Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC. 20549

FORM 10-Q

(Mark One)

☒ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the Quarterly Period ended June 30, 2012**

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	**11-2962080**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
4400 Biscayne Blvd., Suite A-100, Miami, Florida	**33137**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (305) 575-4600

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒

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

48,797,755 shares of the Company's common stock, par value $0.001 per share, were outstanding as of August 10, 2012.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

TABLE OF CONTENTS FOR FORM 10-Q

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

($ in 000s, except per share data)

	June 30, 2012	December 31, 2011
ASSETS	(Unaudited)	
CURRENT ASSETS		
Cash and cash equivalents	$ 1,301	$ 298
Accounts Receivable – trade	8	—
Other receivable – related-party	35	66
Prepaid expenses	158	143
Inventories	1,646	—
Total Current Assets	3,148	507
FIXED ASSETS		
Property and equipment, net	392	470
OTHER ASSETS		
Security deposits	2	2
Deferred financing costs, net	9	14
Total Other Assets	11	16
TOTAL ASSETS	**$ 3,551**	**$ 993**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 1,146	$ 469
Total Current Liabilities	1,146	469
Stockholder loans, including accrued interest (Note 5)	—	2,523
Commitments and contingencies (Note 8)	—	—
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock, $0.001 par value per share, 225,000,000 shares authorized, 48,797,755 and 28,003,755 shares issued and outstanding	49	28
Additional paid-in capital	29,283	20,762
Deficit accumulated during the development stage	(26,927)	(22,789)
Total Stockholders' Equity (Deficit)	2,405	(1,999)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	**$ 3,551**	**$ 993**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

($ in 000s, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,		September 15, 2005 (Inception) to June 30, 2012
	2012	2011	2012	2011	
Revenues	$ 9	$ —	$ 9	$ —	$ 9
Cost of sales	171	—	171	—	171
Gross margin	**(162)**	**—**	**(162)**	**—**	**(162)**
Operating costs and expenses					
Research and development	769	849	1,947	1,505	14,884
Selling, general and administrative	1,068	467	1,981	1,121	10,977
Total operating costs and expenses	1,837	1,316	3,928	2,626	25,861
Operating loss	**(1,999)**	**(1,316)**	**(4,090)**	**(2,626)**	**(26,023)**
Other income and expense					
Other income	—	—	—	—	1,147
Interest income, net	—	—	—	—	79
Amortization of deferred financing cost	(3)	(6)	(5)	(31)	(1,975)
Interest exp	—	—	(43)	—	(155)
Total other income and expense	(3)	(6)	(48)	(31)	(904)
Loss before income tax	(2,002)	(1,322)	(4,138)	(2,657)	(26,927)
Provision for income tax	—	—	—	—	—
Net loss	**$ (2,002)**	**$ (1,322)**	**$ (4,138)**	**$ (2,657)**	**$ (26,927)**
Loss attributable to common stockholders and loss per common share:					
Net loss	(2,002)	(1,322)	(4,138)	(2,657)	(26,927)
Deemed dividend — Series A Preferred Stock	—	—	—	—	(700)
Deemed dividend — Series A Preferred Conversion	—	—	—	—	(4,301)
Dividends—Series A Preferred Stock	—	—	—	—	(366)
Net loss attributable to common stockholders	**$ (2,002)**	**$ (1,322)**	**$ (4,138)**	**$ (2,657)**	**$ (32,293)**
Weighted average shares outstanding, basic and diluted	48,798	28,004	43,314	28,004	
Net loss per basic and diluted share	**$ (0.04)**	**$ (0.05)**	**$ (0.10)**	**$ (0.09)**	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

(A Developmental Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH JUNE 30, 2012

