

SafeStitch Medical, Inc.  
Form 10-Q  
November 12, 2009

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

(Mark One)

☒ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the Quarterly Period ended September 30, 2009**

**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) 575-4145**

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 ☒

17,962,718 shares of the Company's common stock, par value \$0.001 per share, were outstanding as of October 30, 2009.

**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 share and per share data)

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 579	\$ 561
Other receivable related-party	5	13
Prepaid expenses	51	151
Total Current Assets	635	725
<b>FIXED ASSETS</b>		
Property and equipment, net	162	168
<b>OTHER ASSETS</b>		
Security deposits	2	2
Deferred financing costs, net	384	851
Total Other Assets	386	853
LONG-TERM INVESTMENT, net of valuation adjustment of \$1,754		
<b>TOTAL ASSETS</b>	<b>\$ 1,183</b>	<b>\$ 1,746</b>
<b>LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 200	\$ 273
Stockholder loans		
Total Current Liabilities	200	273
Commitments and contingencies (Note 9)		
<b>STOCKHOLDERS EQUITY</b>		
Preferred Stock, \$.01 par value per share, 25,000,000 shares authorized, 2,000,000 and zero shares issued and outstanding	20	
Common Stock, \$.001 par value per share, 225,000,000 shares authorized, 17,962,718 shares issued and outstanding	18	18
Additional Paid-in Capital	12,921	10,817
Deficit accumulated during the development stage	(11,976)	(9,362)
Total Stockholders Equity	983	1,473
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 1,183</b>	<b>\$ 1,746</b>

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 amounts)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>September 15, 2005 (Inception) to September 30, 2009</b>
	<b>September 30, 2009</b>	<b>September 30, 2008</b>	<b>September 30, 2009</b>	<b>September 30, 2008</b>	<b>September 30, 2009</b>
Revenues	\$	\$	\$	\$	\$
Costs and expenses					
Research and development	258	494	1,056	2,111	6,643
General and administrative	324	405	1,072	1,211	3,745
Total costs and expenses	582	899	2,128	3,322	10,388
<b>Loss from operations</b>	<b>(582)</b>	<b>(899)</b>	<b>(2,128)</b>	<b>(3,322)</b>	<b>(10,388)</b>
Other income and expense					
Interest income		7		19	77
Amortization of debt issuance expense	(127)	(213)	(467)	(638)	(1,601)
Interest expense	(6)		(19)	(24)	(64)
Total other income and expense	(133)	(206)	(486)	(643)	(1,588)
Loss before income tax	(715)	(1,105)	(2,614)	(3,965)	(11,976)
Provision for income tax					
<b>Net loss</b>	<b>\$ (715)</b>	<b>\$ (1,105)</b>	<b>\$ (2,614)</b>	<b>\$ (3,965)</b>	<b>\$ (11,976)</b>
Loss attributable to common stockholders and loss per common share:					
Deemed dividend Series A Preferred Stock	(200)		(200)		(200)

<b>Net loss attributable to common stockholders</b>	<b>(915)</b>	<b>(1,105)</b>	<b>(2,814)</b>	<b>(3,965)</b>	<b>\$ (12,176)</b>
Weighted average shares outstanding, basic and diluted	17,963	17,955	17,963	16,967	
Net loss per basic and diluted share	\$ (0.05)	\$ (0.06)	\$ (0.16)	\$ (0.23)	

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 SEPTEMBER 30, 2009  
(in 000s)**

	Preferred Stock		Common Stock		Paid-in	Deficit Accumulated During the	
	Shares	Amount	Shares	Amount	Capital	Development Stage	Total
<b>Inception September 15, 2005</b>		\$		\$	\$	\$	\$
Capital contributed					1		1
Net loss						(76)	(76)
<b>Balance at December 31, 2005</b>		\$		\$	\$ 1	\$ (76)	\$ (75)
Capital contributed			11,256	11	1,493		1,504
Net loss						(1,060)	(1,060)
<b>Balance at December 31, 2006</b>		\$	<b>11,256</b>	<b>\$ 11</b>	<b>\$ 1,494</b>	<b>\$ (1,136)</b>	<b>\$ 369</b>
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)
<b>Balance at December 31, 2007</b>		\$	<b>16,093</b>	<b>\$ 16</b>	<b>\$ 6,582</b>	<b>\$ (4,177)</b>	<b>\$ 2,421</b>
Issuance of common shares in private offering May 2008 at \$2.15 per share, net of offering costs			1,862	2	3,986		3,988
Issuance of common shares as repayment of stockholder note-December 30, 2008 at \$1.22 per share			8		10		10

Stock-based compensation	239	239
Net loss	(5,185)	(5,185)

<b>Balance at December 31, 2008</b>	<b>\$</b>	<b>17,963</b>	<b>\$</b>	<b>18</b>	<b>\$</b>	<b>10,817</b>	<b>\$</b>	<b>(9,362)</b>	<b>\$</b>	<b>1,473</b>
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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			142	142
Net loss				(2,614)

