preferred Stock within the period provided in the Securities Purchase Agreement resulting in gross proceeds to the Company of approximately \$100,000.

At the closing of the Merger, each outstanding share of capital stock of TransEnterix was cancelled and extinguished and converted into the right to receive a portion of the Merger consideration in accordance with the Merger Agreement. The Bridge Notes were terminated at closing of the Merger, and the holders of such Bridge Notes received Merger consideration in accordance with the Merger Agreement. All stock option plans of TransEnterix, each outstanding option to purchase common stock of TransEnterix, whether vested or unvested, and each warrant to acquire capital stock of TransEnterix were assumed by the Company concurrent with the closing of the Merger.

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

The Company's assets and liabilities are presented at their preliminary estimated fair values, with the excess of the purchase price over the sum of these fair values presented as goodwill. The Company has not completed the detailed valuation studies necessary to arrive at the required estimates of fair market value of its assets and liabilities and the related allocations of purchase price. The valuations of assets and liabilities are in process and are not expected to be finalized until later in 2013, as information may become available within the measurement period which indicates a potential change to these valuations. Accordingly, the final allocations of and the effects on the results of operations may differ materially from the preliminary allocations amounts included herein.

The following table summarizes the purchase price:

Common shares outstanding at the date of merger (in thousands)	61,749
Closing price per share	\$1.52
	\$93,858
Cash consideration	293
Total purchase price	\$94,151

The purchase price was allocated to the net assets acquired utilizing the methodology prescribed in ASC 805. The Company recorded goodwill of \$93.7 million after recording net assets acquired at fair value as presented in the following table.

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

Cash and cash equivalents	\$ 597
Accounts receivable	9
Accounts receivable, related party	45
Inventory	50
Other current assets	53
Property and equipment	357
Other long-term asset	2
Intangible assets	10
Goodwill	93,670
Total assets acquired	\$94,793
Accounts payable and other liabilities	642
Total purchase price	\$94,151

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

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

The results of operations of SafeStitch have been included in our consolidated financial statements from the date of the acquisition. The following pro forma results of operations assume the acquisition of SafeStitch as of the beginning of 2012. The pro forma results for the nine months ended September 30, 2013 presented below reflect our historical data and the historical data of the SafeStitch business. The pro forma results of operations presented below may not be indicative of the results the Company would have achieved had the Company completed the acquisition on January 1, 2013, or that the Company may achieve in the future.

	SafeStitch Medical, Inc. (the Company) SafeStitch (in thousands)		Historical Results of SafeStitch Medical, Inc.	Pro Forma Adjustments	Pro Forma Results
Revenue	\$ 1,212	\$ 25	\$ 1,237	\$ -	\$ 1,237
Net loss	\$ (20,327)	\$ (2,062)	\$ (22,389)	\$ -	\$ (22,389)
Historical TransEnterix loss per common share - basic and diluted			\$ (0.13)		
Pro forma loss per common share - basic and diluted:			\$ (0.13)		
Pro forma loss			\$ (22,389)		
Pro forma weighted average common shares			167,502		
Pro forma loss per common share			\$ (0.13)		

15. Subsequent Events

On October 24, 2013, the Company entered into a new warehouse operating lease for a period of 52 months commencing in January 2014, with an option to renew for an additional six years. The future minimum lease payments for this operating lease are as follows:

Year ending December 31,	
2014	\$83
2015	114
2016	117
2017	121
2018	124
	\$559

On or about October 29, 2013, the Company received written consents in lieu of a meeting of stockholders from holders of approximately 89% of our common stock and approximately 98% of our Preferred Stock representing a majority of the total issued and outstanding shares of capital voting stock of the Company to authorize the Board to approve the following:

(1) to file an Amended and Restated Certificate of Incorporation (the “Restated Certificate”) which (a) increases the number of authorized shares of Common Stock from 225,000,000 to 750,000,000 shares, and (b) makes certain other changes;

