

SafeStitch Medical, Inc.  
Form 10-Q  
May 15, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC. 20549

**FORM 10-Q**

(Mark One)

- ☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Quarterly Period ended March 31, 2012**

For the Quarterly Period ended March 31, 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)

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<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>11-2962080</b> (I.R.S. employer identification no.)
<b>4400 Biscayne Blvd., Suite A-100, Miami, Florida</b> (Address of principal executive offices)	<b>33137</b> (Zip code)
<b>Registrant's telephone number, including area code: (305) 575-4600</b>	

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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>

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 May 10, 2012.

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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

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**Table of Contents****SAFESTITCH MEDICAL, INC.****(A Developmental Stage Company)****CONDENSED CONSOLIDATED BALANCE SHEETS**

(\$ in 000s, except per share data)

	March 31, 2012 (Unaudited)	December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,979	\$ 298
Other receivable related-party	25	66
Prepaid expenses	134	143
Inventory	506	
Total Current Assets	4,644	507
<b>FIXED ASSETS</b>		
Property and equipment, net	433	470
<b>OTHER ASSETS</b>		
Security deposits	2	2
Deferred financing costs, net	12	14
Total Other Assets	14	16
<b>TOTAL ASSETS</b>	<b>\$ 5,091</b>	<b>\$ 993</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 798	\$ 469
Total Current Liabilities	798	469
Stockholders loans, including accrued interest		2,523
Commitments and contingencies (Note 8)		
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Common stock, \$0.001 par value per share, 225,000,000 shares authorized, 48,797,755 and 28,003,755 shares issued and outstanding, respectively.	49	28
Additional paid-in capital	29,170	20,762
Deficit accumulated during the development stage	(24,926)	(22,789)
Total Stockholders' Equity (Deficit)	4,293	(1,999)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ 5,091</b>	<b>\$ 993</b>

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

**Table of Contents****SAFESTITCH MEDICAL, INC.****(A Developmental Stage Company)****UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(\$ in 000s, except per share data)

	<b>Three Months Ended March 31,</b>		<b>September 15, 2005 (Inception) to March 31, 2012</b>
	<b>2012</b>	<b>2011</b>	
Revenues	\$	\$	\$
Costs and expenses			
Research and development	1,177	656	14,115
Selling, general and administrative	915	653	9,910
Total costs and expenses	2,092	1,309	24,025
<b>Loss from operations</b>	<b>(2,092)</b>	<b>(1,309)</b>	<b>(24,025)</b>
Other income and expense			
Other income			1,147
Interest income			79
Amortization of debt issuance expense	(2)	(25)	(1,972)
Interest expense	(43)		(155)
Total other income and expense	(45)	(25)	(901)
Loss before income tax	(2,137)	(1,334)	(24,926)
Provision for income tax			
<b>Net loss</b>	<b>\$ (2,137)</b>	<b>\$ (1,334)</b>	<b>\$ (24,926)</b>
Loss attributable to common stockholders and loss per common share:			
Net loss	(2,137)	(1,334)	(24,926)
Deemed dividend - Series A Preferred Stock			(700)
Deemed dividend - Series A Preferred Conversion			(4,301)
Dividends - Series A Preferred Stock			(366)
<b>Net loss attributable to common stockholders</b>	<b>(2,137)</b>	<b>(1,334)</b>	<b>\$ (30,293)</b>
Weighted average shares outstanding, basic and diluted	37,829	28,004	
<b>Net loss per basic and diluted share</b>	<b>\$ (0.06)</b>	<b>\$ (0.05)</b>	

