**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 **March 31, 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** | **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 ☒

61,699,276 shares of the Company's common stock, par value $0.001 per share, were outstanding as of May 10, 2013.

**SAFESTITCH MEDICAL, INC.**
**(A Developmental Stage Company)**

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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

($ in 000s, except per share data)

| | March 31, 2013 | December 31, 2012 |
|---|---|---|
| **ASSETS** | (Unaudited) | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 1,834 | $ 275 |
| Accounts Receivable – trade | 9 | 12 |
| Other receivable – related-party | 62 | 59 |
| Prepaid expenses | 106 | 140 |
| Inventory | 1,594 | 1,600 |
| Total Current Assets | 3,605 | 2,086 |
| FIXED ASSETS | | |
| Property and equipment, net | 297 | 332 |
| OTHER ASSETS | | |
| Security deposits | 2 | 2 |
| Total Other Assets | 2 | 2 |
| **TOTAL ASSETS** | **$ 3,904** | **$ 2,420** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued liabilities - vendors | $ 1,039 | $ 1,224 |
| Accounts payable and accrued liabilities – related party | 96 | $ 39 |
| Stockholders loans, including accrued interest - current | – | $ 912 |
| Total Current Liabilities | 1,135 | 2,175 |
| Commitments and contingencies (Note 8) | – | – |
| STOCKHOLDERS' EQUITY | | |
| Common stock, $0.001 par value per share, 225,000,000 shares authorized, | | |
| 61,699,276 and 49,603,276 shares issued and outstanding, respectively. | 62 | 50 |
| Additional paid-in capital | 32,785 | 29,708 |
| Deficit accumulated during the development stage | (30,078) | (29,513) |
| Total Stockholders' Equity | 2,769 | 245 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | **$ 3,904** | **$ 2,420** |

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 AND COMPREHENSIVE INCOME**

($ in 000s, except per share data)

| | Three Months Ended March 31, | | September 15, 2005 (Inception) to March 31, |
|---|---|---|---|
| | 2013 | 2012 | 2013 |
| Revenues | $ 11 | $ – | $ 46 |
| Cost of sales | 4 | – | 386 |
| **Gross margin** | 7 | – | (340) |
| | | | |
| Costs and expenses | | | |
| Research and development | 148 | 1,177 | 16,002 |
| | | | |
| Selling, general and administrative | 401 | 915 | 12,788 |
| | | | |
| Total costs and expenses | 549 | 2,092 | 28,790 |
| **Loss from operations** | **(542)** | **(2,092)** | **(29,130)** |
| | | | |
| Other income and expense | | | |
| Other income | – | – | 1,147 |
| Interest income | – | – | 79 |
| | | | |
| Amortization of debt issuance expense | – | (2) | (1,984) |
| | | | |
| Interest expense | (23) | (43) | (190) |
| | | | |
| Total other income and expense | (23) | (45) | (948) |
| | | | |
| Loss before income tax | (565) | (2,137) | (30,078) |
| | | | |
| Provision for income tax | – | – | – |
| | | | |
| **Net loss** | **$ (565)** | **$ (2,137)** | **$ (30,078)** |
| Comprehensive income (loss) | **$ 0** | **$ 0** | **$ 0** |
| **Comprehensive loss** | **$ (565)** | **$ (2,137)** | **$ (30,078)** |
| | | | |
| Loss attributable to common stockholders and loss per common share: | | | |
| | | | |
| Net loss | (565) | (2,137) | (30,078) |
| 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** | **(565)** | **(2,137)** | **$ (35,445)** |
| | | | |
| Weighted average shares outstanding, basic and diluted | 50,813 | 37,829 | |
| | | | |
| Loss per share | $ (0.01) | $ (0.06) | |

