SafeStitch Medical, Inc.
Form 10-Q
August 12, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC. 20549
FORM 10-Q

(Mark One)

þ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**

for the Quarterly Period ended June 30, 2011

or

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

for the Transition Period from __________ to __________

Commission File Number 0-19437

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 þ No o

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o **Smaller reporting company þ**

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

28,003,755 shares of the Company s common stock, par value $0.001 per share, were outstanding as of August 9, 2011.

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)

	June 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 594	$ 3,032
Other receivable related-party	76	64
Prepaid expenses	135	117
Inventories	91	91
Total Current Assets	896	3,304
FIXED ASSETS		
Property and equipment, net	345	337
OTHER ASSETS		
Security deposits	2	2
Deferred financing costs, net	20	51
Total Other Assets	22	53
TOTAL ASSETS	**$ 1,263**	**$ 3,694**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 347	$ 221
Notes payable	7	49
Total Current Liabilities	354	270
Stockholder loans (Note 5)		
Commitments and contingencies (Note 8)		
STOCKHOLDERS EQUITY		
Preferred stock, $0.01 par value per share, 25,000,000 shares authorized 10% Series A Cumulative Convertible Preferred Stock, 4,000,000 shares authorized, no shares issued and outstanding, respectively; liquidation preference $0		
Common stock, $0.001 par value per share, 225,000,000 shares authorized, 28,003,755 shares issued and outstanding	28	28
Additional paid-in capital	20,569	20,427
Deficit accumulated during the development stage	(19,688)	(17,031)
Total Stockholders Equity	909	3,424
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	**$ 1,263**	**$ 3,694**

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)
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
($ in 000s, except per share data)

	Three Months Ended June 30, 2011	Three Months Ended June 30, 2010	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	September 15, 2005 (Inception) to June 30, 2011
Revenues	$	$ 2	$	$ 2	$
Cost of sales		1		1	
Gross margin		**1**		**1**	
Operating costs and expenses					
Research and development	849	730	1,505	1,080	11,076
Selling, general and administrative	467	619	1,121	1,047	7,810
Total operating costs and expenses	1,316	1,349	2,626	2,127	18,886
Operating loss	**(1,316)**	**(1,348)**	**(2,626)**	**(2,126)**	**(18,886)**
Other income and expense					
Other income					1,147
Interest income, net		1		1	15
Amortization of debt issuance expense	(6)	(26)	(31)	(153)	(1,964)
Total other income and expense	(6)	(25)	(31)	(152)	(802)
Loss before income tax	(1,322)	(1,373)	(2,657)	(2,278)	(19,688)
Provision for income tax					
Net loss	**$ (1,322)**	**$ (1,373)**	**$ (2,657)**	**$ (2,278)**	**$ (19,688)**
Loss attributable to common stockholders and loss per common share:					

Net loss		(1,322)		(1,373)		(2,657)		(2,278)		(19,688)
Deemed dividend Series A Preferred Stock								(500)		(700)
Deemed dividend Series A Preferred Conversion				(102)				(198)		(4,301)
Dividends Series A Preferred Stock										(366)
Net loss attributable to common stockholders	**$**	**(1,322)**	**$**	**(1,475)**	**$**	**(2,657)**	**$**	**(2,976)**	**$**	**(25,055)**
Weighted average shares outstanding, basic and diluted		28,004		18,783		28,004		18,375		
Net loss per basic and diluted share	**$**	**(0.05)**	**$**	**(0.08)**	**$**	**(0.09)**	**$**	**(0.16)**		

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

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(A Developmental Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)
FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH JUNE 30, 2011
($ in 000s, except per share data)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
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			697	1	(1)		

September 2010					
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			142		142
Net loss				(2,657)	(2,657)
Balance at June 30, 2011 (unaudited)	**$ 28,004**	**$ 28**	**$ 20,569**	**$ (19,688)**	**$ 909**

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)
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in 000s)