(2) to file the Restated Certificate to change the name of the Company to “TransEnterix, Inc.” (the “Name Change”);

(3) to approve the amendment and restatement of our 2007 Incentive Compensation Plan (“2007 Plan”) (a) increasing the number of shares of common stock authorized for issuance under the 2007 Plan from 5,000,000 shares of Common Stock to 24,700,000 shares of common stock, (b) increasing the per-person award limitations for Options or Stock Appreciation Rights from 1,000,000 to 2,500,000 shares and for Restricted Stock, Deferred Stock, Performance Shares and/or Other Stock-Based Awards from 500,000 to 1,000,000 shares, and (c) changing the name of the 2007 Plan to reflect the Name Change; and

(4) to approve an amendment and restatement of our Bylaws, changing the name of our Bylaws to reflect the Name Change.

The Company expects the matters approved by a majority of its common stockholders and Series B preferred stockholders to be effective by December 31, 2013. Following the effectiveness of the Restated Certificate as filed with the State of Delaware, each of the Series B Preferred Shares issued in September 2013 will automatically convert into 10 shares of common stock as set forth in the Certificate of Designation of the Series B Convertible Preferred Stock.

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. 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact contained in this report, including statements regarding future events, our future financial performance, our future business strategy and the plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Readers are urged to carefully review and consider the various disclosures made by us, which attempt to advise interested parties of the risks, uncertainties, and other factors that affect our business, operating results, financial condition and stock price, including without limitation the disclosures made under the captions “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, “Risk Factors”, “Financial Statements” and “Notes to Consolidated Financial Statements” in this report, as well as the disclosures made under the captions “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, “Risk Factors”, “Consolidated Financial Statements” and “Notes to Consolidated Financial Statements” included in the SafeStitch Medical, Inc. Annual Report on Form 10-K for the year ended December 31, 2012 filed on April 1, 2012 and in the case of TransEnterix, Inc. (“TransEnterix”) Form 8-K filed on September 6, 2013 and other filings we make with the Securities and Exchange Commission, or the SEC. 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 SafeStitch Medical, Inc. and the combined enterprise of SafeStitch Medical, Inc. and TransEnterix.

Overview

We are a medical device company founded in 2007 that is pioneering the use of flexible instruments and robotics to improve the outcomes of minimally invasive surgery by specifically addressing the challenges presented to patients, surgeons, hospitals and payers in laparoscopy and robotic surgery today. We believe that future outcomes of minimally invasive surgery will be enhanced through our combination of more advanced tools and robotic functionality which will: (i) empower surgeons with improved precision, dexterity and visualization; (ii) improve post-operative recovery given the lower trauma associated with procedures utilizing fewer incisions and; (iii) provide a cost-effective robotic system, compared to existing alternatives today, for a potentially wide range of clinical applications.

Our strategy is to develop and commercialize a novel robotic assisted surgical system called the SurgiBot System (“SurgiBot”). The SurgiBot utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, at the patient’s bedside. The flexible nature of the SurgiBot allows for multiple instruments to be introduced and deployed through a single space, thereby offering room for visualization and manipulation once in the body. The SurgiBot also integrates three dimensional, or 3-D, high definition vision technology that we believe will enhance the quality of visualization of key structures and will support complex surgical tasks. The Company

gained experience by developing and launching a manual laparoscopic device called the SPIDER[®] Surgical System (the “SPIDER System”). The SPIDER System utilizes flexible instruments and articulating channels controlled directly by the surgeon. The SPIDER System also allows for multiple instruments to be introduced via a single small incision. In July 2009, we received FDA clearance to market the SPIDER System, a Class II device, and, in August 2010, we received CE Mark clearance to market the device in the European Union and other countries requiring CE Mark clearance. The SPIDER System is commercially available in a limited release in select markets worldwide, and the SPIDER System has been used in over 3,000 procedures worldwide. The Company sells its products through a direct sales force and international distributors. The Company has chosen to focus resources on SurgiBot development and therefore away from continued investment in sales and marketing of the SPIDER System. The SPIDER System will remain on the market, and the Company will focus on serving existing customers.