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

Table of ContentsSAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

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

FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH MARCH 31, 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			
<b>Inception September 15, 2005</b>		\$		\$	\$	\$	\$
Capital contributed					1		1
Net loss						(76)	(76)
<b>Balance at December 31, 2005</b>		\$		\$	\$ 1	\$ (76)	\$ (75)
Capital contributed			11,256	11	1,493		1,504
Net loss						(1,060)	(1,060)
<b>Balance at December 31, 2006</b>		\$	11,256	\$ 11	\$ 1,494	\$ (1,136)	\$ 369
Capital contributed			4,837	5	5,088		5,093
Net loss						(3,041)	(3,041)
<b>Balance at December 31, 2007</b>		\$	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)
<b>Balance at December 31, 2008</b>		\$	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)
<b>Balance at December 31, 2009</b>	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

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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)
<b>Balance at December 31, 2010</b>	<b>\$</b>	<b>28,004</b>	<b>\$ 28</b>	<b>\$ 20,427</b>	<b>\$ (17,031)</b>	<b>\$ 3,424</b>
Stock-based compensation				335		335
Net loss					(5,758)	(5,758)
<b>Balance at December 31, 2011 (unaudited)</b>	<b>\$</b>	<b>28,004</b>	<b>\$ 28</b>	<b>\$ 20,762</b>	<b>\$ (22,789)</b>	<b>\$ (1,999)</b>
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				111		111
Net loss					(2,137)	(2,137)
<b>Balance at March 31, 2012 (unaudited)</b>	<b>\$</b>	<b>48,798</b>	<b>\$ 49</b>	<b>\$ 29,170</b>	<b>\$ (24,926)</b>	<b>\$ 4,293</b>

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

**Table of Contents****SAFESTITCH MEDICAL, INC.****(A Developmental Stage Company)****UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(\$ in 000s)

	<b>Three Months Ended March 31,</b>		<b>September 15, 2005 (Inception) to March 31, 2012</b>
	<b>2012</b>	<b>2011</b>	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (2,137)	\$ (1,334)	\$ (24,926)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	2	25	1,972
Stock-based compensation expense	111	44	1,416
Stock-based compensation expense related to Share Exchange			77
Depreciation and amortization	42	27	384
Loss from disposal of assets			20
Gain on sale of TruePosition investment			(903)
Inventory disposals			139
Changes in operating assets and liabilities			
Inventory	(506)		(645)
Other current assets	50	47	(139)
Other assets			(2)
Accounts payable and accrued liabilities	329	8	514
Accrued Interest	(48)		
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,157)</b>	<b>(1,183)</b>	<b>(22,093)</b>
<b>INVESTING ACTIVITIES</b>			
Purchase of equipment	(5)		(837)
Proceeds from sale of True Position investment			903
Payment received under Rule 16b			4
<b>NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>	<b>(5)</b>		<b>70</b>
<b>FINANCING ACTIVITIES</b>			
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		(21)	(141)
Proceeds from stockholders loans	500		5,835
Repayment of stockholders loans	(2,975)		(5,751)
Exercise of options			35
<b>NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>	<b>5,843</b>	<b>(21)</b>	<b>26,002</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,681</b>	<b>(1,204)</b>	<b>3,979</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>298</b>	<b>3,032</b>	



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CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 3,979	\$ 1,828	\$ 3,979
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## Supplemental disclosures:

Cash paid for interest	\$ 91	\$	\$ 155
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## Non cash activities:

Non-cash dividend upon issuance & conversion of Preferred		\$	5,001
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Stock dividends		\$	366
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Stockholder loans contributed to capital	\$	\$	\$ 84
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Warrants issued in connection with credit facility	\$	\$	\$ 1,985
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The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 BASIS OF PRESENTATION AND LIQUIDITY**

The (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 three months ended March 31, 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, 2011.

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, 2012, the Company has accumulated a deficit of \$24.9 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 March 31, 2013. However, if the Company does not generate sufficient revenue from sales of the AMID Stapler® 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, the Company anticipates that additional 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. 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. 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.

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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**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 at least annually for impairment. The \$506,000 inventory balance at March 31, 2012 consists of parts and components for the AMID Stapler. 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 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.

**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 \$38,000 and \$9,000, respectively, for the three months ended March 31, 2012 and 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.