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

**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

**FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH MARCH 31, 2013**

($ 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 |
| Issuance of 805,521 shares of Common Stock for Warrants as $0.25 per share for cash in October 2012 | – | – | 805 | 1 | 200 | – | 201 |
| Stock-based compensation | – | – | – | – | 448 | – | 448 |
| Net loss | – | – | – | – | – | (6,724) | (6,724) |
| **Balance at December 31, 2012** | **–** | **$ –** | **49,603** | **$ 50** | **$ 29,708** | **$ (29,513)** | **$ 245** |
| Issuance of 12,096,000 shares of Common Stock at $0.25 per share for cash in March 2013 | – | – | 12,096 | 12 | 3,012 | – | 3,024 |
| Stock-based compensation | – | – | – | – | 65 | – | 65 |
| Net loss | – | – | – | – | – | (565) | (565) |
| **Balance at March 31, 2013** | **–** | **$ –** | **61,699** | **$ 62** | **$ 32,785** | **$ (30,078)** | **$ 2,796** |

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)

| | Three Months Ended March 31, | | September 15, 2005 (Inception) to March 31, |
|---|---|---|---|
| | **2013** | **2012** | **2013** |
| OPERATING ACTIVITIES | | | |
| Net loss | $ (565) | $ (2,137) | $ (30,078) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Amortization of deferred finance costs | – | 2 | 1,984 |
| Stock-based compensation expense | 65 | 111 | 1,818 |
| Stock-based compensation expense related to Share Exchange | – | – | 77 |
| Depreciation and amortization | 35 | 42 | 544 |
| Loss from disposal of assets | – | – | 20 |
| Gain on sale of TruePosition investment | – | – | (903) |
| Inventory disposals | – | – | 337 |
| Changes in operating assets and liabilities | | | |
| Inventory | 6 | (506) | (1,931) |
| Other current assets | 34 | 50 | (157) |
| Other assets | – | – | (2) |
| Accounts payable and accrued liabilities | (128) | 329 | 851 |
| Accrued Interest | (12) | (48) | – |
| **NET CASH USED IN OPERATING ACTIVITIES** | **(565)** | **(2,157)** | **(27,440)** |
| | | | |
| INVESTING ACTIVITIES | | | |
| Purchase of equipment | – | (5) | (861) |
| Proceeds from sale of True Position investment | – | – | 903 |
| Payment received under Rule 16b | – | – | 4 |
| **NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES** | **–** | **(5)** | **46** |
| | | | |
| FINANCING ACTIVITIES | | | |
| Net cash provided in connection with the acquisition of SafeStitch LLC | – | – | 3,192 |
| Issuance of Common Stock, net of offering costs | 3,024 | 8,318 | 20,305 |
| Issuance of Preferred Stock, net of offering costs | – | – | 3,980 |
| Capital contributions | – | – | 1,431 |
| Proceeds from notes payable | – | – | 141 |
| Repayment of notes payable | – | – | (141) |
| Proceeds from stockholders loans | 200 | 500 | 6,935 |
| Repayment of stockholders loans | (1,100) | (2,975) | (6,851) |
| Exercise of warrants | – | – | 201 |
| Exercise of options | – | – | 35 |
| **NET CASH PROVIDED BY FINANCING ACTIVITIES** | **2,124** | **5,843** | **29,228** |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 1,559 | 3,681 | 1,834 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 275 | 298 | – |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 1,834 | $ 3,979 | $ 1,834 |
| Supplemental disclosures: | | | |
| Cash paid for interest | $ 35 | $ 91 | $ 191 |
| 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

## NOTE 1 – BASIS OF PRESENTATION AND LIQUIDITY

The (a) condensed consolidated balance sheet as of December 31, 2012, 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 amounts) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2013 and cash flows for the three months ended March 31, 2013, are not necessarily indicative of results that may be expected for the year ending December 31, 2013 or for future periods. 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, 2012 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on April 1, 2013.

Certain prior year amounts in the condensed consolidated balance sheet have been reclassified to conform to the current period's presentation. These reclassifications had no impact on our results of operations.

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 March 31, 2013, the Company has accumulated a deficit of $30.0 million and has not generated positive cash flows from operations.