On September 3, 2013, TransEnterix merged with a wholly owned subsidiary of SafeStitch Medical, Inc. Prior to the Merger, SafeStitch was focused on developing its Gastroplasty Device for the treatment of obesity and GERD, and has developed surgical devices, including the SMART Dilator and Bite Blocks, to be utilized in treating obesity, GERD, esophageal strictures and airway problems during endoscopy. SafeStitch also has a 510k cleared and CE Mark approved stapler called the AMID Hernia Fixation Device.

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 trials, manufacturing, recruiting qualified personnel and raising capital.

On September 3, 2013, through a wholly owned subsidiary the Merger Sub, we consummated the Merger with TransEnterix pursuant to the Merger Agreement. Under the terms of the Merger Agreement, Merger Sub merged with and into SafeStitch Medical, Inc., with TransEnterix remaining as the surviving corporation and as a wholly-owned subsidiary of the Company.

Upon the closing of the Merger, and in accordance with the terms of the Merger Agreement, we issued an aggregate of 105,549,746 shares of the Company's common stock as merger consideration.

During July 2013, TransEnterix issued promissory notes (the "Bridge Notes") in the aggregate principal amount of \$2.0 million. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, among Silicon Valley Bank and Oxford Finance LLC, and TransEnterix. The Bridge Notes were converted into Series B convertible preferred stock at the effective time of the Merger.

Concurrent with the closing of the Merger, and in accordance with the terms of a Securities Purchase Agreement, we issued to certain investors, 7,544,704.4 shares of Series B Convertible Preferred Stock ("Preferred Stock"), par value \$0.01 per share, each share of which is convertible, subject to certain conditions, into ten (10) shares of Common Stock, for a purchase price of \$4.00 per share of Preferred Stock, which was paid in cash, cancellation of certain Bridge Notes of TransEnterix or a combination thereof. Pursuant to the Securities Purchase Agreement, we issued and sold an additional 25,000 shares of Preferred Stock within the period provided in the Securities Purchase Agreement resulting in gross proceeds to the Company of approximately \$100,000.

At the closing of the Merger, each outstanding share of capital stock of TransEnterix was cancelled and extinguished and converted into the right to receive a portion of the Merger consideration in accordance with the Merger Agreement. The Bridge Notes were terminated at closing of the Merger, and the holders of such Bridge Notes received Merger consideration in accordance with the Merger Agreement. All stock option plans of TransEnterix, each outstanding option to purchase common stock of TransEnterix, whether vested or unvested, and each warrant to acquire capital stock of TransEnterix were assumed by the Company concurrent with the closing of the Merger.

As of September 30, 2013, we have incurred \$2.9 million of Merger related expenses which were included in operating expenses.

Following the announcement of the Merger, the SafeStitch stock price increased prior to the Merger closing date of September 3, 2013, generating additional goodwill. As of September 30, 2013, the net carrying value of our goodwill and other intangible assets totaled approximately \$93.7 million. In accordance with generally accepted accounting principles, we annually assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and market capitalization declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

Since inception, we have been unprofitable. As of September 30, 2013 we had an accumulated deficit of \$90.2 million.

We expect to continue to invest in research and development and related clinical trials, 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.

Results of Operations

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

Revenue

The Company records revenue when persuasive evidence of an arrangement exists, delivery has occurred which is typically at shipping point, the fee is fixed and determinable and collectability is reasonably assured. Shipping and handling costs billed to customers are included in revenue.

Cost of Goods Sold

Cost of goods sold consists of materials, labor and overhead incurred internally to produce the products. Shipping and handling costs incurred by the Company are included in cost of goods sold.

Research and Development

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. In future periods, we expect research and development expenses to grow as we continue to invest in basic research, clinical trials, product development and intellectual property. Research and development expenses are expensed as incurred.

