

SafeStitch Medical, Inc.
Form 10-Q
August 13, 2010

Table of Contents

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

(Mark One)

☒ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the Quarterly Period ended June 30, 2010**

or

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

Commission File Number 0-19437

SAFESTITCH MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

11-2962080

(State or other jurisdiction of
incorporation or organization)

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

4400 Biscayne Blvd., Suite A-100, Miami, Florida

33137

(Address of principal executive offices)

(Zip code)

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

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

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

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

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

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

22,940,718 shares of the Company's common stock, par value \$0.001 per share, were outstanding as of August 6, 2010.

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
TABLE OF CONTENTS FOR FORM 10-Q

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS 3

Condensed Consolidated Balance Sheets as of June 30, 2010 (unaudited) and December 31, 2009 3

Unaudited Condensed Consolidated Statements of Operations for the Three and Six Months ended June 30, 2010 and 2009, and for the period from September 15, 2005 (inception) to June 30, 2010 4

Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the period from September 15, 2005 (inception) through June 30, 2010 (unaudited) 5

Unaudited Condensed Consolidated Statements of Cash Flows for the Six Months ended June 30, 2010 and 2009, and for the period from September 15, 2005 (inception) to June 30, 2010 6

Notes to unaudited condensed consolidated financial statements 7

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 16

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 19

ITEM 4. CONTROLS AND PROCEDURES 19

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS 20

ITEM 1A. RISK FACTORS 20

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS 20

ITEM 3. DEFAULTS UPON SENIOR SECURITIES 20

ITEM 4. (REMOVED AND RESERVED) 20

ITEM 5. OTHER INFORMATION 20

ITEM 6. EXHIBITS 20

SIGNATURES

21

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

Exhibit 32.2

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(in 000s, except share and per share data)

	June 30, 2010 (Unaudited)	December 31, 2009
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 5,929	\$ 871
Accounts receivable trade	2	
Other receivable related-party	55	21
Prepaid expenses	130	131
Inventories	161	
Total Current Assets	6,277	1,023
FIXED ASSETS		
Property and equipment, net	387	147
OTHER ASSETS		
Security deposits	2	2
Deferred financing costs, net	102	255
Total Other Assets	104	257
TOTAL ASSETS	\$ 6,768	\$ 1,427
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 542	\$ 93
Notes payable	7	50
Total Current Liabilities	549	143
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, 4,000,000 and 2,000,000 shares issued and outstanding, respectively; liquidation preference \$4,286 and \$2,088, respectively	40	20
Common stock, \$0.001 par value per share, 225,000,000 shares authorized, 22,940,718 and 17,962,718 shares issued and outstanding, respectively	23	18
Additional paid-in capital	20,162	12,974
Deficit accumulated during the development stage	(14,006)	(11,728)
Total Stockholders Equity	6,219	1,284
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 6,768	\$ 1,427

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 amounts)

	Three Months Ended		Six Months Ended		September 15, 2005
	June 30,		June 30,		(Inception) to June 30, 2010
	2010	2009	2010	2009	2010
Revenues	\$ 2	\$	\$ 2	\$	\$ 2
Cost of sales	1		1		1
Gross margin	1		1		1
Operating costs and expenses					
Research and development	730	449	1,080	798	7,923
Selling, general and administrative	619	417	1,047	748	5,118
Total operating costs and expenses	1,349	866	2,127	1,546	13,041
Operating loss	(1,348)	(866)	(2,126)	(1,546)	(13,040)
Other income and expense					
Other income					903
Interest income (expense), net	1	(13)	1	(13)	14
Amortization of debt issuance expense	(26)	(128)	(153)	(340)	(1,883)
Total other income and expense	(25)	(141)	(152)	(353)	(966)
Loss before income tax	(1,373)	(1,007)	(2,278)	(1,899)	(14,006)
Provision for income tax					
Net loss	\$ (1,373)	\$ (1,007)	\$ (2,278)	\$ (1,899)	\$ (14,006)
Loss attributable to common stockholders and loss per common share:					
Net loss	(1,373)	(1,007)	(2,278)	(1,899)	(14,006)
Deemed dividend Series A Preferred Stock			(500)		(700)

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

Dividends	Series A Preferred Stock	(102)		(198)		(286)
Net loss attributable to common stockholders		\$	(1,475)	\$	(1,007)	\$ (2,976) \$ (1,899) \$ (14,992)
Weighted average shares outstanding, basic and diluted			18,783		17,963	18,375 17,963
Net loss per basic and diluted share		\$	(0.08)	\$	(0.06)	\$ (0.16) \$ (0.11)