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

**Stock-based compensation.** The Company accounts for all share-based payments, including grants of stock options, as operating expenses, based on their grant date fair values. 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 approved by the government agency which 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 and accrued expenses 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.

**NOTE 3 PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

	Estimated Useful Lives	March 31, 2012	December 31, 2011
Machinery and equipment	5 years	\$ 660,000	\$ 660,000
Furniture, fixtures and leasehold improvements	3-5 years	86,000	81,000
Software	3-5 years	57,000	57,000
		803,000	798,000
Accumulated depreciation and amortization		(371,000)	(328,000)
<b>Property and equipment, net</b>		<b>\$ 432,000</b>	<b>\$ 470,000</b>

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 \$42,000 and \$27,000, respectively for the three months ended March 31, 2012 and 2011.

**NOTE 4 STOCK-BASED COMPENSATION**

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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 6, 2011 to increase the number of shares of Common Stock available for issuance thereunder from 2,000,000 to 3,000,000. 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 3,000,000 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.

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

The Company granted 813,500 and 562,500 stock options under the 2007 Plan during the three months ended March 31, 2012 and 2011, respectively. 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 three months ended March 31, 2012 and 2011 was \$0.54 per share and \$0.89 per share, respectively.

Total stock-based compensation recorded for the three months ended March 31, 2012 and 2011 was \$111,000 and \$44,000, respectively, and is included in general and administrative costs and expenses. The stock-based compensation recorded for the three months ended March 31, 2011 included a credit of \$113,000 for a change in the forfeitures experience. 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 and 2011 was estimated using the following assumptions.

	<b>Three months ended March 31, 2012</b>	<b>Three months ended March 31, 2011</b>
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 three months ended March 31, 2012:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2011	1,628,167	\$ 1.35	6.26	
Granted	813,500	\$ 0.66	9.89	
Exercised				
Canceled or expired	(88,667)	\$ 2.60		
Outstanding at March 31, 2012	2,353,000	\$ 1.06	7.37	\$ 226,975
Exercisable at March 31, 2012	1,123,125	\$ 1.30	5.65	\$ 26,325
Vested and expected to vest at March 31, 2012	2,298,660	\$ 1.06	7.34	\$ 220,163

None of the 813,500 options granted during the first three months of the Company's 2012 fiscal year were vested as of March 31 2012. At March 31, 2012, there was \$558,000 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 1.72 years.



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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

No options were exercised during the three months ended March 31, 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 \$2,000 and \$25,000, respectively, for the three months ended March 31, 2012 and 2011.

The Company had a principal balance outstanding of \$2,975,000 under the Credit Facility in February 2012 during which period the Credit Facility was paid off in its entirety, plus approximately \$91,000 in accrued interest, using the proceeds of the 2012 Private Placement of Common Stock described below in Note 6. There are no amounts due or outstanding under the Credit Facility as of March 31, 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 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 Investments, L.P. ("Hsu Gamma"), an entity of which Dr. Jane Hsiao, the Company's Chairman of the Board, is general partner, Frost Gamma, as well as Grandtime Associates Limited ("Grandtime"), a Taiwan-based investment company. Each of Hsu Gamma, Frost Gamma and Grandtime 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.



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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*10.0% Series A Cumulative Convertible Preferred Stock.* In June 2009, the Company authorized a new series of preferred stock, designated as 10.0% Series A Cumulative Convertible Preferred Stock, par value \$0.01 per share ( Series A Preferred Stock ). Holders of the Series A Preferred Stock are entitled to receive, when, as and if declared by the Company's Board of Directors, dividends on each share of Series A Preferred Stock at a rate per annum equal to 10.0% of the sum of (a) \$1.00, plus (b) any and all declared and unpaid and accrued dividends thereon, subject to adjustment for any stock split, combination, recapitalization or other similar corporate action (the Liquidation Amount ). Holders of the Series A Preferred Stock also have the right to receive notice of any meeting of holders of Common Stock or Series A Preferred Stock and to vote (on an as-converted into Common Stock basis) upon any matter submitted to a vote of the holders of Common Stock or Series A Preferred Stock. With respect to dividend distributions and distributions upon liquidation, winding up or dissolution of the Company, the Series A Preferred Stock ranks senior to all classes of Common Stock and to each other class of the Company's capital stock existing now or hereafter created that are not specifically designated as ranking senior to or *pari passu* with the Series A Preferred Stock. The Company may not issue any capital stock that is senior to or *pari passu* with the Series A Preferred Stock unless such issuance is approved by the holders of at least 66 2/3% of the issued and outstanding Series A Preferred Stock voting separately as a class.