Sales and Marketing

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshow, marketing clinical studies and consulting expenses.

General and Administrative

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

Merger Expenses

Merger expenses consist primarily of legal, investment banking, accounting and other professional fees related to the Merger.

Other Expense, net

Other expense is primarily composed of interest expense on long-term debt, remeasurement of fair value of preferred stock warrant liability and gains or losses on disposal of fixed assets.

Comparison of the Three Months Ended September 30, 2012 and 2013

Revenues

Sales decreased from \$0.5 million in the three months ended September 30, 2012 to \$0.4 million in the three months ended September 30, 2013. The \$0.1 million decrease resulted primarily from lower sales volumes as a result of the reduction in our U.S. sales force headcount.

Cost of Goods Sold

Cost of goods sold increased from \$1.1 million in the three months ended September 30, 2012 to \$2.1 million in the three months ended September 30, 2013. The \$1.0 million increase was primarily related to an increase in the reserve for obsolete inventory of \$0.7 million for raw material inventory that we do not anticipate utilizing, as we limit sales of our SPIDER System to our existing customers and for manufacturing property and equipment impairment charges of \$0.3 million to reflect a change in the estimate of useful lives.

Research and Development

Research and development expenses increased from \$1.2 million in the three months ended September 30, 2012 to \$2.9 million in the three months ended September 30, 2013, primarily due to activities associated with SurgiBot development. Personnel-related expenses increased by \$0.7 million from the three months ended September 30, 2012 compared to the three months ended September 30, 2013 as we increased the headcount in our research and development and regulatory functions. In addition, contract engineering services increased by \$0.8 million for the three months ended September 30, 2012 to the three months ended September 30, 2013. Research and development expenses incurred by SafeStitch from the date of the Merger through September 30, 2013 were also \$0.1 million.

Sales and Marketing

Sales and marketing expenses decreased from \$1.0 million in the three months ended September 30, 2012 to \$0.4 million in the three months ended September 30, 2013. The decrease in expenses from 2012 to 2013 of \$0.6 million was primarily due to \$0.4 million lower personnel-related costs of as we decreased our direct sales and marketing personnel and reduced expenditures for demonstration product of \$0.1 million.

General and Administrative

General and administrative expenses increased from \$0.8 million in the three months ended September 30, 2012 to \$1.3 million in the three months ended September 30, 2013. The increase in expenses of \$0.5 million was primarily due to an increase in general and administrative expenses incurred by SafeStitch from the date of the Merger through

September 30, 2013.

Merger Expenses

We incurred \$2.9 million of Merger related expenses for the three months ended September 30, 2013. These expenses consist primarily of legal, investment banking, accounting and other professional fees related to the Merger.

Other Expense, net

Other expense increased from \$94,000 in the three months ended September 30, 2012 to \$2.1 million in the three months ended September 30, 2013. The increase of \$2.0 million was primarily related to the remeasurement of fair value of preferred stock warrant liability prior to the effective date of the Merger of \$1.8 million and an increase in interest expense of \$0.1 million as a result of the issuance of term debt of \$4.0 million in January 2012 and \$6.0 million in December 2012.

Comparison of the Nine Months Ended September 30, 2012 and 2013

Revenue

Sales decreased from \$1.7 million in the nine months ended September 30, 2012 to \$1.2 million in the nine months ended September 30, 2013. The \$0.5 million decrease resulted primarily from lower sales volumes as a result of the reduction in our U.S. sales force headcount.

Cost of Goods Sold

Cost of goods sold increased from \$3.5 million for the nine months ended September 30, 2012 to \$4.1 million for the nine months ended September 30, 2013. The \$0.6 million increase was primarily related to an increase in the reserve for obsolete inventory of \$0.7 million for raw material inventory that we do not anticipate utilizing, as we limit sales of our SPIDER System to our existing customers and for manufacturing property and equipment impairment charges of \$0.3 million to reflect a change in the estimate of useful lives, offset by a decrease of \$0.4 million in cost of finished goods as a result of a decrease in sales during the same period.