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

Table of Contents**SAFESTITCH MEDICAL, INC.****(A Developmental Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)****FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH JUNE 30, 2010**

(in 000s, except per share amounts)

		Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
		Shares	Amount	Shares	Amount			
Inception	September 15, 2005		\$		\$	\$	\$	\$
Capital contributed						1		1
Net loss							(76)	(76)
Balance at December 31, 2005			\$		\$	\$ 1	\$ (76)	\$ (75)
Capital contributed				11,256	11	1,493		1,504
Net loss							(1,060)	(1,060)
Balance at December 31, 2006			\$	11,256	\$ 11	\$ 1,494	\$ (1,136)	\$ 369
Exercise of options (CTS)-September 23, 2007 at \$0.79 per share				42		35		35
Stock-based compensation-September 4, 2007						77		77
Issuance of shares in recapitalization September 4, 2007 at \$0.64 per share				4,795	5	3,078		3,083
SafeStitch expenses associated with recapitalization						(156)		(156)
Stock-based compensation						65		65
Warrants issued in connection with credit facility-September 4, 2007 at \$2.46 per share						1,985		1,985
Rule 16 payment received						4		4
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				8		10		10

per share			
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, net of offering costs	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)

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, net of offering costs	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	4,970	4,975
Stock-based compensation				240	240
Net loss					(2,278)

Balance at June 30, 2010									
(unaudited)	4,000	\$	40	22,941	\$	23	\$	20,162	\$ (14,006) \$ 6,219

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)

	Six Months Ended June 30,		September 15, 2005 (Inception) to June 30, 2010
	2010	2009	
OPERATING ACTIVITIES			
Net loss	\$ (2,278)	\$ (1,899)	\$ (14,006)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	153	340	1,883
Stock-based compensation expense	240	88	739
Stock-based compensation expense related to Share Exchange			77
Depreciation and amortization	30	27	145
Gain on sale of TruePosition investment			(903)
Changes in operating assets and liabilities			
Inventories	(161)		(161)
Other current assets	(35)	22	(167)
Other assets			(2)
Accounts payable and accrued liabilities	449	136	257
NET CASH USED IN OPERATING ACTIVITIES	(1,602)	(1,286)	(12,138)
INVESTING ACTIVITIES			
Purchase of equipment	(270)	(36)	(532)
Proceeds from sale of True Position investment			903
Payment received under Rule 16b			4
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(270)	(36)	375
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		8,963
Issuance of Preferred Stock, net of offering costs	1,998		3,980
Capital contributions			1,431
Proceeds from notes payable			71
Repayment of notes payable	(43)		(64)
Proceeds from stockholder loans		800	2,860
Repayment of stockholder loans			(2,776)
Exercise of options			35

NET CASH PROVIDED BY FINANCING ACTIVITIES	6,930	800	17,692
 NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	 5,058	 (522)	 5,929
 CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	 871	 561	
 CASH AND CASH EQUIVALENTS AT END OF PERIOD	 \$ 5,929	 \$ 39	 \$ 5,929

Supplemental disclosures:

Cash paid for interest	\$	\$	\$	64
Non cash activities:				
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.

Table of Contents

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, 2009, 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 and six months ended June 30, 2010 are not necessarily indicative of results that may be expected for the year ending December 31, 2010. 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, 2009 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 31, 2010.

SafeStitch 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 Agreement) with SafeStitch LLC, a limited liability company formed in Virginia on September 15, 2005. Pursuant to the Share Exchange Agreement, on September 4, 2007, Cellular acquired all of the members' equity of SafeStitch LLC in exchange for 11,256,369 shares of Cellular's common stock (the Share Exchange), which represented a majority of Cellular's outstanding shares immediately following the Share Exchange. 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). Effective January 8, 2008, Cellular changed its name to SafeStitch Medical, Inc. and increased the aggregate number of shares of the Company's capital stock that it may issue 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.