($ in 000s, except per share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			
Inception — September 15, 2005	—	$ —	—	$ —	$ —	$ —	$ —
Capital contributed	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	(76)	(76)
Balance at December 31, 2005	—	$ —	—	$ —	$ 1	$ (76)	$ (75)
Capital contributed	—	—	11,256	11	1,493	—	1,504
Net loss	—	—	—	—	—	(1,060)	(1,060)
Balance at December 31, 2006	—	$ —	11,256	$ 11	$ 1,494	$ (1,136)	$ 369
Capital contributed	—	—	4,837	5	5,088	—	5,093
Net loss	—	—	—	—	—	(3,041)	(3,041)
Balance at December 31, 2007	**—**	**$ —**	**16,093**	**$ 16**	**$ 6,582**	**$ (4,177)**	**$ 2,421**
Issuance of common shares in private offering — May 2008 at $2.15 per share, net of offering costs	—	—	1,862	2	3,986	—	3,988
Issuance of common shares as repayment of stockholder note- December 30, 2008 at $1.22 per share			8	—	10	—	10
Stock-based compensation	—	—	—	—	239	—	239
Net loss	—	—	—	—	—	(5,185)	(5,185)
Balance at December 31, 2008	**—**	**$ —**	**17,963**	**$ 18**	**$ 10,817**	**$ (9,362)**	**$ 1,473**
Issuance of Series A Preferred Stock in July 2009 at $1.00 per share	2,000	20		—	1,962	—	1,982
Fair value of beneficial conversion feature of Series A Preferred Stock	—	—	—	—	200	—	200
Deemed dividend to Series A Preferred Stockholders, charged to additional paid-in capital in the absence of retained earnings	—	—	—	—	(200)	—	(200)
Stock-based compensation	—	—	—	—	195	—	195
Net loss	—	—	—	—	—	(2,366)	(2,366)
Balance at December 31, 2009	**2,000**	**$ 20**	**17,963**	**$ 18**	**$ 12,974**	**$ (11,728)**	**$ 1,284**
Issuance of Series A Preferred Stock in January 2010 at $1.00 per share	2,000	20		—	1,978	—	1,998
Fair value of beneficial conversion feature of Series A Preferred Stock	—	—	—	—	500	—	500
Deemed dividend to Series A Preferred Stockholders, charged to additional paid-in capital in the absence of retained earnings	—	—	—	—	(500)	—	(500)
Issuance of common shares in private offering —June 2010 at $1.00 per share, net of offering costs	—	—	4,978	5	4,969	—	4,974
Conversion of 4,000 shares of Series A Preferred Stock and accumulated dividends into 4,366 shares of Common Stock in September 2010	(4,000)	(40)	4,366	4	36	—	—
Issuance of 697 shares of Common Stock as Consideration Shares in September 2010	—	—	697	1	(1)	—	—
Intrinsic value of 5,063 aggregate shares of Common Stock issued on conversion of Series A Preferred Stock	—	—	—	—	4,301	—	4,301
Dividend paid to Series A Preferred Stockholders on conversion, charged to additional paid-in capital in the absence of retained earnings	—	—	—	—	(4,301)	—	(4,301)
Stock-based compensation	—	—	—	—	471	—	471
Net loss	—	—	—	—	—	(5,303)	(5,303)
Balance at December 31, 2010	**—**	**$ —**	**28,004**	**$ 28**	**$ 20,427**	**$ (17,031)**	**$ 3,424**
Stock-based compensation	—	—	—	—	335	—	335
Net loss	—	—	—	—	—	(5,758)	(5,758)
Balance at December 31, 2011	**—**	**$ —**	**$ 28,004**	**$ 28**	**$ 20,762**	**$ (22,789)**	**$(1,999)**
Issuance of 20,794,000 shares of Common Stock at $0.40 per share for cash in February 2012	—	—	20,794	21	8,297	—	8,318
Stock-based compensation	—	—	—	—	224	—	224
Net loss	—	—	—	—	—	(4,138)	(4,138)
Balance at June 30, 2012 (unaudited)	**—**	**$ —**	**$ 48,798**	**$ 49**	**$ 29,283**	**$ (26,927)**	**$ 2,405**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

($ in 000s)

	Six Months Ended June 30,		September 15, 2005 (Inception) to June 30,
	2012	2011	2012
OPERATING ACTIVITIES			
Net loss	$(4,138)	$(2,657)	$ (26,927)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	5	31	1,975
Stock-based compensation expense	224	142	1,529
Stock-based compensation expense related to Share Exchange	—	—	77
Depreciation and amortization	84	57	426
Loss from disposal of assets	—	20	20
Inventory Adjustments	—	—	139
Gain on sale of TruePosition investment	—	—	(903)
Changes in operating assets and liabilities			
Inventories	(1,646)	—	(1,785)
Other current assets	8	(30)	(181)
Other assets	—	—	(2)
Accounts payable and accrued liabilities	677	126	862
Accrued Interest	(48)	—	—
NET CASH USED IN OPERATING ACTIVITIES	**(4,834)**	**(2,311)**	**(24,770)**
INVESTING ACTIVITIES			
Purchase of equipment	(6)	(85)	(838)
Proceeds from sale of True Position investment	—	—	903
Payment received under Rule 16b	—	—	4
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	**(6)**	**(85)**	**69**
FINANCING ACTIVITIES			
Net cash provided in connection with the acquisition of SafeStitch LLC	—	—	3,192
Issuance of Common Stock, net of offering costs	8,318	—	17,280
Issuance of Preferred Stock, net of offering costs	—	—	3,980
Capital contributions	—	—	1,431
Proceeds from notes payable	—	—	141
Repayment of notes payable	—	(42)	(141)
Proceeds from stockholder loans	500	—	5,835
Repayment of stockholder loans	(2,975)	—	(5,751)
Exercise of options	—	—	35
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	**5,843**	**(42)**	**26,002**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,003	(2,438)	1,301
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	298	3,032	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 1,301	$ 594	$ 1,301
Supplemental disclosures:			
Cash paid for interest	$ 91	$ —	$ 155
Non cash activities:			
Non-cash dividend upon issuance & conversion of Preferred	$ —	$ —	$ 5,001
Stock dividends	$ —	$ —	$ 366
Stockholder loans contributed to capital	$ —	$ —	$ 84
Warrants issued in connection with credit facility	$ —	$ —	$ 1,985

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BASIS OF PRESENTATION AND LIQUIDITY

The following (a) condensed consolidated balance sheet as of December 31, 2011, which has been derived from audited financial statements, and (b) the unaudited condensed consolidated interim financial statements of SafeStitch Medical, Inc. ("SafeStitch" or the "Company") have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2012 are not necessarily indicative of results that may be expected for the year ending December 31, 2012. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on March 30, 2012.

SafeStitch Medical, Inc. (together with its consolidated subsidiaries, "SafeStitch" or the "Company") is a developmental stage medical device company focused on the development of medical devices that manipulate tissues for endoscopic and minimally invasive surgery for the treatment of obesity, gastroesophageal reflux disease ("GERD"), Barrett's Esophagus, esophageal obstructions, upper gastrointestinal bleeding, hernia formation and other intraperitoneal abnormalities.