	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	September 15, 2005 (Inception) to June 30, 2011
OPERATING ACTIVITIES			
Net loss	$ (2,657)	$ (2,278)	$ (19,688)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	31	153	1,964
Stock-based compensation expense	142	240	1,112
Stock-based compensation expense related to Share Exchange			77
Depreciation and amortization	57	30	259
Loss from disposal of assets	20		20
Inventory Adjustments			53
Gain on sale of TruePosition investment			(903)
Changes in operating assets and liabilities			
Inventories		(161)	(144)
Other current assets	(30)	(35)	(191)
Other assets			(2)
Accounts payable and accrued liabilities	126	449	63
NET CASH USED IN OPERATING ACTIVITIES	**(2,311)**	**(1,602)**	**(17,380)**
INVESTING ACTIVITIES			
Purchase of equipment	(85)	(270)	(624)
Proceeds from sale of True Position investment			903
Payment received under Rule 16b			4
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	**(85)**	**(270)**	**283**
FINANCING ACTIVITIES			
Net cash provided in connection with the acquisition of SafeStitch LLC			3,192
Issuance of Common Stock, net of offering costs		4,975	8,962
Issuance of Preferred Stock, net of offering costs		1,998	3,980
Capital contributions			1,431
Proceeds from notes payable			141
Repayment of notes payable	(42)	(43)	(134)
Proceeds from stockholder loans			2,860

Repayment of stockholder loans						(2,776)
Exercise of options						35
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES		**(42)**		**6,930**		**17,691**
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS		(2,438)		5,058		594
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		3,032		871		
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$	594	$	5,929	$	594
Supplemental disclosures:						
Cash paid for interest	$		$		$	64
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

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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 following (a) condensed consolidated balance sheet as of December 31, 2010, which has been derived from audited financial statements, and (b) the unaudited condensed consolidated interim financial statements of SafeStitch Medical, Inc. (SafeStitch or the Company) have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2011 are not necessarily indicative of results that may be expected for the year ending December 31, 2011. 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, 2010 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 June 30, 2011, the Company has accumulated a deficit of $19.7 million and has not generated positive cash flows from operations. At June 30, 2011, the Company had cash of $594,000 and working capital of $542,000. The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain its operations. The Company s efforts have been devoted principally to developing its technologies and commercializing its products. In order to fund all planned operations, including the commercialization of certain of the Company s products 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 beyond the $4.0 million Credit Facility described in Note 5. If adequate funds are not available, in order to continue its operations 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.

Management does not believe that the Company will be able to fund its operations through and beyond June 30, 2012 without securing 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. This uncertainty raises substantial doubt about the Company s ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might be necessary as a result of the outcome of such uncertainty. In addition to securing additional funds, the Company s ability to continue as a going concern is ultimately dependent upon generating revenues from those products that do not require further marketing clearance by the U.S. Food and Drug Administration (FDA), obtaining FDA clearance to market its other product candidates, and achieving profitable operations and generating sufficient cash flows from operations to meet future obligations.

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SAFESTITCH Medical, INC.
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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 $91,000 inventory balance at June 30, 2011 and December 31, 2010 consists of reinforcing mesh used for hernia surgery. Provisions for potentially obsolete or slow-moving inventory are made based on management s analysis of inventory levels, obsolescence and future sales forecasts.

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

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

Advertising Costs. The Company expenses all costs of advertising as incurred. Advertising and promotional costs are included in selling, general and administrative costs and expenses for all periods presented, and totaled $0 and $9,000, respectively, for the three and six months ended June 30, 2011. Advertising and promotional costs and expenses totaled $8,000 and $12,000, respectively, for the three and six months ended June 30, 2010.

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.

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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, accrued expenses and notes payable approximate fair value based on their short-term maturity. Related party receivables and stockholder loans are carried at cost.

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

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

Comprehensive income (loss). Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company s comprehensive net loss is equal to its net loss for all periods presented.