Research and Development

Research and development expenses increased from \$4.6 million in the nine months ended September 30, 2012 to \$7.9 million in the nine months ended September 30, 2013, primarily due to activities associated with SurgiBot development. Personnel-related expenses increased by \$1.7 million from the nine months ended September 30, 2012 compared to the nine months ended September 30, 2013 as we increased the headcount in our research and development and regulatory functions. In addition, R&D contract engineering services increased by \$1.0 million and supplies increased by \$0.5 million in the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. Research and development expenses incurred by SafeStitch from the date of the Merger through September 30, 2013 were also \$0.1 million.

Sales and Marketing

Sales and marketing expenses decreased from \$3.0 million in the nine months ended September 30, 2012 to \$1.5 million in the nine months ended September 30, 2013. The decrease in expenses from 2012 to 2013 of \$1.5 million was primarily due to lower personnel-related costs of \$1.1 million and travel related expenses of \$0.1 million as we decreased our direct sales and marketing personnel and reduced expenditures for marketing clinical studies, demonstration product and tradeshows and other marketing expenses of \$0.3 million.

General and Administrative

General and administrative expenses increased from \$2.2 million in the nine months ended September 30, 2012 to \$2.7 million in the nine months ended September 30, 2013. The increase in expenses of \$0.5 million was primarily due to an increase in general and administrative expenses related to SafeStitch from the date of the Merger through September 30, 2013.

Merger Expenses

We incurred \$2.9 million of Merger related expenses for the nine months ended September 30, 2013. These expenses consist primarily of legal, investment banking, accounting and other professional fees related to the Merger.

Other Expense, net

Other expense increased from \$0.3 million in the nine months ended September 30, 2012 to \$2.5 million in the nine months ended September 30, 2013. The increase of \$2.2 million was primarily related to the remeasurement of fair value of preferred stock warrant liability prior to the effective date of the Merger of \$1.8 million and increase in interest expense of \$0.4 million as a result of the issuance of an additional \$6.0 million in December 2012.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2007, we have incurred significant losses and, as of September 30, 2013, we had an accumulated deficit of \$90.2 million. We have not yet achieved profitability and we cannot assure investors that we will achieve profitability with our existing capital resources. Our recurring losses raise substantial doubt about our ability to continue as a going concern. As a result, SafeStitch's independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2012 with respect to this uncertainty. We expect to continue to fund research and development, sales and marketing and

general and administrative expenses at similar to current or higher levels and, as a result, we will need to generate significant revenues to achieve profitability. Our principal sources of cash have been proceeds from private placements of common and preferred stock, incurrence of debt and the sale of equity securities held as investments.

Cash and cash equivalents increased from \$8.9 million at December 31, 2012 to \$23.8 million at September 30, 2013. The increase of \$14.9 million was primarily the result of net cash provided by our private placement transaction of \$28.2 million, proceeds from issuance of bridge notes of \$2.0 million, offset by net cash used in operating activities of \$14.0 million, payments on term debt of \$0.6 million and purchases of property and equipment of \$0.7 million.

Cash Flows

Net Cash Used in Operating Activities. Net cash used in operating activities was \$14.0 million in the nine months ended September 30, 2013. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation and amortization, stock-based compensation, remeasurement of fair value of preferred stock warrant liability, property and equipment impairment charge, plus the net change in operating assets and liabilities for the nine months ended September 30, 2013, which consisted primarily of increases in accounts payable and accrued expenses and a decrease in inventory.

Net Cash Used in Investing Activities. Net cash used in investing activities was \$0.6 million in the nine months ended September 30, 2013. This amount reflected the net cash paid for the purchases of property and equipment of \$0.7 million and purchase of investments, net of sales of \$0.2 million, offset by cash received in the acquisition, net of cash paid of \$0.3 million.