Upon the occurrence of a Liquidation Event (as defined in the Series A Preferred Stock's Certificate of Designation, which is referred to as the Certificate of Designation ), holders of Series A Preferred Stock are entitled to be paid, subject to applicable law, out of the assets of the Company available for distribution to its stockholders, an amount in cash (the Liquidation Payment ) for each share of Series A Preferred Stock equal to the greater of (x) the Liquidation Amount for each share of Series A Preferred Stock outstanding, or (y) the amount for each share of Series A Preferred Stock the holders would be entitled to receive pursuant to the Liquidation Event if all of the shares of Series A Preferred Stock had been converted into Common Stock as of the date immediately prior to the date fixed for determination of stockholders entitled to receive a distribution in such Liquidation Event. Such Liquidation Payment will be paid before any cash distribution will be made or any other assets distributed in respect of any class of securities junior to the Series A Preferred Stock, including, without limitation, Common Stock. The holder of any share of Series A Preferred Stock may at any time and from time to time convert such share into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the share by (B) the conversion price, which was initially \$1.00, subject to adjustment as provided in the Certificate of Designation. To the extent it is lawfully able to do so, the Company may redeem all of the then outstanding shares of Series A Preferred Stock by paying in cash an amount per share equal to \$1.00 plus all declared or accrued unpaid dividends on such shares, subject to adjustment for any stock dividends or distributions, splits, subdivisions, combinations, reclassifications, stock issuances or similar events with respect to the Common Stock.

*2010 Issuance of Series A Preferred Stock.* On July 21, 2009, the Company entered into a second securities purchase agreement (the Future Purchase Agreement ) with certain private investors (the Future Investors, together with the 2009 Investor, the Preferred Investors ), pursuant to which the Future Investors agreed to purchase, at the Company's election upon ten days written notice delivered to the Future Investors by the Company, an aggregate of up to 2,000,000 shares of Series A Preferred Stock (the Future Shares, together with the 2009 Shares, the Preferred Shares ) at a purchase price of \$1.00 per share. On December 30, 2009, the Company provided notice to the Future Investors that the Company intended to consummate the sale of the Future Shares on January 12, 2010, and on January 12, 2010, the Company closed on the issuance of 2,000,000 Future Shares under the Future Purchase Agreement for aggregate consideration of \$2.0 million. Among the Future Investors who purchased an aggregate of 995,000 Future Shares were Hsu Gamma, Frost Gamma and Mr. Spragens, each of whom is the beneficial owner of more than 10% of the Common Stock.

The Company issued the Preferred Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act. On July 22, 2009 and January 12, 2010, the closing prices of the Common Stock on the OTCBB were \$1.10 and \$1.25, respectively, resulting in beneficial conversion features of \$0.10 and \$0.25 per share of Series A Preferred Stock on the respective issue dates. The \$200,000 and \$500,000 aggregate beneficial conversion features of the Series A Preferred Stock on the issue dates were deemed discounts on the issuance of the Preferred Shares and were recorded as increases to additional paid-in capital in the consolidated financial statements. Because the Series A Preferred Stock was immediately convertible by the holders thereof into Common Stock, the \$200,000 and \$500,000 aggregate intrinsic value was deemed a dividend paid to the Preferred Investors on the relevant closing date. In the absence of retained earnings, such deemed dividends were recorded as reductions of additional paid-in capital and, for calculating net loss per common share, as increases in losses attributable to common stockholders (see Note 7).