<b>Balance at September 30, 2009</b>									
(unaudited)	2,000	\$	20	17,963	\$	18	\$	12,921	\$ (11,976) \$ 983

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)

	<b>Nine Months Ended September 30,</b>		<b>September 15, 2005 (Inception) to September 30, 2009</b>
	<b>2009</b>	<b>2008</b>	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (2,614)	\$ (3,965)	\$ (11,976)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	467	638	1,601
Stock-based compensation expense	142	204	446
Stock-based compensation expense related to Share Exchange			77
Depreciation and amortization	42	42	101
Changes in operating assets and liabilities			
Other current assets	108	33	(36)
Other assets		20	2
Accounts payable and accrued liabilities	(73)	(99)	(85)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(1,928)</b>	<b>(3,127)</b>	<b>(9,874)</b>
<b>INVESTING ACTIVITIES</b>			
Purchase of equipment	(36)	(25)	(263)
Payment received under Rule 16b			4
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(36)</b>	<b>(25)</b>	<b>(259)</b>
<b>FINANCING ACTIVITIES</b>			
Net cash provided in connection with the acquisition of SafeStitch LLC			3,192
Issuance of Common Stock, net of offering costs		3,988	3,988
Issuance of Preferred Stock, net of offering costs	1,982		1,982
Capital Contributions			1,431
Proceeds from stockholder loans	900	1,000	2,860
Repayment of stockholder loans	(900)	(1,000)	(2,776)
Exercise of options			35
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>1,982</b>	<b>3,988</b>	<b>10,712</b>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>18</b>	<b>836</b>	<b>579</b>

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		561		631	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	579	\$	1,467	\$ 579
Supplemental disclosures:					
Cash paid for interest	\$	19	\$	24	\$ 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.

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**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 BASIS OF PRESENTATION AND LIQUIDITY**

The condensed consolidated balance sheet as of December 31, 2008, which has been derived from audited financial statements, and 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 the quarterly report on 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 nine months ended September 30, 2009 are not necessarily indicative of results that may be expected for the year ending December 31, 2009. 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, 2008 included in the Company s annual report on form 10-K, filed with the Securities and Exchange Commission ( SEC ) on March 27, 2009.

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

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 limited liability company formed in Virginia on September 15, 2005. 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, 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 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 Company s 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 September 30, 2009, the Company has accumulated a deficit of \$12.0 million and has not generated positive cash flows from operations. At September 30, 2009, the Company had cash of \$579,000 and working capital of \$435,000. The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain its operations, including the July 2009 Series A Preferred Stock transactions described in Note 7. The Company s efforts have been principally devoted to developing its technologies and commercializing its products. Based upon its current cash position; its budget for business operations; the commitment from private investors for an additional \$2.0 million of Series A Preferred Stock (as hereinafter defined); availability under its \$4.0 million credit facility with The Frost Group LLC and the Company s President and CEO, Jeffrey G. Spragens, and by monitoring its discretionary expenditures, management believes that the Company will be able to fund operations through September 30, 2010. Management considered the June 30, 2010 expiration of the \$4.0 million 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.

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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 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 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. Balances in excess of FDIC limitations may not be insured.

**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.

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

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

**Stock-based compensation.** The Company accounts for all share-based payments, including grants of stock options, as an operating expense in the income statement, based on their grant date fair values. Stock-based compensation is included in general and administrative costs and expenses for all periods presented.

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

**Long-lived assets.** The Company reviews the carrying values of its long-lived assets, including long-term investments, 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.

**Subsequent events.** The Company has evaluated subsequent events through November 10, 2009, which is the date the financial statements were issued.

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**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 3 PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

	Estimated Useful Lives	September 30, 2009	December 31, 2008
Machinery and equipment	5 years	\$ 189,000	\$ 153,000
Furniture and fixtures	3-5 years	37,000	37,000
Software	3-5 years	37,000	37,000
		263,000	227,000
Accumulated depreciation and amortization		(101,000)	(59,000)
<b>Property and equipment, net</b>		<b>\$ 162,000</b>	<b>\$ 168,000</b>

Depreciation of fixed assets utilized in research and development activities is included in research and development expense. All other depreciation is included in general and administrative costs and expenses. Depreciation and amortization expense was \$15,000 and \$42,000, respectively, for the three and nine months ended September 30, 2009, and was \$17,000 and \$42,000, respectively, for the three and nine months ended September 30, 2008.