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, 2010, the Company has accumulated a deficit of \$14.0 million and has not generated positive cash flows from operations. At June 30, 2010, the Company had cash of \$5.9 million and working capital of \$5.7 million. The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain its operations, including the January 2010 and June 2010 equity transactions described in Note 6. The Company's efforts have been devoted principally to developing its technologies and commercializing its products. Based upon its current cash position; the availability under its \$4.0 million credit facility with The Frost Group LLC (The Frost Group) and the Company's President and CEO, Jeffrey G. Spragens (the Credit Facility), and by monitoring its discretionary expenditures, management believes that the Company will be able to fund its existing operations through June 30, 2011. However, in order to fund all planned operations, including the commercialization of certain of the Company's products and the anticipated commencement in 2010 of clinical trials for certain of the Company's product candidates, the Company anticipates that additional external financing will be required before June 30, 2011. Management considered the June 30, 2011 expiration of the Credit Facility when it evaluated the Company's ability to continue funding its operations. 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.

Table of Contents

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 GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Such items include the collectability of receivables, the useful lives of property and equipment, input variables relating to valuation of stock-based compensation and other financial instruments. Actual results could differ from those estimates.

Cash and cash equivalents. We consider all highly liquid investments purchased 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 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. Inventories at June 30, 2010 primarily consist of AMID Staplers and 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 \$8,000 and \$12,000, respectively, for the three and six months ended June 30, 2010. Advertising and promotional costs and expenses totaled \$1,000 for each of the three and six months ended June 30, 2009.

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 devices to be used in clinical trials 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 selling, general and administrative costs and expenses for all periods presented.

Fair value of financial instruments. The carrying amounts of cash and cash equivalents, accounts receivable, 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, 2010	December 31, 2009
Machinery and equipment	5 years	\$ 456,000	\$ 190,000
Furniture and fixtures	3-5 years	39,000	35,000
Software	3-5 years	37,000	37,000
		532,000	262,000
Accumulated depreciation and amortization		(145,000)	(115,000)
Property and equipment, net		\$ 387,000	\$ 147,000

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 \$19,000 and \$14,000, respectively for the three months ended June 30, 2010 and 2009, and was \$30,000 and \$27,000, respectively, for the six months ended June 30, 2010 and 2009.

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"). 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 2,000,000 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.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company granted 120,000 and 679,000 stock options, respectively under the 2007 Plan during the three and six months ended June 30, 2010. The options granted during 2010 were issued at exercise prices between \$1.10 and \$1.20 per share and had an estimated aggregate grant date fair value of \$593,000. The Company granted zero and 358,500 stock options, respectively, under the 2007 Plan during the three and six months ended June 30, 2009. The options granted during the six months ended June 30, 2009 were issued at an exercise price of \$0.80 per share and had an estimated aggregate grant date fair value of \$180,000. The weighted average grant date fair value of the options granted during the six months ended June 30, 2010 and 2009 was \$0.87 per share and \$0.50 per share, respectively. Total stock-based compensation recorded for the three and six months ended June 30, 2010 was \$114,000 and \$240,000, respectively. Total stock-based compensation recorded for the three and six months ended June 30, 2009 was \$52,000 and \$88,000, 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, 2010 and 2009 was estimated using the following assumptions.

	Six months ended June 30, 2010		Six months ended June 30, 2009	
Expected volatility	87.09%	107.94%	74.59%	86.43%
Expected dividend yield	0.00%		0.00%	
Risk-free interest rate	1.89%	3.11%	1.39%	1.79%
Expected life	4.0	7.0 years	4.0	5.5 years
Forfeiture rate	0% 2.50%		2.50%	

The following summarizes the Company's stock option activity for the six months ended June 30, 2010:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	615,167	\$ 1.63	5.98	\$ 162,540
Granted	679,000	\$ 1.18	6.66	
Exercised				
Canceled or expired	(17,000)	\$ 3.06		
Outstanding at June 30, 2010	1,277,167	\$ 1.38	6.19	\$ 681,440
Exercisable at June 30, 2010	404,500	\$ 1.73	5.80	\$ 185,890

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

Vested and expected to vest at June 30, 2010	1,229,082	\$	1.38	6.19	\$	652,611
--	-----------	----	------	------	----	---------

57,500 of the 679,000 options granted during the first six months of the Company's 2010 fiscal year were vested as of June 30, 2010. At June 30, 2010, there was approximately \$470,000 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 1.80 years.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

No options were exercised during the three and six months ended June 30, 2010 and 2009. The \$88,000 of stock-based compensation recorded for the six months ended June 30, 2009 is net of an approximately \$15,000 credit related to the January 2009 modification of 17,000 stock option awards for certain former employees. On the modification date, the Compensation Committee accelerated and fully vested the former employees' options, which were originally scheduled to vest on various dates through 2012. Additionally, the Compensation Committee extended the term of these options to one year following the modification date. All 17,000 modified options expired during the six months ended June 30, 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, 2010 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 6.19% and maturing in August 2010.