Cellular Technical Services Company, Inc. ("Cellular"), a non-operating public company, was incorporated in 1988 as NCS Ventures Corp. under the laws of the State of Delaware. On July 25, 2007 Cellular entered into a Share Transfer, Exchange and Contribution Agreement (the "Share Exchange") with SafeStitch LLC, a Virginia limited liability company. On September 4, 2007, Cellular acquired all of the members' equity interests in SafeStitch LLC in exchange for 11,256,369 shares of Cellular's common stock, which represented a majority of Cellular's outstanding shares immediately following the Share Exchange. Effective January 8, 2008, Cellular changed its name to SafeStitch Medical, Inc. and increased the aggregate number of shares of capital stock that may be issued from 35,000,000 to 250,000,000, comprising 225,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 25,000,000 shares of preferred stock, par value $0.01 per share. For accounting purposes, the acquisition has been treated as a recapitalization of SafeStitch LLC, with SafeStitch LLC as the acquirer (reverse acquisition). The historical financial statements prior to September 4, 2007 are those of SafeStitch LLC, which began operations on September 15, 2005. The accompanying financial statements give retroactive effect to the recapitalization as if it had occurred on September 15, 2005 (inception).

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. For the period from September 15, 2005 (inception) through June 30, 2012, the Company has accumulated a deficit of $26.9 million and has not generated positive cash flows from operations.

The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain operations. The Company's efforts have been principally devoted to developing its technologies and commercializing its products. Based upon its current cash position, availability under the extended term of its $4.0 million line of credit from The Frost Group LLC ("The Frost Group") and the Company's President and CEO, Jeffrey G. Spragens (the "Credit Facility"), and by monitoring its discretionary expenditures, management believes that the Company will be able to fund its existing operations through June 30, 2013 when the Credit Facility matures. However, if the Company does not generate sufficient revenue from sales of the AMID™ Hernia Fixation Device (the "AMID HFD") to fund all planned operations, including the commercialization of certain of the Company's products and product candidates, including the Intraluminal Gastroplasty Device for Obesity and GERD ("Gastroplasty Device"), and the anticipated expansion in 2012 of clinical trials for certain of the Company's product candidates, external financing will be required. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate its research and development programs, reduce its planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that it might otherwise seek to develop or commercialize independently.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Although the Company plans to secure additional funds through the issuance of equity and/or debt, no assurance can be given that additional financing will be available to the Company on acceptable terms, or at all. Our management believes that based on our current cash position, together with the availability under our existing line of credit, which matures on June 30, 2013, and by monitoring our discretionary expenditures, we will be able to fund our current cash flow requirements through June 30, 2013. However, unless the Credit Facility Maturity Date is extended, additional funding will be required to repay the Credit Facility and to continue operations. This uncertainty raises substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements do not include any adjustments that might be necessary as a result of the outcome of such uncertainty. In addition to securing additional funds, the Company's ability to continue as a going concern is ultimately dependent upon generating revenues from those products that do not require further marketing clearance by the U.S. Food and Drug Administration ("FDA"), obtaining FDA clearance to market its other product candidates, and achieving profitable operations and generating sufficient cash flows from operations to meet future obligations.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Isis Tele-Communications, Inc., which has no current operations, and SafeStitch LLC. All inter-company accounts and transactions have been eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions, such as useful lives of property and equipment, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents. We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company holds cash and cash equivalent balances in banks and other financial institutions, and includes overnight repurchase agreements collateralizing its depository bank accounts (sweep accounts) in its cash balances. Balances in excess of Federal Deposit Insurance Corporation ("FDIC") limitations may not be insured.

Allowances for Doubtful Accounts. The Company provides an allowance for receivables it believes it may not collect in full. Receivables are written off when they are deemed to be uncollectible and all collection attempts have ceased. The amount of bad debt recorded each period and the resulting adequacy of the allowance for doubtful accounts at the end of each period are determined using a combination of customer-by-customer analysis of the Company's accounts receivable each period and subjective assessments of the Company's future bad debt exposure.

Inventories. Inventories are stated at lower of cost or market using the weighted average cost method and are evaluated for impairment when conditions exist that suggests impairment may be necessary. The $1.6 million inventory balance at June 30, 2012 consists of $972,000 in components, $671,000 in finished units of the AMID HFD and $3,000 in standard mesh. Scrap materials and quality testing costs are included in Cost of Goods Sold ("COGS"), as incurred. Provisions for potentially obsolete or slow-moving inventory are made based on management's analysis of inventory levels, obsolescence and future sales forecasts.

Property and equipment. Property and equipment are carried at cost less accumulated depreciation. Major additions and improvements are capitalized, while maintenance and repairs that do not extend the lives of assets are expensed. Gain or loss, if any, on the disposition of fixed assets is recognized currently in operations. Depreciation is calculated primarily on a straight-line basis over estimated useful lives of the assets.

Revenue Recognition. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, the goods are shipped and title has transferred, the price is fixed or determinable, and the collection of the sales proceeds is reasonably assured.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Advertising Costs. The Company expenses all costs of advertising as incurred. Advertising and promotional costs are included in selling, general and administrative costs and expenses for all periods presented, and totaled $45,000 and $83,000, respectively, for the three and six months ended June 30, 2012. Advertising and promotional costs and expenses totaled $0 and $9,000, respectively, for the three and six months ended June 30, 2011.