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	Estimated Useful Lives	June 30, 2011	December 31, 2010
Machinery and equipment	5 years	$ 458,000	$ 452,000
Furniture and fixtures	3-5 years	76,000	50,000
Software	3-5 years	57,000	37,000
		591,000	539,000
Accumulated depreciation and amortization		(246,000)	(202,000)
Property and equipment, net		**$ 345,000**	**$ 337,000**

Depreciation of fixed assets utilized in research and development activities is included in research and development costs and expenses. All other depreciation is included in selling, general and administrative costs and expenses. Depreciation and amortization expense was $30,000 and $57,000, respectively for the three and six months ended June 30, 2011, and was $19,000 and $30,000, respectively for the three and six months ended June 30, 2010.

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 further amended on June 6, 2011 by the Company s stockholders. Under the 2007 Plan, which is administered by the Compensation Committee of the Board of

Directors, the Company is allowed to grant awards of 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 the Company s 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.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company granted 562,500 and 679,000 stock options under the 2007 Plan during the six months ended June 30, 2011 and 2010, respectively. 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 options granted during 2010 were issued at an exercise price of $1.10 to $1.20 per share and had an estimated aggregate grant date fair value of $593,000. The weighted average grant date fair value of the options granted during the six months ended June 30, 2011 and 2010 was $0.89 per share and $0.87 per share, respectively.

Total stock-based compensation recorded for the three and six months ended June 30, 2011 was $98,000 and $142,000, respectively. The stock-based compensation recorded for the six months ended June 30, 2011 included a credit of $113,000 for forfeiture true-up. Total stock-based compensation recorded for the three and six months ended June 30, 2010 was $114,000 and $240,000, respectively. All stock-based compensation is included in selling, general and administrative costs and expenses. The fair values of options granted are estimated on the date of their grant using the Black-Scholes option pricing model based on the assumptions included in the table below. The fair value of the Company s stock option awards is expensed over the vesting life of the underlying stock options using the graded vesting method, with each tranche of vesting options valued separately. Expected volatility is based on the historical volatility of the Common Stock. The risk-free interest rate for periods within the contractual life of the stock option award is based on the yield of U.S. Treasury bonds on the grant date with a maturity equal to the expected term of the stock option. The expected life of stock option awards granted to employees and non-employee directors is based upon the simplified method for plain vanilla options described in SEC Staff Accounting Bulletin No. 107, as amended by SEC Staff Accounting Bulletin No. 110. The expected life of all other stock option awards is the contractual term of the option. Forfeiture rates are based on management s estimates. The fair value of each option granted during the six months ended June 30, 2011 and 2010 was estimated using the following assumptions.

	Six months ended June 30, 2011	**Six months ended June 30, 2010**
Expected volatility	76.91% 102.63%	87.09% 107.94%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.25% 3.25%	1.89% 3.11%
Expected life	5.5 10.0 years	4.0 7.0 years
Forfeiture rate	0% 5%	0% 2.50%

The following summarizes the Company s stock option activity for the six months ended June 30, 2011:

	Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (Years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2010	1,334,667	$ 1.41	5.74	
Granted	562,500	$ 1.12	9.70	
Exercised				
Canceled or expired	(267,500)	$ 1.19		
Outstanding at June 30, 2011	1,629,667	$ 1.34	6.76	$ 35,520
Exercisable at June 30, 2011	849,167	$ 1.49	5.47	$ 27,660

Vested and expected to vest at June 30, 2011	1,586,072	$ 1.35	6.74	$ 34,854

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68,000 of the 562,500 options granted during the first six months of the Company s 2011 fiscal year were vested as of June 30, 2011. At June 30, 2011, there was approximately $435,000 of total unrecognized compensation cost related to non- vested employee and director share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.76 years.

No options were exercised during the three and six months ended June 30, 2011 and 2010.