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 in March 2009 to extend the maturity date to June 2010, and was amended again in March 2010 to extend the maturity date to June 2011.

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 \$26,000 and \$153,000, respectively, for the three and six months ended June 30, 2010 and \$128,000 and \$340,000, respectively, for the three and six months ended June 30, 2009.

The Company borrowed \$800,000 under the Credit Facility during the six months ended June 30, 2009 and repaid the entire then-outstanding balance in July 2009 using the proceeds of the 2009 Issuance of Series A Preferred Stock described in Note 6. The Company recognized interest expense related to the outstanding borrowings of \$13,000 and \$13,000, respectively, for the three and six months ended June 30, 2009. The Company has not borrowed any funds under the Credit Facility nor recorded any related interest expense during the six months ended June 30, 2010 and has no outstanding loans as of June 30, 2010.

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 the Company's common stock, par value \$0.001 (the "PIPE Shares"), at a price of \$1.00 per share. Among the PIPE Investors who purchased a portion of the PIPE Shares are 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 and 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. Each PIPE Investor represented to the Company that such person was an accredited investor as defined in Rule 501(a) under the Securities Act and that the PIPE Shares were being acquired for investment purposes. The PIPE Shares have not been registered under the Securities Act and are restricted securities as that term is defined by Rule 144 promulgated thereunder. The Company has not undertaken to register the PIPE Shares and no registration rights have been granted to the PIPE Investors in respect of the PIPE Shares.

Table of Contents

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), 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 other 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.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company issued the Preferred Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act. The Preferred Investors each represented to the Company that such person was an accredited investor as defined in Rule 501(a) of the Securities Act and that the Preferred Shares were being acquired for investment purposes. The Preferred Shares have not been registered under the Securities Act and are restricted securities as that term is defined by Rule 144 promulgated thereunder. The Company has not undertaken to register the Preferred Shares, and no registration rights have been granted to the Preferred Investors in respect of the Preferred Shares.

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 is immediately convertible by the holders thereof to 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. Such deemed dividends have been recorded as increases in losses attributable to common stockholders and, in the absence of retained earnings, as reductions of additional paid-in capital.

As of June 30, 2010, the 4,000,000 outstanding shares of Series A Preferred Stock had accumulated undeclared and unpaid dividends totaling approximately \$286,000.

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, 2010 and 2009, 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, 2010	June 30, 2009
Stock options	1,277,167	615,167
Stock warrants	805,521	805,521
Series A Preferred Stock	4,286,083	
Total	6,368,771	1,420,688

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 \$25,000 and \$50,000 for the three and six months ended June 30, 2010, respectively, and \$25,000 and \$53,000 for the three and six months ended June 30, 2009, 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 StaplerTM, for a period of ten years from the first commercial sale of such product. Less than \$100 of royalty expense has been recorded for the three and six months ended June 30, 2010, and no royalties were recorded for the three and six months ended June 30, 2009.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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. The Company recorded research and development costs and expenses related to the 20% facility reimbursement obligation totaling approximately \$11,000 and \$32,000, respectively for the three and six months ended June 30, 2010, and \$10,000 and \$20,000, respectively, for the three and six months ended June 30, 2009.

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, 2010 or December 31, 2009.

The tax years 2005-2008 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. There were no advances under the Credit Facility during the three and six months ended June 30, 2010. Advances under the Credit Facility totaled \$500,000 and \$800,000, respectively, for the three and six months ended June 30, 2009, and \$800,000 was outstanding as of June 30, 2009. The Company recognized interest expense related to the outstanding borrowings of \$13,000 and \$13,000, respectively, for the three and six months ended June 30, 2009. No interest expense related to the Credit Facility has been recorded for the three and six months ended June 30, 2010, and there were no outstanding borrowings at June 30, 2010.

Table of Contents

SAFESTITCH MEDICAL, INC.
(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company entered into a five-year lease for office space in Miami, Florida with a company controlled by Dr. Frost. Current rental payments under the Miami office lease, which commenced January 1, 2008, are approximately \$6,000 per month and escalate 4.5% annually over the life of the lease. The Company recorded rent expense related to the Miami lease totaling approximately \$20,000 and \$38,000, respectively, for the three and six months ended June 30, 2010, and \$19,000 and \$40,000, respectively, for the three and six months ended June 30, 2009.