Research and development. Research and development costs principally represent salaries of the Company's medical and biomechanical engineering professionals, material and shop costs associated with manufacturing product prototypes and payments to third parties for clinical trials and additional product development and testing. All research and development costs are charged to expense as incurred.

Patent costs. Costs incurred in connection with acquiring patent rights and the protection of proprietary technologies are charged to expense as incurred.

Stock-based compensation. The Company accounts for all share-based payments to employees and directors, based on their grant date fair values. Compensation for share-based payments to non-employees is based on the fair value at the measurement date, which is generally the performance completion date. The fair value is initially measured at the grant date and subsequently measured at each reporting period until the final measurement date. The fair value of the Company's stock option awards is expensed over the vesting life of the underlying stock options using the graded vesting method, with each tranche of vesting options valued separately. Stock-based compensation is included in general and administrative costs and expenses for all periods presented.

Therapeutic discovery project tax credit. The Company records the therapeutic discovery project tax credit on an accrual basis when the credit is considered realized, which is generally when approved by the government agency. Such credit is reported as other income in the accompanying financial statements.

Fair value of financial instruments. The carrying amounts of cash and cash equivalents, accounts payable, accrued expenses and notes payable approximate fair value based on their short-term maturity. Related party receivables and stockholder loans are carried at cost.

Long-lived assets. The Company reviews the carrying values of its long-lived assets for possible impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less costs to sell.

Income taxes. The Company follows the liability method of accounting for income taxes, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of the assets and liabilities. The Company's policy is to record a valuation allowance against deferred tax assets, when the deferred tax asset is not recoverable. The Company considers estimated future taxable income or loss and other available evidence when assessing the need for its deferred tax valuation allowance.

Comprehensive income (loss). Comprehensive income (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. The Company's comprehensive net loss is equal to its net loss for all periods presented, and, as a result, no statement of comprehensive income (loss) has been included in the condensed consolidated financial statements.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	Estimated Useful Lives	June 30, 2012	December 31, 2011
Machinery and equipment	5 years	$ 660,000	$ 660,000
Furniture, fixtures and leasehold improvements	3-5 years	87,000	81,000
Software	3-5 years	57,000	57,000
		804,000	798,000
Accumulated depreciation and amortization		(412,000)	(328,000)
Property and equipment, net		**$ 392,000**	**$ 470,000**

Depreciation of fixed assets utilized in research and development activities is included in research and development costs and expenses. All other depreciation is included in selling, general and administrative costs and expenses. Depreciation and amortization expense was $42,000 and $84,000, respectively for the three and six months ended June 30, 2012, and was $30,000 and $57,000, respectively for the three and six months ended June 30, 2011.

NOTE 4 – STOCK-BASED COMPENSATION

On November 13, 2007, the Board of Directors and a majority of the Company's stockholders approved the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan (the "2007 Plan"), which was amended on June 19, 2012 to increase the number of shares of Common Stock available for issuance to 5,000,000. Under the 2007 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 up to an aggregate of 5,000,000 shares of Common Stock, which are fully reserved for future issuance. 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 and, within any 12 month period, no person may receive stock options or stock appreciation rights for more than one million shares. Additionally, no stock options or stock appreciation rights granted under the 2007 Plan may have a term exceeding ten years.

The Company granted 813,500 and 562,500 stock options under the 2007 Plan during the six months ended June 30, 2012 and 2011, respectively, including 218,000 and 68,000 stock options that were issued to consultants. The options granted during 2012 were issued at an exercise price ranging from $0.65 to $0.85 per share and had an estimated aggregate grant date fair value of $441,000. The options granted during 2011 were issued at an exercise price of $1.12 per share and had an estimated aggregate grant date fair value of $502,000. The weighted average grant date fair value of the options granted during the six months ended June 30, 2012 and 2011 was $0.54 per share and $0.89 per share, respectively.

Total stock-based compensation recorded for the three and six months ended June 30, 2012 was $113,000 and $224,000, respectively. Total stock-based compensation recorded for the three and six months ended June 30, 2011 was $98,000 and $142,000, respectively. The stock-based compensation recorded for the six months ended June 30, 2011 included a credit of $113,000 for a change in forfeiture experience. All stock-based compensation is included in selling, general and administrative costs and expenses. The fair values of options granted are estimated on the date of their grant using the Black-Scholes option pricing model based on the assumptions included in the table below. The fair value of the Company's stock option awards is expensed over the vesting life of the underlying stock options using the graded vesting method, with each tranche of vesting options valued separately. Expected volatility is based on the historical volatility of the Common Stock. The risk-free interest rate for periods within the contractual life of the stock option award is based on the yield of U.S. Treasury bonds on the grant date with a maturity equal to the expected term of the stock option. The expected life of stock option awards granted to employees and non-employee directors is based upon the "simplified" method for "plain vanilla" options described in SEC Staff Accounting Bulletin No. 107, as amended by SEC Staff Accounting Bulletin No. 110. The expected life of all other stock option awards is the contractual term of the option. Forfeiture rates are based on management's estimates. The fair value of each option granted during the six months ended June 30, 2012 and 2011 was estimated using the following assumptions.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	Six months ended June 30, 2012	Six months ended June 30, 2011
Expected volatility	85.41% -111.36%	76.91% -102.63%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.02% –1.98%	2.25% –3.25%
Expected life	5.5 – 10.0 years	5.5 –10.0 years
Forfeiture rate	0% - 2%	0% - 5%

The following summarizes the Company's stock option activity for the six months ended June 30, 2012:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011	1,628,167	$ 1.35	6.26	
Granted	813,500	$ 0.66	9.64	
Exercised	—	—		
Canceled or expired	(97,167)	$ 2.43		
Outstanding at June 30, 2012	2,344,500	$ 1.06	7.11	$ 0
Exercisable at June 30, 2012	1,128,125	$ 1.30	5.39	$ 0
Vested and expected to vest at June 30, 2012	2,292,060	$ 1.07	7.08	$ 0

None of the 813,500 options granted during the first six months of the Company's 2012 fiscal year were vested as of June 30, 2012. At June 30, 2012, there was approximately $446,000 of total unrecognized compensation cost related to non-vested employee and director share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.59 years.