On March 22, 2013, the Company sold approximately 12,100,000 shares of our common stock (the "2013 PIPE Shares") in a private placement at a price of $0.25 per share, with net proceeds to the Company of approximately $3.0 million (Note 6). Included in this private placement was the issuance of warrants (the "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. Approximately 50% of the shares and warrants offered were purchased by our officers, directors and significant shareholders. The capital raised will be primarily used for the expansion of our Gastroplasty Device study in Hungary scheduled for 2013, continued development of the Gastroplasty Device and sales and marketing efforts for the AMID™ Hernia Fixation Device (the "AMID HFD"). Approximately $1.1 million of the proceeds was used to pay off amounts outstanding under the Credit Facility and promissory notes. Based upon the Company's current cash position and by monitoring our discretionary expenditures, we anticipate that the Company will likely be able to fund operations through the end of this year. We based this belief on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. Beyond this year, the Company will need to raise additional funds in order to continue its operations.

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, one of the largest beneficial holders 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 (see Note 5). We believe it is probable that the Credit Facility will not be extended beyond its June 30, 2013 maturity date and additional funding will be required to continue operations. We intend to seek external financing for our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. The Company currently does not have any commitments for future external funding. Almost all of the Company's equity and financing to date has been provided from the Company's principal existing stockholders and there is no assurance that the Company's stockholders will continue to provide the necessary financing for us to continue our operations or that any additional equity or debt financing will be available to the Company on acceptable terms, or at all. If adequate funds are not available when needed, the Company may be required to delay, further reduce the scope of or eliminate our research and development programs, including the development of the Gastroplasty Device, all of which may not significantly extend the period of time that the Company will be able to continue operations without raising additional funding.

It is uncertain as to the length of time the Company can sustain continued operations without the availability of additional funds and with the probability that the Credit Facility will not be extended. This uncertainty raises substantial doubt about the Company's ability to continue as a going concern. The Company's financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. Provisions for potentially obsolete or slow-moving inventory are made based on management's analysis of inventory levels, obsolescence and future sales forecasts. The Company had approximately 5,775 AMID HFD units in inventory at March 31, 2013.

***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 will be 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.

The Company's revenue was a result of AMID HFD product sales. There were 36 units sold for the three months ended March 31, 2013 and there were no units available for sale during the three months ended March 31, 2012. In addition, there were 18 AMID HFD units used for demonstration purposes during the year ended March 31, 2013 and no units were available for demonstration purposes during the year ended March 31, 2012.

***Advertising Costs.*** The Company expenses all costs of advertising as incurred. Advertising and promotional costs are included in selling, general and administrative ("SG&A") costs and expenses for all periods presented, and totaled $520 and $38,000, respectively, for the three months ended March 31, 2013 and 2012.

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

***Fair value of financial instruments***. Authoritative guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy consists of three broad levels, as described below:

- Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 - Inputs that are both significant to the fair value measurement and unobservable.

***Long-lived assets.*** Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value, or carrying amount for cost basis assets, of the asset.

***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.

**NOTE 3 – PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

| | Estimated Useful Lives | March 31, 2013 | December 31, 2012 |
|---|---|---|---|
| Machinery and equipment | 5 years | $ 682,000 | $ 682,000 |
| Furniture, fixtures and leasehold improvements | 3-5 years | 88,000 | 88,000 |
| Software | 3-5 years | 57,000 | 57,000 |
| | | 827,000 | 827,000 |
| Accumulated depreciation and amortization | | (530,000) | (495,000) |
| **Property and equipment, net** | | **$ 297,000** | **$ 332,000** |

Depreciation of fixed assets utilized in research and development activities is included in research and development expense. All other depreciation is included in general and administrative costs and expenses. Depreciation and amortization expense was $35,000 and $42,000, respectively for the three months ended March 31, 2013 and 2012.

**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 exceeding 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 did not grant any stock options under the 2007 Plan during the three months ended March 31, 2013 and granted 813,500 stock options during the three months ended March 31, 2012. 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 weighted average grant date fair value of the options granted during the three months ended March 31, 2012 was $0.54 per share.