During 2008 and until August 2009, Dr. Hsiao served as a director of Great Eastern Bank of Florida, a bank where the Company maintains a bank account in the normal course of business. As of June 30, 2010, the Company had approximately \$97,000 on deposit with Great Eastern Bank of Florida.

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, Cardo Medical, Inc. (Cardo), a publicly-traded medical device company, and SearchMedia Holdings Limited (SearchMedia), a publicly-traded media company operating primarily in China. Director Richard Pfenniger is also a shareholder of NIMS. The Company's Chief Financial Officer also serves as the Chief Financial Officer and supervises the accounting staffs of NIMS and 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 Cardo. The Company has recorded reductions to selling, general and administrative costs and expenses to account for the sharing of costs under these arrangements of \$62,000 and \$125,000, respectively, for the three and six months ended June 30, 2010, and \$20,000 and \$39,000, respectively, for the three and six months ended June 30, 2009. Aggregate accounts receivable from NIMS, Aero, Cardo and SearchMedia were approximately \$55,000 as of June 30, 2010.

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 \$17,000, respectively, for the three and six months ended June 30, 2010 and \$5,000 and \$11,000, respectively, for the three and six months ended June 30, 2009.

NOTE 13 RECENT ACCOUNTING PRONOUNCEMENTS

Subsequent Events Effective June 30, 2009, the Company adopted authoritative guidance which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. In February 2010, the FASB issued additional guidance to remove the requirement for SEC filers to disclose the date through which an entity has evaluated subsequent events. This change removes potential conflicts with current SEC guidance. The guidance was effective upon issuance and had no impact on the Company's consolidated financial statements.

NOTE 14 SUBSEQUENT EVENTS

In late July 2010, the Company voluntarily suspended sales of the AMID Stapler™ in order to implement a more robust and reliable commercial manufacturing process. The Company intends to recommence stapler sales before the end of the year. The suspension of stapler sales and the cost of any necessary design or process modifications implemented will result in increased expenses in 2010 and will delay revenues associated with the sale of the staplers. No adjustments have been included in the accompanying financial statements as a result of the suspension of stapler sales.

Table of Contents**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 within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA), Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act), 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, including improving the quality of and recommencing manufacturing and sales of the AMID Stapler; 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. We intend that all forward-looking statements be subject to the safe harbor provisions of PSLRA. 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 medical device company focused on the development of medical devices that manipulate tissues for endoscopic and minimally invasive surgery for the treatment of obesity, GERD, hernia formation, esophageal obstructions, Barrett's Esophagus, upper gastrointestinal bleeding and other intraperitoneal abnormalities.

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. As 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. Clinical trials for our gastroplasty product candidates are anticipated to begin in the second half of 2010.

Products and Product Candidates

Three of our products may currently be marketed in the United States without further FDA clearance. We received the necessary FDA 510(k) clearances to market the AMID Stapler™ and SMART Dilator™ as Class II devices in November 2009 and February 2009, respectively. The AMID Stapler™ was further granted CE Mark clearance in February 2010 to market the stapler in the European Union and other countries requiring CE clearance. We believe that our standard and airway bite blocks are Class I 510(k)-exempt devices that require no preclearance from the FDA prior to marketing. We believe our Intraluminal Gastroplasty Device for Obesity and GERD (the Gastroplasty Device), and our Barrett's Excision and Ablation Device (the Barrett's Device), which are both still in development, will require investigational device exemption (IDE) clinical data for FDA approval as Class II 510(k) devices. We are preparing our clinical trial protocols for the Gastroplasty Device and anticipate submitting IDE trial plans to the FDA for review by the end of August 2010, with in human trials beginning before the end of 2010. We submitted applications to the FDA in June and July 2010 for approval to market individual components of the Gastroplasty Device for general indications, and anticipate responses before the end of October 2010. We are beginning preparation

of the clinical trial protocols for the Barrett's Device and anticipate conducting the first human testing of this device in 2011.

Table of Contents***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, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including the carrying values of our receivables, inventories, long term investments, property and equipment and contingencies. 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, 2009. Actual results may differ from these estimates.