No options were exercised during the three and six months ended June 30, 2012 and 2011.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.

NOTE 5 – DEBT

Credit Facility. In connection with the acquisition of SafeStitch LLC, the Company entered into a Note and Security Agreement (the "Credit Facility") with both The Frost Group and Jeffrey G. Spragens, the Company's Chief Executive Officer and President and a director. The Frost Group is a Florida limited liability company whose members include Frost Gamma Investments Trust ("Frost Gamma"), a trust controlled by Dr. Phillip Frost, the largest beneficial holder of the issued and outstanding shares of Common Stock, Dr. Jane H. Hsiao, the Company's Chairman of the Board, and Steven D. Rubin, a director. The Credit Facility provides $4.0 million in total available borrowings, consisting of $3.9 million from The Frost Group and $100,000 from Mr. Spragens. The Company has granted a security interest in all present and subsequently acquired collateral in order to secure prompt, full and complete payment of the amounts outstanding under the Credit Facility. The collateral includes all assets of the Company, inclusive of intellectual property (patents, patent rights, trademarks, service marks, etc.). Outstanding borrowings under the Credit Facility accrue interest at a 10% annual rate. The Credit Facility had an initial term of 28 months, expiring in December 2009, and was amended on four occasions to extend the Maturity Date, which is now June 30, 2013.

In connection with the Credit Facility, the Company granted warrants to purchase an aggregate of 805,521 shares of Common Stock to The Frost Group and Mr. Spragens. The fair value of the warrants was determined to be $1,985,000 on the grant date based on the Black-Scholes valuation model using the following assumptions: expected volatility of 82%, dividend

yield of 0%, risk-free interest rate of 4.88% and expected life of 10 years. The fair value of the warrants was recorded as deferred financing costs and is being amortized over the life of the Credit Facility. The Company recorded amortization expense related to these deferred financing costs of $3,000 and $5,000, respectively, for the three and six months ended June 30, 2012 and $6,000 and $31,000, respectively, for the three and six months ended June 30, 2011. The Company has no outstanding loans as of June 30, 2012.

NOTE 6 – CAPITAL TRANSACTIONS

2012 Private Placement of Common Stock. On February 17, 2012, the Company entered into a stock purchase agreement (the "2012 Stock Purchase Agreement") with 35 investors (the "2012 PIPE Investors") pursuant to which the 2012 PIPE Investors agreed to purchase an aggregate of 20,794,000 shares of Common Stock (the "2012 PIPE Shares") at a price of $0.40 per share for aggregate consideration of $8.3 million. Among the Investors purchasing Shares were Frost Gamma, Dr. Jane Hsiao, the Company's Chairman of the Board, Jeffrey Spragens, the Company's President and Chief Executive Officer and Richard Pfenniger, a member of the Company's Board of Directors. Frost Gamma and Dr. Hsiao each purchased 4,500,000 shares, Mr. Spragens purchased 250,000 shares, and Mr. Pfenniger purchased 125,000 shares. The Company issued the 2012 PIPE Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 of Regulation D promulgated thereunder.

NOTE 7 – 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 for the period reported. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding for the period reported. 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 three and six months ended June 30, 2012 and 2011, 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 is anti-dilutive.

Potential common shares not included in calculating diluted net loss per share are as follows:

	June 30, 2012	June 30, 2011
Stock options	2,344,500	1,629,667
Stock warrants	805,521	805,521
Total	**3,150,021**	**2,435,188**

NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company is obligated under various operating lease agreements for office space. Generally, the lease agreements require the payment of base rent plus escalations for increases in building operating costs and real estate taxes. Rental expense under operating leases amounted to $73,000 and $133,000 for the three and six months ended June 30, 2012, respectively, and $52,000 and $105,000 for the three and six months ended June 30, 2011, respectively.

The Company is obligated to pay royalties to Creighton University ("Creighton") on the sales of products licensed from Creighton pursuant to an exclusive license and development agreement (see Note 9). The Company is also obligated under an agreement with Dr. Parviz Amid to pay a 4% royalty to Dr. Amid on the sales of any product developed with Dr. Amid's assistance, including the AMID HFD, for a period of ten years from the first commercial sale of such product. Royalties to Dr. Parviz Amid in the amount of $400 have been incurred during the three and six months ended June 30, 2012. No royalties have been incurred or paid for the three and six months ended June 30, 2011.

The Company has placed orders with various suppliers for the purchase of certain tooling, contract engineering and research services. Each of these orders has a duration or expected completion within the next twelve months. The Company currently has no material commitments with terms beyond twelve months.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 9 – AGREEMENT WITH CREIGHTON UNIVERSITY

On May 26, 2006, SafeStitch LLC entered into an exclusive license and development agreement (the "Creighton Agreement") with Creighton, granting the Company a worldwide exclusive (even as to the university) license, with rights to sublicense, to all the Company's product candidates and associated know-how based on Creighton technology, including the exclusive right to manufacture, use and sell the product candidates.