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

The $7,000 notes payable balance at June 30, 2011 relates to the third-party financing of certain of the Company s insurance policies. This note is a self-amortizing installment loan bearing interest at 5.94% and maturing in August 2011.

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, 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 $6,000 and $31,000, respectively, for the three and six months ended June 30, 2011 and $26,000 and $153,000, respectively, for the three and six months ended June 30, 2010. The Company has no outstanding loans as of June 30, 2011.

NOTE 6 CAPITAL TRANSACTIONS

2010 Private Placement of Common Stock. On June 15, 2010, the Company entered into a stock purchase agreement (the Stock Purchase Agreement) with 20 investors (the PIPE Investors) pursuant to which the PIPE Investors agreed to purchase an aggregate of 4,978,000 shares of Common Stock (the PIPE Shares) at a price of $1.00 per share for aggregate consideration of $4,978,000. Among the 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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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.

2009 Issuance of Series A Preferred Stock. On July 21, 2009, the Company entered into a securities purchase agreement with a private investor (the 2009 Investor), pursuant to which the 2009 Investor agreed to purchase an aggregate of up to 2,000,000 shares (the 2009 Shares) of the Series A Preferred Stock at a purchase price of $1.00 per share. On July 22, 2009, the Company closed on the issuance of the 2009 Shares for aggregate consideration of $2.0 million. A portion of the proceeds from the issuance was used to repay all principal and interest outstanding under the Credit Facility described in Note 5.

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).

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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 and six months ended June 30, 2011 and 2010, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants and conversion of preferred stock is anti-dilutive.

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

	June 30, 2011	**June 30, 2010**
Stock options	1,629,667	1,277,167
Stock warrants	805,521	805,521
Series A Preferred Stock		4,286,083
Total	**2,435,188**	**6,368,771**

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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 $52,000 and $105,000 for the three and six months ended June 30, 2011, respectively, and $25,000 and $50,000 for the three and six months ended June 30, 2010, 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 Stapler®, for a period of ten years from the first commercial sale of such product. No royalties have been incurred or paid for the three and six months ended June 30, 2011, and for the three and six months ended June 30, 2010.

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

NOTE 9 AGREEMENT WITH CREIGHTON UNIVERSITY

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

Pursuant to the Creighton Agreement, the Company is obligated to pay Creighton, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from the sale of any product licensed under the Creighton Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The Creighton Agreement does not provide for minimum royalties. Also pursuant to the Creighton Agreement, the Company agreed to invest, in the aggregate, at least $2.5 million over 36 months, beginning May 26, 2006, towards development of any licensed product. This $2.5 million investment obligation excluded the first $150,000 of costs related to the prosecution of patents, which the Company invested outside of the Creighton Agreement. The Company is further obligated to pay to Creighton an amount equal to 20% of certain of the Company s research and development expenditures as reimbursement for the use of Creighton s facilities. Failure to comply with the payment obligations above will result in all rights in the licensed patents and know-how reverting back to Creighton. As of December 31, 2007, the Company had satisfied the $2.5 million investment obligation described above. The Company recorded research and development costs and expenses related to the 20% facility reimbursement obligation totaling approximately $11,000 and $21,000, respectively for the three and six months ended June 30, 2011, and $11,000 and $32,000, respectively, for the three and six months ended June 30, 2010.

NOTE 10 INCOME TAXES

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

The Company has recognized no adjustment for uncertain tax provisions. SafeStitch recognizes interest and penalties related to uncertain tax positions in selling, general and administrative costs and expenses; however no such provisions for accrued interest and penalties related to uncertain tax positions have been recorded as of June 30, 2011 or December 31, 2010.

The tax years 2007-2009 remain open to examination by the major tax jurisdictions in which the Company operates.

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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. There were no advances under the Credit Facility during the three and six months ended June 30, 2011 and there were no advances under the Credit Facility during the three and six months ended June 30, 2010. No interest expense related to the Credit Facility has been recorded for the three and six months ended June 30, 2011 and 2010 and there were no outstanding borrowings at June 30, 2011 and 2010.