Total stock-based compensation recorded for the three months ended March 31, 2013 and 2012 was $65,000 and $111,000, respectively, and is included in 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. 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 three months ended March 31, 2012 was estimated using the following assumptions.

| | Three months ended March 31, 2012 |
|---|---|
| Expected volatility | 85.41% - 111.36% |
| Expected dividend yield | 0.00% |
| Risk-free interest ratey | 1.02% – 1.98% |
| Expected life | 5.5 – 10.0 years |
| Forfeiture rate | 0% - 2% |

The following summarizes the Company's stock option activity for the three months ended March 31, 2013:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2012 | 2,079,000 | $ 1.03 | 6.77 | |
| Granted | – | – | | |
| Exercised | – | – | | |
| Canceled or expired | (140,500) | $ 1.25 | | |
| Outstanding at March 31, 2013 | 1,938,500 | $ 1.01 | 6.49 | $ – |
| Exercisable at March 31, 2013 | 1,561,375 | $ 1.05 | 6.14 | $ |
| Vested and expected to vest at March 31, 2013 | 1,930,975 | $ 1.02 | 6.44 | $ – |

At March 31, 2013, there was $156,513 of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.78 years.

No options were exercised during the three months ended March 31, 2013 and 2012.

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 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, one of the largest beneficial holders 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 $0 and $2,000, respectively, for the three months ended March 31, 2013 and 2012. In October 2012, The Frost Group and Mr. Spragens exercised the warrants for the purchase of 805,521 shares of Common Stock at an exercise price of $0.25 per share with net proceeds to the Company of $201,000.

The Company had a principal balance outstanding of $300,000 under the Credit Facility in March 2013 during which period the Credit Facility was paid off in its entirety, plus approximately $15,000 in accrued interest, using the proceeds of the 2013 Private Placement of Common Stock described below in Note 6. There were no amounts due or outstanding under the Credit Facility as of March 31, 2013.

On November 20, 2012, the Company entered into a Promissory Note in the principal amount of $300,000 with Hsu Gamma Investments, L.P. ("Hsu Gamma"), an entity controlled by the Company's Chairman of the Board, Jane H. Hsiao, (the "Hsu Gamma Note"). The interest rate payable by the Company on the Hsu Gamma Note is 10% per annum, payable on the maturity date of June 30, 2013. The Hsu Gamma Note may be prepaid in advance of the Maturity Date without penalty. In March 2013, the Hsu Gamma Note was paid off in its entirety, plus approximately $10,000 in accrued interest, using the proceeds of the 2013 Private Placement of Common Stock described below in Note 6.

On December 26, 2012, the Company entered into a Promissory Note in the principal amount of $300,000 with Frost Gamma, an entity controlled by one of the Company's largest beneficial holders of common stock, Dr. Phillip Frost (the "Frost Gamma Note"). The interest rate payable by the Company on the Frost Gamma Note is 10% per annum, payable on the maturity date of June 30, 2013. The Frost Gamma Note may be prepaid in advance of the Maturity Date without penalty. In March 2013, the Frost Gamma Note was paid off in its entirety, plus approximately $8,000 in accrued interest, using the proceeds of the 2013 Private Placement of Common Stock described below in Note 6.

On February 22, 2013 the Company entered into a promissory note in the principal amount of $200,000 with Jane Hsiao, the Company's Chairman of the Board (the "Hsiao Note"). The interest payable by the Company on the Hsiao Note is 10% per annum, payable on the maturity date of June 30, 2013 (the "Maturity Date"). The Hsiao Note may be prepaid in advance of the Maturity Date without penalty. In March 2013, the Hsiao Note was paid off in its entirety, plus approximately $2,000 in accrued interest, using the proceeds of the 2013 Private Placement of Common Stock described below in Note 6.

**NOTE 6 – CAPITAL TRANSACTIONS**

*2013 Private Placement of Common Stock.* On March 22, 2013, the Company 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 Frost Gamma, Dr. Jane Hsiao, the Company's Chairman of the Board and Jeffrey Spragens, the Company's President and Chief Executive Officer. Frost Gamma purchased 2.0 million shares and received 1.0 million warrants, Dr. Hsiao purchased 4.0 million shares and received 2.0 million warrants and Mr. Spragens purchased 400,000 shares and received 200,000 warrants. The Company issued the 2013 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.

*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 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.