Pursuant to the Creighton Agreement, the Company is obligated to pay Creighton, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from the sale of any product licensed under the Creighton Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The Creighton Agreement does not provide for minimum royalties. Also pursuant to the Creighton Agreement, the Company agreed to invest, in the aggregate, at least $2.5 million over 36 months, beginning May 26, 2006, towards development of any licensed product. This $2.5 million investment obligation excluded the first $150,000 of costs related to the prosecution of patents, which the Company invested outside of the Creighton Agreement. The Company is further obligated to pay to Creighton an amount equal to 20% of certain of the Company's research and development expenditures as reimbursement for the use of Creighton's facilities. Failure to comply with the payment obligations above will result in all rights in the licensed patents and know-how reverting back to Creighton. As of December 31, 2007, the Company had satisfied the $2.5 million investment obligation described above. The Company recorded research and development costs and expenses related to the 20% facility reimbursement obligation totaling approximately $11,000 and $23,000, respectively for the three and six months ended June 30, 2012, and $11,000 and $21,000, respectively, for the three and six months ended June 30, 2011.

NOTE 10 – INCOME TAXES

The Company accounts for income taxes using the asset and liability method, the objective of which is to establish deferred tax assets and liabilities for the temporary differences between the financial reporting and the tax bases of the Company's assets and liabilities at enacted tax rates expected to be in effect when such amounts are realized or settled. A valuation allowance related to deferred tax assets is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. All of the Company's deferred tax assets have been fully reserved by a valuation allowance due to management's uncertainty regarding the future profitability of the Company.

The Company has recognized no adjustment for uncertain tax provisions. SafeStitch recognizes interest and penalties related to uncertain tax positions in selling, general and administrative costs and expenses; however no such provisions for accrued interest and penalties related to uncertain tax positions have been recorded as of June 30, 2012 or December 31, 2011.

The tax years 2008-2011 remain open to examination by the major tax jurisdictions in which the Company operates.

NOTE 11 – CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

As more fully described in Note 5, the Company entered into a $4.0 million Credit Facility with both Jeffrey G. Spragens, the Company's President, Chief Executive Officer and director, and The Frost Group.

The Company entered into a five-year lease for office space in Miami, Florida with a company controlled by Dr. Frost. The non-cancelable lease, which commenced January 1, 2008, provides for a 4.5% annual rent increase over the life of the lease. The Miami office lease was amended in August 2011 to include additional office space in the same building, and current rental payments under the lease are approximately $19,000 per month. The Company recorded rent expense related to the Miami lease totaling approximately $69,000 and $126,000, respectively, for the three and six months ended June 30, 2012, and $47,000 and $94,000, respectively, for the three and six months ended June 30, 2011.

Dr. Hsiao, Dr. Frost and director Steven Rubin are each significant stockholders and/or directors of Non-Invasive Monitoring Systems, Inc. ("NIMS"), a publicly-traded medical device company, Aero Pharmaceuticals, Inc. ("Aero"), a privately-held pharmaceutical distribution company that dissolved in December 2011, Tiger X Medical, Inc. ("Tiger X") (formerly known as Cardo Medical, Inc.), a publicly-traded medical device company, and SearchMedia Holdings Limited

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

("SearchMedia"), a publicly-traded media company operating primarily in China, and Sorrento Therapeutics, Inc. ("Sorrento"), a publicly-traded development stage biopharmaceutical company. Director Richard Pfenniger is also a shareholder of NIMS. The Company's Chief Financial Officer also serves as the Chief Financial Officer and supervises the accounting staffs of NIMS and, until its dissolution, Aero, under a Board-approved cost sharing arrangement whereby the total salaries of the accounting staffs of the three companies are shared. Aero has not participated in the cost sharing arrangement since June 30, 2011 and was dissolved in December 2011. Since December 2009, the Company's Chief Legal Officer has served under a similar Board-approved cost sharing arrangement as Corporate Counsel of SearchMedia and as the Chief Legal Officer of each of NIMS and Tiger X, and since June 2011, as Corporate Counsel for Sorrento. The Company has recorded reductions to selling, general and administrative costs and expenses to account for the sharing of costs under these arrangements of $52,000 and $103,000, respectively, for the three and six months ended June 30, 2012, and $78,000 and $154,000, respectively, for the three and six months ended June 30, 2011. Aggregate accounts receivable from NIMS, Aero, Tiger X and SearchMedia were approximately $35,000 and $66,000 as of June 30, 2012 and December 31, 2011, respectively.

NOTE 12 – EMPLOYEE BENEFIT PLANS

Effective May 1, 2008, the SafeStitch 401(k) Plan (the "401k Plan") permits employees to contribute up to 100% of qualified annual compensation up to annual statutory limitations. Employee contributions may be made on a pre-tax basis to a regular 401(k) account or on an after-tax basis to a "Roth" 401(k) account. The Company contributes to the 401k Plan a "safe harbor" match of 100% of each participant's contributions to the 401k Plan up to a maximum of 4% of the participant's qualified annual earnings. The Company recorded 401(k) Plan matching expense of approximately $4,000 and $15,000, respectively, for the three and six months ended June 30, 2012 and $9,000 and $19,000, respectively, for the three and six months ended June 30, 2011.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Quarterly Report on Form 10-Q contains certain forward-looking statements about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual operations or results to differ materially from the operations and results anticipated in forward-looking statements. These factors include, but are not limited to: our ability to obtain additional funding to continue our operations; our ability to successfully commercialize our existing products; our ability to successfully develop, clinically test and commercialize our products and product candidates; the timing and outcome of the regulatory review process for our product candidates; 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; 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 product candidates, as well as the factors contained in "Item 1A—Risk Factors" of our Annual Report on Form 10-K. We do not undertake any obligation to update forward-looking statements, except as required by applicable law. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Overview