Results of Operations

We incurred losses of \$2.3 million and \$1.9 million for the six months ended June 30, 2010 and 2009, respectively, and we had an accumulated deficit of \$14.0 million at June 30, 2010. Since we do not currently generate significant revenue from any of our products, including those already cleared for commercial marketing by the FDA, we expect to continue to generate losses in connection with the initial 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, particularly as we commence clinical trials for our Gastroplasty Device and other of our product candidates. We are also continuing to build our marketing and distribution infrastructure in support of the commercial launch of the AMID Stapler™, including the hiring and training of 11 marketing, sales and customer service personnel and the purchase of inventory. We may further expand our marketing and distribution throughout 2010 and beyond.

We commenced production of the AMID Stapler™ at a contract manufacturing facility during the first quarter of 2010, and began commercial sales of the AMID Stapler™ in June 2010. In late July 2010, we voluntarily suspended sales of our stapler so that we could implement a more robust and reliable commercial manufacturing process. We intend to recommence stapler sales before the end of the year, however, there can be no assurance our efforts will result in the improvements or reliability we are seeking. The suspension of stapler sales and the cost of any necessary design or process modifications will result in increased expenses in 2010 and will delay revenues associated with the sale of the staplers.

Three and Six Months ended June 30, 2010 Compared to Three and Six Months Ended June 30, 2009

We commenced sales of the AMID Stapler™ at the end of June 2010 and recorded approximately \$2,000 of net revenue in the three and six months then ended. Cost of sales, including product costs, shipping and handling costs and royalty expense, totaled approximately \$1,000 for the period, resulting in a \$1,000 gross margin for the three and six months ended June 30, 2010. No revenue, cost of sales or gross margin was recorded in 2009 or any prior period. Research and development (R&D) costs and expenses were \$730,000 and \$1.1 million, respectively, for the three and six months ended June 30, 2010 as compared to \$449,000 and \$798,000, respectively, for the three and six months ended June 30, 2009. These \$281,000 and \$282,000 respective increases resulted primarily from an approximately \$75,000 increase in payroll costs related to the addition of R&D staff during the six months ended June 30, 2010 and increased expenditures during the six months ended June 30, 2010 of approximately \$600,000 for contract research, animal testing and other R&D costs primarily related to the development of prototypes for, and manufacture of devices to be used in upcoming clinical trials of, our Gastroplasty Device. These increases were offset in part by an approximately \$400,000 reduction in contract research spending in the six months ended June 30, 2010 related to the development of the AMID Stapler™, which was completed in 2009. We expect R&D costs and expenses to increase significantly in the second half of 2010 and beyond as we enter into more advanced stages of development for our Gastroplasty Device and other surgical product candidates. These increased costs are expected to come from increased payroll costs related to the expansion of our engineering and product development staff, as well as the anticipated commencement of clinical trials.

Table of Contents

Selling, general and administrative (SG&A) costs and expenses were \$619,000 and \$1.0 million, respectively, for the three and six months ended June 30, 2010, as compared to \$417,000 and \$748,000, respectively for the three and six months ended June 30, 2009. These \$202,000 and \$299,000 respective increases primarily related to increased payroll costs from the addition of administrative, marketing and sales personnel, increased stock-based compensation expense, and increased advertising, travel and trade show expenses related to the commercialization of the AMID Stapler™. These increases were offset in part by reductions in accounting and legal fees. SG&A costs and expenses consist primarily of salaries and other related costs, including stock-based compensation expense. 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 significantly in the second half of 2010 and beyond from the addition of sales and marketing personnel as we continue commercialization activities, primarily for the AMID Stapler™.

Liquidity and Capital Resources

We have not generated significant 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 commence clinical trials for our Gastroplasty Device and other of our product candidates. We are also continuing to build our marketing and distribution infrastructure in support of the commercialization of the AMID Stapler, including significant investment in tooling and inventory and the hiring and training of marketing, sales and customer service personnel. 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. We believe that our \$5.9 million cash balance as of June 30, 2010, together with the \$4.0 million availability under our existing line of credit, will be sufficient to fund our current cash flow requirements through June 2011. However, in order to fund all of our planned operations through 2011 and beyond, including the anticipated commencement in 2010 of clinical trials for the Gastroplasty Device, we believe we will need to obtain additional external financing prior to June 2011. We considered the June 30, 2011 expiration of the \$4.0 million line of credit when evaluating our ability to continue funding operations.

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. If adequate funds are not available, we 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.

Table of Contents

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.

Table of Contents

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, 2009.

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 |

Table of Contents

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 13, 2010

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

Date: August 13, 2010

By: /s/ Adam S. Jackson
Adam S. Jackson
Chief Financial Officer