*2010 Private Placement of Common Stock.* On June 15, 2010, the Company entered into a stock purchase agreement (the "2010 Stock Purchase Agreement") with 20 investors (the "2010 PIPE Investors") pursuant to which the 2010 PIPE Investors agreed to purchase an aggregate of 4,978,000 shares of Common Stock (the "2010 PIPE Shares") at a price of $1.00 per share for aggregate consideration of $4,978,000. Among the 2010 PIPE Investors who purchased a portion of the PIPE Shares were Hsu Gamma and Frost Gamma. Hsu Gamma and Frost Gamma each purchased 1,300,000 PIPE Shares. The Company issued the 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 months ended March 31, 2013 and 2012, 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:

| | March 31, 2013 | March 31, 2012 |
|---|---|---|
| Stock options | 1,938,500 | 2,353,000 |
| Stock warrants | 6,050,000 | 805,521 |
| **Total** | **7,988,500** | **3,158,521** |

## NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company was obligated under various operating lease agreements for office space that expired in 2012. 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 $51,000 and $60,000 for the three months ended March 31, 2013 and 2012, respectively. At March 31, 2013, the Company was no longer obligated under any non-cancellable operating leases.

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 were incurred in the amount of $400 during the three months ended March 31, 2013 and no royalties were incurred during the three months ended March 31, 2012.

The Company has placed orders with various suppliers for the purchase of certain tooling, inventory and 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.

## 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. For the three months ended March 31, 2013 and 2012, the Company paid Creighton $3,000 and $12,000, respectively, in satisfaction of the 20% facility reimbursement obligation.

Pursuant to the Creighton Agreement, the Company is entitled to exercise its own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion and other commercial exploitation of any licensed products, provided that, if the Company has not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the Creighton Agreement or the date such technology is disclosed to and accepted by the Company, then the licensed patent and associated know-how shall revert back to the university, with no rights retained by the Company, and the university will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless the Company purchases one or more one-year extensions. The Company is in accordance with these provisions.

## 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 March 31, 2013 or December 31, 2012.

The tax years 2009-2012 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 $17,000 per month. The Company recorded $51,000 and $57,000 of rent expense related to the Miami lease for the three months ended March 31, 2013 and 2012, respectively.

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 TigerMedia, Inc. ("TigerMedia) (formerly known as SearchMedia Holdings Limited), a publicly-traded media company operating primarily in China. 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 TigerMedia and as the Chief Legal Officer of each of NIMS and Tiger X. The Company has recorded reductions to SG&A costs and expenses for the three months ended March 31, 2013 and 2012 of $7,000 and $8,000, respectively, to account for the sharing of accounting costs under this arrangement. The Company has recorded $43,000 and $43,000 of reductions to SG&A costs and expenses for the three months ended March 31, 2013 and 2012, respectively, to account for the sharing of legal costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X and TigerMedia were approximately $62,000 and $25,000 as of March 31, 2013 and December 31, 2012, respectively and are included in other receivable—related party.

**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 $5,000 and $11,000 for the three months ended March 31, 2013 and 2012, respectively.

**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; whether the Credit Facility is extended or replaced with similar terms; 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 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. Certain of our products did not or may not require clinical trials, including our AMID HFD, SMART Dilator™, and standard and airway bite blocks. Where required, we intend to, 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***

In November 2009, we received FDA clearance to market the AMID HFD in the U.S. as a Class II device, and, in February 2010, we received CE Mark clearance to market the stapler in the European Union and other countries requiring CE clearance. After we commenced production of the AMID HFD in 2010, we voluntarily suspended sales in order to implement several design 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 manufacture the AMID HFD in the United States. 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 24 month follow-up in September 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 Hungary in 2013 to gather additional data. We are preparing 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 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. We continue to evaluate commercialization options for the 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 stock based compensation, revenue recognition, inventory, 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, 2012. Actual results may differ from these estimates.

***Results of Operations***

We incurred losses of $565,000 and $2,137,000 for the three months ended March 31, 2013 and 2012, respectively, and we had an accumulated deficit of $30.0 million at March 31, 2013. 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 Months ended March 31, 2013 Compared to Three Months Ended March 31, 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 costs and expenses were $0.1 million for the three months ended March 31, 2013 as compared to $1.2 million for the same period in 2012. This $1.1 million decrease resulted primarily from the reduction of R&D staff and decreased expenditures for hardware, consulting and contract engineering services as a result of product commercialization of the AMID HFD.