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

*2010 Conversion of Series A Preferred Stock.* Effective September 10, 2010 (the *Conversion Date*), the Preferred Investors elected to convert an aggregate of 4.0 million shares of the Series A Preferred Stock pursuant to the terms of the Certificate of Designation. Following conversion of the Series A Preferred Stock, the Company had no issued and outstanding shares of any class of preferred stock. On the Conversion Date, for each converted share of Series A Preferred Stock, the holder thereof became entitled to receive one share of Common Stock, plus all accrued and unpaid dividends ( *Unpaid Dividends* ) thereon through the Conversion Date, which Unpaid Dividends were paid in shares of Common Stock in accordance with the Certificate of Designation. Approximately \$366,000 of Unpaid Dividends had accumulated through the Conversion Date and an aggregate of 365,575 shares of Common Stock were issued as a result of the Unpaid Dividends (the *Dividend Shares* ), of which 29,709 Dividend Shares were issued to each of Hsu Gamma and Frost Gamma, and 6,638 Dividend Shares were issued to Mr. Spragens.

To encourage the Preferred Investors to voluntarily convert their respective shares of Series A Preferred Stock, the Company offered to each Preferred Investor who converted his or her shares of Series A Preferred Stock on or prior to the Conversion Date the number of shares of Common Stock (the *Consideration Shares* ) equal to the difference between (a) the number of shares of Common Stock issuable pursuant to a holder-initiated conversion of Series A Preferred Stock on March 31, 2012 and (b) the number of shares of Common Stock issuable pursuant to a holder-initiated conversion of Series A Preferred Stock on the Conversion Date, each as calculated in accordance with the Certificate of Designation. The Preferred Investors voluntarily elected to convert all of their respective shares of Series A Preferred Stock, and an aggregate of 697,462 Consideration Shares were issued, of which 76,261 Consideration Shares were issued to each of Hsu Gamma and Frost Gamma, and 17,042 Consideration Shares were issued to Mr. Spragens.

On September 10, 2010, the closing price of the Common Stock on the OTCBB was \$1.85, resulting in an intrinsic value of \$0.85 per share for the 4,000,000 shares of Common Stock issued upon conversion of the Series A Preferred Stock and the 365,575 shares of Common Stock issued as Dividend Shares. These 4,365,575 shares of Common Stock had an aggregate intrinsic value of \$3.7 million on the Conversion Date, which was considered a deemed dividend. The 697,462 Consideration Shares issued on the Conversion Date had an aggregate market value of approximately \$1.3 million, which was also considered a deemed dividend on the Conversion Date. In the absence of retained earnings, the \$366,000 accumulated dividends and the \$5.0 million aggregate deemed dividends were recorded as reductions of additional paid-in capital and, for calculating net loss per common share, as increases in losses attributable to common stockholders.

**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, 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:

	March 31, 2012	March 31, 2011
Stock options	2,353,000	1,629,667
Stock warrants	805,521	805,521
<b>Total</b>	<b>3,158,521</b>	<b>2,435,188</b>



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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**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 \$60,000 and \$53,000 for the three months ended March 31, 2012 and 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 Staple<sup>TM</sup>, for a period of ten years from the first commercial sale of such product. No royalties have been incurred or paid for the three months ended March 31, 2012 or 2011.

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, 2012 and 2011, the Company paid Creighton \$12,000 and \$10,000, 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.

**NOTE 10 INCOME TAXES**

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.