We are a developmental stage FDA-registered medical device company focused on the design and development of medical devices that manipulate tissues for the treatment of obesity, gastroesophageal reflux disease ("GERD"), hernia formation, esophageal obstructions, Barrett's Esophagus, upper gastrointestinal bleeding, and other intraperitoneal abnormalities through endoscopic and minimally invasive surgery.

We have utilized our expertise in intraperitoneal surgery to test certain of our devices in *in vivo* and *ex vivo* animal trials and *ex vivo* human trials, and with certain products, in limited *in vivo* human trials. We have also commercially developed the AMID HFD that has received FDA clearance to market in the United States. Certain of our products did not require clinical trials, including our AMID HFD, SMART Dilator™, and standard and airway bite blocks. Where required, we intend to rapidly, efficiently and safely move into clinical trials for certain other devices, including those utilized in surgery for the treatment of obesity, GERD and for the treatment and diagnosis of Barrett's Esophagus.

Products and Product Candidates

We received the necessary FDA 510(k) clearances to market the SMART Dilator™ as Class II devices in February 2009. Our standard and airway bite blocks are Class I 510(k)-exempt devices that require no preclearance from the FDA prior to marketing. In November 2009, we received FDA clearance to market the AMID Stapler® in the U.S. as a Class II device, and, in February 2010, we received the Conformité Européenne (the "CE Mark") which enables the eventual commercialization in the European Economic Area and other countries that recognize the European CE Mark. After we commenced production of the AMID Stapler® in 2010, we voluntarily suspended sales in order to implement several design for manufacturability improvements and a more robust and reliable commercial manufacturing process. As a result of these design improvements, we submitted a "Special 510(k)" to FDA that was cleared in February 2012, and allows us to market the AMID Stapler® in the United States. In May 2012, we changed the name of the AMID Stapler® to the AMID™ Hernia Fixation Device (the "AMID HFD"). Additionally, we will supplement our Technical File prior to marketing the AMID HFD in the European Union.

We have successfully tested our first investigational Gastroplasty Device in five patients in Hungary. At the 18 month follow-up in March 2012, we observed, through endoscopic visualization, that the operative site showed significant scar tissue as intended, with the scar forming a restrictive ring for weight loss or, in the case of GERD, a barrier to prevent acid from refluxing into the esophagus. We expect to continue *in vivo* human testing of this device in 2013. We are preparing separate GERD and obesity clinical trial protocols for this device and anticipate submitting the final investigational device exemption ("IDE") trial plans to the FDA for review in 2013. We intend to apply to the FDA for clearance of the Gastroplasty Device for the GERD indication and approval for the obesity indication.

We continue to evaluate commercialization options for our SMART Dilator™ and our standard and airway bite blocks.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth below under "Results of Operations" and "Liquidity and Capital Resources" should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this Form 10-Q. 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 estimates, including the carrying value of our long term investments, property and equipment, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note 2 in the Notes to the Consolidated Financial Statements set forth in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2011. Actual results may differ from these estimates.

Results of Operations

We began marketing and commercial sales of the AMID HFD in the second quarter of 2012 with direct sales representatives, indirect sales representatives and distributors located throughout the United States. Our experience has been that there is a sales cycle of approximately three to twelve months in which the institutional purchasing committees and surgeons must evaluate the product before receiving clearance to purchase.

We incurred losses of $4.1 million and $2.7 million for the six months ended June 30, 2012 and 2011, respectively, and we had an accumulated deficit of $26.9 million at June 30, 2012. Since we do not currently generate significant revenue from any of our products, including those already cleared for commercial marketing by the FDA, we expect to continue to generate losses in connection with the commercial launch of such FDA-cleared products and the continual development of our other products and technologies. Our research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe our operating losses are likely to be substantial over the next several years.

Three and Six Months ended June 30, 2012 Compared to Three and Six Months Ended June 30, 2011

Sales were $9,000 for the three and six months ended June 30, 2012, as compared to no sales for the three and six months ended June 30, 2011. The $9,000 of sales is the result of our first commercial shipment of the AMID HFD.

Costs of goods sold ("COGS") were $171,000 for the three and six months ended June 30, 2012, as compared to no COGS for the three and six months ended June 30, 2011. The COGS for the three and six months ended June 30, 2012 included $166,000 for scrap materials and quality testing costs. The costs associated with scrap materials and quality testing is expected to decrease in the future as the manufacturing line matures. Excluding scrap materials and quality testing costs, the COGS were $5,000 and gross margin was $4,000 for the three and six months ended June 30, 2012.

Research and development ("R&D") expenses primarily consist of engineering, product development and clinical and regulatory expenses, incurred in the development of our products and product candidates. R&D expenses were $769,000 and $1.9 million, respectively, for the three and six months ended June 30, 2012 as compared to $849,000 and $1.5 million, respectively, for the three and six months ended June 30, 2011. The year over year three month decrease of $80,000 is primarily related to decreases in hardware, contract research and trial costs associated with the Gastroplasty device and reductions in the AMID HFD contract engineering services and hardware as a result of product commercialization. The year over year six month increase of $0.4 million resulted primarily from an increase of R&D consulting and contract engineering services, increase in manufacturing staff, and increased expenditures for AMID HFD hardware during the first quarter.