Net Cash Provided by Financing Activities. Net cash provided by financing activities in the nine months ended September 30, 2013 was \$29.6 million, which reflected the \$28.2 million net proceeds from the sale of preferred stock under the Securities Purchase Agreement, proceeds from issuance of bridge notes of \$2.0 million, offset by the payment on debt of \$0.6 million.

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 not be sufficient to meet our anticipated cash needs through September 30, 2014. We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will need to pursue a plan to license or sell our assets, cease operations and/or seek bankruptcy protection.

During July 2013, TransEnterix issued promissory notes (the “Bridge Notes”) in the aggregate principal amount of \$2.0 million, as contemplated by the Merger Agreement. The Bridge Notes bore interest at a rate of 8% per annum. The Bridge Notes were not secured by any collateral and were subordinated in right of payment to the loan evidenced by the Loan and Security Agreement dated as of January 17, 2012, among Silicon Valley Bank, Oxford Finance LLC and TransEnterix. The Bridge Notes were converted into Series B preferred stock at the effective time of the Merger.

On September 3, 2013, we consummated the Merger between TransEnterix and SafeStitch Medical, Inc.

Concurrent with the closing of the Merger, and in accordance with the terms of a Securities Purchase Agreement, we issued to certain investors, 7,544,704.4 shares of Series B Convertible Preferred Stock, par value \$0.01 per share, each share of which is convertible, subject to certain conditions, into ten (10) shares of Common Stock, for a purchase price of \$4.00 per share of Preferred Stock, which was paid in cash, cancellation of certain Bridge Notes of TransEnterix or a combination thereof. Pursuant to the Securities Purchase Agreement, we issued and sold an additional 25,000 shares of Series B Preferred Stock within the period provided in the Securities Purchase Agreement resulting in gross proceeds to the Company of approximately \$100,000.

At the closing of the Merger, each outstanding share of capital stock of TransEnterix was cancelled and extinguished and converted into the right to receive a portion of the Merger consideration in accordance with the Merger Agreement. The Bridge Notes were terminated at closing of the Merger, and the holders of such Bridge Notes received Merger consideration in accordance with the Merger Agreement. All stock option plans of TransEnterix, each outstanding option to purchase common stock of TransEnterix, whether vested or unvested, and each warrant to acquire capital stock of TransEnterix were assumed by the Company concurrent with the closing of the Merger.

In connection with the Merger, the Company assumed and became the borrower under TransEnterix’s outstanding credit facility pursuant to the terms of the Loan and Security Agreement, dated as of January 17, 2012, (the “Loan Agreement”), among the Company, Silicon Valley Bank, as collateral agent (the “Collateral Agent”), and Silicon Valley Bank and Oxford Finance, LLC, as lenders (the “Lenders”). The Second Amendment to Loan Agreement amends the Loan and Security Agreement, dated as of September 3, 2013, among the Collateral Agent, the lenders party thereto, and SafeStitch (as so amended, the “Amended Loan Agreement”). The Amended Loan Agreement evidences a term loan, which will mature on January 1, 2016 (the “Term Loan”).

The Term Loan bears interest at a fixed rate equal to 8.75%. Commencing August 2013, the Amended Loan Agreement provides for the amortization of principal (in the form of level monthly payments of principal and

interest). The Term Loan will be required to be prepaid if the Term Loan is accelerated following an event of default. In addition, the Company is permitted to prepay the Term Loan in full at any time upon 10 days' written notice to the Lenders. Upon the earliest to occur of the maturity date, acceleration of the Term Loan, or prepayment of the Term Loan, the Company is required to make a final payment equal to the original principal amount of the Term Loan multiplied by 3.33% (the "Final Payment Fee"). Any prepayment, whether mandatory or voluntary, must include the Final Payment Fee, interest at the default rate (which is the rate otherwise applicable plus 5%) with respect to any amounts past due, the Collateral Agent's and the Lenders' expenses, and all other obligations that are due and payable to the Collateral Agent and the Lenders.