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 July 2010 to include additional office space in the same building, and current rental payments under the lease are approximately $14,000 per month. The Company recorded rent expense related to the Miami lease totaling approximately $47,000 and $94,000, respectively, for the three and six months ended June 30, 2011, and $20,000 and $38,000, respectively, for the three and six months ended June 30, 2010.

Dr. Jane Hsiao, the Company s Chairman of the Board, served as a director of Great Eastern Bank of Florida until August 2009, a bank where the Company maintains a bank account in the normal course of business.

Dr. Hsiao, Dr. Frost and Mr. Rubin are each significant shareholders 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, Tiger X Medical, Inc. (Tiger X) (Formerly known as Cardo Medical, Inc. (Cardo), a publicly-traded shell company, SearchMedia Holdings Limited (SearchMedia), a publicly-traded media company operating primarily in China and Sorrento Therapeutics, Inc. (Sorrento), a 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 Aero under a Board-approved cost sharing arrangement whereby the total salaries of the accounting staffs of the three companies are shared. 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 served as Corporate Counsel for Sorrento. The Company has recorded reductions to selling, general and administrative costs and expenses to account for the sharing of costs under these arrangements of $78,000 and $154,000, respectively, for the three and six months ended June 30, 2011, and $62,000 and $125,000, respectively, for the three and six months ended June 30, 2010. Aggregate accounts receivable from NIMS, Aero, Tiger X and SearchMedia were approximately $64,000 and $64,000 as of June 30, 2011 and December 31, 2010, respectively. Aero will no longer participate in the shared cost arrangement after June 2011.

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 $9,000 and $19,000, respectively, for the three and six months ended June 30, 2011 and $9,000 and $17,000, respectively, for the three and six months ended June 30, 2010.

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NOTE 13 SUBSEQUENT EVENTS

On August 10, 2011, the Company, the Frost Group and Mr. Spragens amended the Credit Facility discussed in Note 5 above to further extend the Credit Facility s Maturity Date from June 30, 2012 to June 30, 2013. All other terms and conditions of the Credit Facility remain unchanged.

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 *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 will submit a Special 510(k) to FDA for clearance prior to marketing 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 expect to begin commercial sales of the AMID Stapler® the first quarter of 2012.

We have successfully tested our first investigational Intraluminal Gastroplasty Device for Obesity and GERD (Gastroplasty Device) in five patients in Hungary. At the nine month follow-up, we observed that the weight loss and esophageal symptom scores were satisfactory and as expected. We expect to continue *in vivo* human testing of this device in the United States during 2012, following anticipated FDA review of our clinical trial protocols and IDE submission. We intend to apply for approval of the Gastroplasty Device for both GERD and obesity by the FDA in accordance with all applicable requirements. In addition we are planning continuation of clinical trials in Europe in the first half of 2012. In order to fund all of our planned operations, including the anticipated expansion of clinical trials for the Gastroplasty Device, we will require additional external financing.

We are currently evaluating 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, 2010. Actual results may differ from these estimates.

Results of Operations

We incurred losses of $2.7 million and $2.3 million for the six months ended June 30, 2011 and 2010, respectively, and we had an accumulated deficit of $19.7 million at June 30, 2011. 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 and Six Months ended June 30, 2011 Compared to Three and Six Months Ended June 30, 2010

Research and development (R&D) costs and expenses were $849,000 and $1.5 million, respectively, for the three and six months ended June 30, 2011 as compared to $730,000 and $1.1 million, respectively, for the three and six months ended June 30, 2010. These $119,000 and $400,000 respective increases resulted primarily from addition of R&D and manufacturing staff and increased expenditures for contract engineering services, Amid stapler® redesign, preparing for US human feasibility trials.