Selling, general and administrative ("SG&A") expenses consist primarily of salaries, market development and other related costs, including stock based compensation. Other SG&A costs and expenses include facility-related costs not otherwise included in R&D costs and expenses, costs associated with attending medical conferences, professional fees for legal, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, accounting services, consulting fees and travel expenses. SG&A expenses were $1.1 million and $2.0 million, respectively, for the three and six months ended June 30, 2012, as compared to $467,000 and $1.1 million, respectively for the three and six months ended June 30, 2011. These $601,000 and $0.9 million respective increases resulted primarily from the addition of personnel in sales and marketing, manufacturing and quality and regulatory departments, increase in sales and marketing travel expenses, AMID HFD marketing cost, rental cost and manufacturing cost associated with the production of the AMID HFD. These increases were offset in part by reductions in accounting staff and a stock-based compensation forfeiture true-up credit recorded in 2011.

Liquidity and Capital Resources

As a result of our significant R&D expenditures and the lack of any significant product sales revenue, we have generated operating losses since inception and we expect to incur losses from operations for the foreseeable future. We expect to incur continued R&D costs and expenses, including expenses for product development and conducting clinical trials. We expect that SG&A costs and expenses will increase in future years as we expand our regulatory compliance and administrative staff and continue to add sales and marketing personnel and infrastructure.

To date, we have funded our operations primarily with proceeds from private placement of common and preferred stock and our $4.0 million credit facility. Our ability to sell additional shares of our stock and/or borrow cash under existing or new credit facilities could be materially adversely affected by, among other things, any economic turmoil in the world's equity and credit markets. There can therefore be no assurance that we will be able to raise funds on acceptable terms or at all, which may materially adversely affect our ability to continue our operations. Additionally, uncertain economic conditions could reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our product candidates. Such delay could have a material adverse impact on our expected cash flows, liquidity, results of operations and financial position.

We have received FDA clearance to begin marketing the AMID HFD in the United States and we are preparing to commence clinical trials of our Gastroplasty Device. We began marketing and commercial sales of the AMID HFD in the second quarter of 2012. Commencing such commercialization and clinical trial activities is anticipated to significantly increase our cash requirements for 2012 and into the foreseeable future. Our management believes that based on our current cash position, together with the availability under our existing line of credit, which matures on June 30, 2013, and by monitoring our discretionary expenditures, we will be able to fund our current cash flow requirements through June 30, 2013. However, unless the Credit Facility Maturity Date is extended, additional funding will be required to repay the Credit Facility and to continue operations.

However, if the Company does not generate sufficient revenue from sales of the AMID HFD to fund all planned operations, including the commercialization of certain of our products and the anticipated expansion of clinical trials for certain of our product candidates, additional external financing will be required. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the precise amounts of capital outlays and operating expenditures associated with our current and anticipated commercialization efforts and clinical trials. This uncertainty raises substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might be necessary as a result of the outcome of such uncertainty.

Our actual future capital requirements will depend on many factors, including sales of the AMID HFD, the progress and results of our clinical trials, the duration and cost of discovery and preclinical development, and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our R&D programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies as defined in Rule 12b-2 of the Exchange Act.

Item 4. Controls and Procedures.

We maintain a system of disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) that is designed to provide reasonable assurance that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to management in a timely manner. Our Chief Executive Officer and Chief Financial Officer evaluated this system of disclosure controls and procedures as of the end of the period covered by this quarterly report and have concluded that the system is operating effectively to ensure appropriate disclosure.

There were no significant changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act that occurred during period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

There have been no material changes in our risk factors since the filing of our Annual Report on Form 10-K for the year ended December 31, 2011.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibits:

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*

* 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.

SIGNATURES

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

SAFESTITCH MEDICAL, INC.

Date: August 14, 2012

By: /s/ Jeffrey G. Spragens
Jeffrey G. Spragens
President and Chief Executive Officer

Date: August 14, 2012

By: /s/ James J. Martin
James J. Martin
Chief Financial Officer

Exhibit 31.1

CERTIFICATIONS

I, Jeffrey G. Spragens, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SafeStitch Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Jeffrey G. Spragens
Jeffrey G. Spragens
Chief Executive Officer (Principal Executive Officer)
August 14, 2012

Exhibit 31.2

CERTIFICATIONS

I, James J. Martin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SafeStitch Medical, Inc.;

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

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

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

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

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

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

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

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

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

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

By: /s/ James J. Martin
James J. Martin
Chief Financial Officer
August 14, 2012

Exhibit 32.1

CERTIFICATION PURSUANT
TO 18 U.S.C. Section 1350, as Adopted Pursuant to
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report on Form 10-Q of SafeStitch Medical, Inc. (the "Company") for the quarter ended June 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey G. Spragens, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Jeffrey G. Spragens
Jeffrey G. Spragens
Chief Executive Officer and President
August 14, 2012

Exhibit 32.2

CERTIFICATION PURSUANT
TO 18 U.S.C. Section 1350, as Adopted Pursuant to
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report on Form 10-Q of SafeStitch Medical, Inc. (the "Company") for the quarter ended June 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James J. Martin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ James J. Martin
James J. Martin
Chief Financial Officer
August 14, 2012