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, 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 cost and expenses were $0.4 million for the three months ended March 31, 2013 as compared to $0.9 million for the three months ended March 31, 2012. This $0.5 million decrease is primarily related to decreased payroll costs from the reduction of quality and regulatory personnel, sales and marketing personnel, marketing materials, trade shows, consulting arrangements, facilities expansion, stock based compensation expense and other costs associated with our production and commercialization of the AMID HFD.

***Liquidity and Capital Resources***

As a result of our significant R&D costs and the lack of any significant product sales revenue, we have generated operating losses since inception and we expect to continue to incur losses from operations for the foreseeable future. Sales of the AMID HFD have been slower than anticipated since our commercial launch during the second quarter of 2012. We have taken several steps to preserve cash, including eliminating staff and focusing efforts on development of our Gastroplasty Device.

On March 22, 2013, we sold approximately 12,100,000 shares of our common stock (the "2013 PIPE Shares") in a private placement at a price of $0.25 per share, with net proceeds to the Company of approximately $3.0 million (Note 6). Included in this private placement was the issuance of warrants (the “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. Approximately 50% of the shares and warrants offered were purchased by our officers, directors and significant shareholders. The capital raised will be primarily used for the expansion of our Gastroplasty Device study in Hungary scheduled for 2013, continued development of the Gastroplasty Device and sales and marketing efforts for the AMID HFD. Approximately $1.1 million of the proceeds was used to pay the $300,000 outstanding under the Credit Facility and the $800,000 outstanding under certain promissory notes, which each had a maturity date of June 30, 2013. As of March 31, 2013, we had remaining cash of $1.8 million and no indebtedness upon the Credit Facility or any promissory notes. Based upon our current cash position and by monitoring our discretionary expenditures, we anticipate that we will likely be able to fund operations through the end of this year. We based this belief on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. Beyond this year, the Company will need to raise additional funds in order to continue its operations.

We believe it is probable that the Credit Facility will not be extended beyond its June 30, 2013 maturity date and we intend to seek external financing for 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. Almost all of our equity and financing to date has been provided from our principal existing stockholders and there is no assurance that our stockholders will continue to provide the necessary financing for us to continue our operations or that any additional equity or debt financing will be available to the Company on acceptable terms, or at all. If adequate funds are not available when needed, we may be required to delay, further reduce the scope of or eliminate our research and development programs, including the development of our Gastroplasty Device, all of which may not significantly extend the period of time that we will be able to continue operations without additional funding. It is uncertain as to the length of time the Company can sustain continued operations without the availability of additional funds and with the probability that the Credit Facility will not be extended. This uncertainty raises substantial doubt about the Company’s ability to continue as a going concern. The Company’s financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To the extent we raise additional capital by issuing equity securities or obtaining borrowings convertible into equity, ownership dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. The incurrence of indebtedness or debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. The current economic crisis and disruptions in the U.S. and global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been, and continue to be volatile. Continued instability in these market conditions may limit our ability to access the capital necessary to fund and grow our business.

**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, 2012.

**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* |
| 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 otherwise not subject to liability.

**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: May 15, 2013 | By: | /s/ Jeffrey G. Spragens<br>Jeffrey G. Spragens<br>President and Chief Executive Officer |
| Date: May 15, 2013 | By: | /s/ James J. Martin<br>James J. Martin<br>Chief Financial Officer |

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

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 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 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.

/s/ Jeffrey G. Spragens
Jeffrey G. Spragens
Chief Executive Officer (Principal Executive Officer)
May 15, 2013

**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

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 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 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.

/s/ James J. Martin
James J. Martin
Chief Financial Officer
May 15, 2013

**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 March 31, 2013, 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
May 15, 2013

**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 March 31, 2013, 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 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.

/s/ James J. Martin
James J. Martin
Chief Financial Officer
May 15, 2013