Selling, general and administrative (SG&A) costs and expenses were $467,000 and $1.1 million, respectively, for the three and six months ended June 30, 2011, as compared to $619,000 and $1.0 million, respectively for the three and six months ended June 30, 2010. The year over year three month decrease of $152,000 is primarily attributed to reduction of our AMID Stapler® sales efforts compared to the prior year and decrease in accounting staff. The year over year six month increase of $0.1 million is primarily related to increased payroll costs from the addition of quality and regulatory personnel, consulting arrangements, facilities expansion and other costs associated with our efforts to develop a more reliable manufacturing process. These increases were offset in part by reductions in accounting staff and a stock-based compensation forfeiture true-up credit. SG&A costs and expenses consist primarily of salaries 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, and professional fees for legal and accounting services. We expect that our SG&A costs and expenses will remain relatively consistent in the short term until such time as we recommence commercialization activities for the AMID Stapler®, after which we anticipate that SG&A costs and expenses will increase.

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Liquidity and Capital Resources

We have not generated revenues and have incurred operating losses since inception, and we expect to continue incurring losses from operations for the foreseeable future. Until we recommence sales of the AMID Stapler® or commercialize another product, we will not generate any revenues. Our research and development expenditures are expected to expand significantly as we expand clinical trials for our Gastroplasty Device and other of our product candidates. While we have reduced marketing and distribution expenditures during the suspension of sales of the AMID Stapler®, we expect to make significant investment in inventory and the hiring and training of marketing, sales and customer service personnel prior to recommencing sales in the first quarter of 2012. We have funded our operations to date primarily with proceeds from the private placement of equity and from advances under credit facilities available to us. Because of the numerous risks and uncertainties associated with the development and commercialization of our products and product candidates, we are unable to estimate the precise amounts of capital outlays and operating expenditures associated with such development and commercialization activities. Our future capital requirements will depend on many factors, including 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 and results of commercialization activities, including product marketing, sales and distribution activities and the implementation of improved commercial manufacturing processes. In order to fund all of our planned operations, including the anticipated expansion of clinical trials for the Gastroplasty Device, we will require additional external financing beyond the Credit Facility. However, if adequate funds are not available, in order to continue operations the Company may be required to delay, reduce the scope of or eliminate our research and development 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. We believe that our $594,000 cash balance as of June 30, 2011, together with the $4.0 million availability under our existing line of credit, will not be able to fund operations through and beyond June 30, 2012 without securing 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. This uncertainty raises substantial doubt about the Company s ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might be necessary as a result of the outcome of such uncertainty.

We intend to obtain external financing for our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, or at all. We may need to raise additional funds more quickly than anticipated if our estimates are 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 before we need them if the conditions for raising capital are favorable. The sale of additional equity or convertible debt securities may result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations, and the terms of such indebtedness could include covenants restricting, among other things, our operations, our ability to incur additional indebtedness, our ability to pay dividends on our capital stock or our ability to merge or otherwise enter into business combination transactions.

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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, 2010.

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.

On August 10, 2011, we entered into the Fourth Amendment (the Fourth Amendment) to the Credit Facility. The Fourth Amendment extended the Maturity Date of the Credit Facility from June 30, 2012 to June 30, 2013. The description of the Credit Facility set forth in Note 5 to our consolidated financial statements contained in this Quarterly Report on Form 10-Q is incorporated by reference in this Item 5.

The foregoing description of the Fourth Amendment is only a summary and is qualified in its entirety by reference to the full text of the Fourth Amendment, which is attached as Exhibit 10.1 to this Quarterly Report on Form 10-Q is incorporated by reference in this Item 5.

Item 6. Exhibits.

Exhibits:

10.1	Fourth Amendment to Note and Security Agreement, dated August 10, 2011, by and among the Company, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on August 12, 2011.
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: August 12, 2011	By: /s/ Jeffrey G. Spragens Jeffrey G. Spragens President and Chief Executive Officer
Date: August 12, 2011	By: /s/ James J. Martin James J. Martin Chief Financial Officer