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**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

The Company has recognized no adjustment for uncertain tax provisions. SafeStitch recognizes interest and penalties related to uncertain tax positions in 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, 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 \$57,000 and \$47,000 of rent expense related to the Miami lease for the three months ended March 31, 2012 and 2011, 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 Cardio Medical, Inc.), a publicly-traded medical device company, and SearchMedia Holdings Limited ( 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 SG&A costs and expenses for the three months ended March 31, 2012 and 2011 of \$8,000 and \$29,000, respectively, to account for the sharing of accounting costs under this arrangement. The Company has recorded \$43,000 and \$47,000 of reductions to SG&A costs and expenses for the three months ended March 31, 2012 and 2011, respectively, to account for the sharing of legal costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X, Sorrento and SearchMedia were approximately \$25,000 and \$66,000 as of March 31, 2012 and December 31, 2011, 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 \$11,000 and \$10,000 for the three months ended March 31, 2012 and 2011, respectively.

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### **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 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 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 Stapler®, 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 CE Mark clearance to market the stapler in the European Union and other countries requiring CE clearance. After we commenced production of the AMID Stapler® 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 Stapler® in the United States. Additionally, we will supplement our Technical File prior to marketing the AMID Stapler® in the European Union. We began marketing and commercial sales of the AMID Stapler® in the second quarter of 2012.

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 the United States 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.

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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 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 incurred losses of \$2,137,000 and \$1,334,000 for the three months ended March 31, 2012 and 2011, respectively, and we had an accumulated deficit of \$24.9 million at March 31, 2012. Since we do not currently generate 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, 2012 Compared to Three Months Ended March 31, 2011***

Research and development ( R&D ) costs and expenses were \$1.2 million for the three months ended March 31, 2012 as compared to \$0.7 million for the same period in 2011. This \$0.5 million increase resulted primarily from the addition of R&D and staff and increased expenditures for contract engineering services, pre-clinical testing, R&D equipment, controlled environment infrastructure and costs associated with the redesign of the AMID Stapler®. The activities involving the AMID Stapler® were inclusive of prototypes, modifications to the design and modifications to the process to provide a reliable product that was designed to be manufactured. We expect our R&D costs and expenses will increase in 2012 in connection with our continued development of the Gastroplasty Device.

Selling, general and administrative ( SG&A ) costs and expenses were \$0.9 million for the three months ended March 31, 2012 as compared to \$0.7 million for the three months ended March 31, 2011. This \$0.2 million increase is primarily related to increased payroll costs from the addition of quality and regulatory personnel, sales and marketing personnel, legal expense, marketing materials, trade shows, consulting arrangements, facilities expansion and other costs associated with our commercialization of the AMID Stapler and efforts to develop a reliable manufacturing process. SG&A costs and expenses consist primarily of salaries and other related costs, including stock based compensation. The stock-based compensation recorded for the three months ended March 31, 2011 included a credit of \$0.1 million for a change in the forfeitures experience. Other SG&A costs and expenses include facility-related costs not otherwise included in R&D costs and expenses, and professional fees for legal and accounting services. We expect that our SG&A costs and expenses will increase in 2012 in connection with our commercial launch of the AMID Stapler®.

### ***Liquidity and Capital Resources***

As a result of our significant R&D expenditures and the lack of any 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 increasing R&D costs and expenses, including expenses related to hiring new personnel and conducting clinical trials. We expect that SG&A costs and expenses will also increase as we expand our regulatory compliance and administrative staff and add sales and marketing personnel and infrastructure.

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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.

On February 17, 2012, we sold 20,794,000 shares of our common stock in a private placement at a price of \$0.40 per share, with net proceeds to the Company of \$8.3 million (Note 6). Approximately 54% of the shares offered were purchased by our officers, directors and significant shareholders. A portion of the proceeds was used to pay off all amounts outstanding under the credit facility.

We have received FDA clearance to begin marketing the AMID Stapler® 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 Stapler® 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 in June 2013, and by monitoring our discretionary expenditures, we will be able to fund our current cash flow requirements through March 31, 2013.

However, if the Company does not generate sufficient revenue from sales of the AMID Stapler® 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, we anticipate that 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.

Our actual future capital requirements will depend on many factors, including sales of the AMID Stapler®, 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.

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**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.

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**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. (Removed and Reserved).**

**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.

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**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, 2012

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

Date: May 15, 2012

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