The Amended Loan Agreement is secured by a security interest in substantially all assets of the Company and any future subsidiaries, other than intellectual property. The Amended Loan Agreement contains customary representations (tested on a continual basis) 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; fail to appoint a chief executive officer, chief financial officer or chief technology officer upon vacancy; undergo a change in control; add or change business locations; and engage in businesses that are not related to the Company's existing business

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On an on-going basis, we evaluate our estimates, including those related to accounts receivable reserves, inventory valuation, stock-based compensation, accrued expenses, income tax valuation and purchase price accounting related to the acquisition of SafeStitch. We base our estimates on historical experience and various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions.

For a description of our critical accounting policies and estimates, please refer to the “Critical Accounting Policies and Estimates” section of the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section contained in our Form 8-K filed September 6, 2013. There have been no material changes in any of our accounting policies since December 31, 2012, however we have adopted the following new accounting policies related to the Merger.

Identifiable Intangible Assets and Goodwill

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 10 years. Similar to tangible personal property and equipment, 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 and certain trademarks, 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, using a fair value based test.

Debt Issuance Costs

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

Business Acquisitions and Goodwill

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 us 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.

New Accounting Standards

New accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standards setting bodies that the Company adopts according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company’s result of operations, financial position or cash flow.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2013. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2013, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

We discuss various risks that may materially affect our business in our Form 8-K filed September 6, 2013. The following additional risk should be read in connection with the Form 8-K filed on September 6, 2013.

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

As of September 30, 2013, the net carrying value of our goodwill and other intangible assets totaled approximately \$93.7 million. In accordance with generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Significant negative industry or economic trends, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, divestitures and market capitalization declines may impair our goodwill and other intangible assets. Any charges relating to such impairments would adversely affect our results of operations in the periods recognized.

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

As permitted by the Securities Purchase Agreement dated September 3, 2013, the Company sold an additional 25,000 shares of the Company's Series B Preferred Stock on or prior to September 17, 2013, each share of which is convertible, subject to certain conditions, into ten (10) shares of Common Stock for a purchase price of \$4.00 per share of Series B Preferred Stock. The terms of the subsequent sale on or prior to September 17, 2013 was made on the same terms, and subject to the same conditions, as the September 3, 2013 preferred stock closing. The Company offered and sold the additional shares of Series B Preferred Stock in reliance upon the exemptions from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The acquirer of the Series B Preferred Stock shares represented to the Company that such person was an "accredited investor" as defined in Rule 501(a) under the Securities Act and that such person was acquiring the Series B Preferred Stock for investment and not with a view to distribution thereof.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibits:

Edgar Filing: SafeStitch Medical, Inc. - Form 10-Q

Agreement and Plan of Merger, dated as of August 13, 2013, by and among SafeStitch Medical, Inc., Tweety Acquisition Corp. and TransEnterix, Inc. (incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K, filed with the SEC on August 14, 2013).

- 2.1(a) First Amendment to Agreement and Plan of Merger, dated as of August 30, 2013, by and among Medical, Inc., Tweety Acquisition Corp and TransEnterix, Inc. (incorporated by reference to Exhibit 2.2 to the registrant's Current Report on Form 8-K, filed with the SEC on September 6, 2013).
- 4.1 Certificate of Designation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed with the SEC on September 6, 2013).
- 10.1 Loan and Security Agreement dated as of January 17, 2012, by and among TransEnterix, Inc., Silicon Valley Bank and Oxford Finance LLC, as amended, and associated notes and warrants issued by TransEnterix to Silicon Valley Bank and Oxford Finance LLC (incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K, filed with the SEC on September 6, 2013).
- 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**

* Pursuant to Item 601(b)(32) of Regulation S-K, this exhibit is furnished, rather than filed, with this Quarterly Report on Form 10-Q.

** Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Act of 1934 and ot

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.

SafeStitch Medical, Inc.

Date: November 14, 2013

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

Date: November 14, 2013

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