**NOTE 4 LONG-TERM INVESTMENT**

In November 1999, Cellular invested in a one-year, \$1.0 million 10% convertible note of KSI, Inc. ( KSI ) and also received warrants to purchase KSI common stock. In August 2000, all of the outstanding stock of KSI was acquired by TruePosition, Inc., a majority owned subsidiary of Liberty Media Corporation ( Liberty Media ). Prior to such acquisition, the convertible note was exchanged for KSI common stock, and Cellular exercised the KSI warrants and purchased additional KSI common stock for approximately \$754,000. Cellular's investment in KSI common stock was exchanged for TruePosition common stock on the date of the acquisition. The Company currently holds 191,118 shares of TruePosition common stock and accounts for the investment in TruePosition using the cost method. In December 2002, Cellular received certain valuation information from TruePosition, indicating a range of values for TruePosition. Based upon its review of available information and communications with Liberty Media, Cellular concluded there had been an other-than-temporary decline in estimated fair value of its investment and reduced the recorded carrying value of this investment from its cost basis of \$1,754,000 to zero, representing its best estimate of the then-current fair value of Cellular's investment in the net equity of TruePosition. TruePosition's operations have required significant infusions of cash by Liberty Media, and the Company's investment in TruePosition common stock has been diluted by these advances, which were converted to preferred stock in late 2002. In August 2007, the Company was informed that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of TruePosition's outstanding capital stock, was being merged into TruePosition. Pursuant to the terms of the merger, TruePosition's minority stockholders, including the Company, were entitled to receive \$3.5116 in cash in exchange for each share held. The Company has exercised its statutory appraisal rights in respect of this merger, and is now a party to an appraisal action and a securities fraud litigation (see Note 9). The Company may possibly receive proceeds from the merger, the litigation or other disposition of this investment, but no such amount can be estimated at this time.

**NOTE 5 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 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.

Total stock-based compensation recorded for the three and nine months ended September 30, 2009 was \$54,000 and \$142,000, respectively, and is included in general and administrative costs and expenses. Total stock-based compensation recorded for the three and nine months ended September 30, 2008 was \$33,000 and \$204,000, respectively. 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.

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**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

The Company granted zero and 358,500 options, respectively, under the 2007 Plan during the three and nine months ended September 30, 2009. The options granted during the nine months ended September 30, 2009 were issued at an exercise price of \$.80 per share and had an estimated aggregate grant date fair value of \$180,000. The Company granted 6,000 and 154,500 options, respectively, under the 2007 Plan during the three and nine months ended September 30, 2008. The options granted during the nine months ended September 30, 2008 were issued at exercise prices between \$2.80 and \$3.10 per share and had an estimated aggregate grant date fair value of \$309,000. The fair value of options granted is estimated on the date of their grant using the Black-Scholes option pricing model based on the assumptions included in the table below. Expected volatility is based on the historical volatility of the Company's stock. Due to the short period of time that the Company has been publicly traded since the Share Exchange, the historical volatilities of similar publicly traded entities are reviewed to validate the Company's expected volatility assumption. 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 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. Forfeiture rates are based on management's estimates. The fair value of each option granted during the nine months ended September 30, 2009 and 2008 was estimated using the following assumptions.

	<b>Nine months ended September 30, 2009</b>		<b>Nine months ended September 30, 2008</b>	
Expected volatility	74.59%	86.43%	63.05%	94.46%
Expected dividend yield	0.00%		0.00%	
Risk-free interest rate	1.39%	1.79%	1.96%	3.35%
Expected life	4.0	5.5 years	3.5	5.5 years
Forfeiture rate	2.50%		2.50%	

The following summarizes the Company's stock option activity for the Nine months ended September 30, 2009:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2008	256,667	\$ 2.80	7.12	
Granted	358,500	\$ 0.80	6.10	
Exercised				
Canceled or expired				
Outstanding at September 30, 2009	615,167	\$ 1.63	6.23	\$ 53,775
Exercisable at September 30, 2009	167,001	\$ 2.89	5.94	\$
Vested and expected to vest at September 30, 2009	592,826	\$ 1.65	6.23	\$ 51,049



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None of the 358,500 options granted during the first nine months of the Company's 2009 fiscal year were vested as of September 30, 2009. A summary of the status of the Company's non-vested options and changes during the nine months ended September 30, 2009 is presented below.

	<b>Stock Options</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-Vested at December 31, 2008	146,833	\$ 2.00
Options Granted	358,500	0.50
Options Vested	(57,167)	1.50
Non-Vested at September 30, 2009	448,166	\$ 0.79

At September 30, 2009, there was \$195,000 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 1.58 years.

No options were exercised during the nine months ended September 30, 2009 and 2008. The \$142,000 of stock-based compensation recorded for the nine months ended September 30, 2009 is net of an approximately \$15,000 credit related to the modification of stock option awards for certain former employees. On the modification date, the Company's 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.

**NOTE 6 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, LLC ("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 the Company's Common Stock, Dr. Jane H. Hsiao, the Company's Chairman of the Board, and Steven D. Rubin, a director. The Credit Facility provides for \$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 due 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 its maturity date to June 2010.

In connection with the Credit Facility, the Company granted warrants to purchase an aggregate of 805,521 shares of its 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 will be amortized over the life of the Credit Facility. The Company recorded amortization expense related to these deferred financing costs of \$127,000 and \$467,000, respectively, for the three and nine months ended September 30, 2009 and \$212,000 and \$638,000, respectively, for the three and nine months ended September 30, 2008.

The Company borrowed \$1.0 million under the Credit Facility during the nine months ended September 30, 2008 and repaid the entire outstanding balance in June 2008 using the proceeds of the 2008 Private Placement of Common

Stock described in Note 7. The Company borrowed \$900,000 under the Credit Facility during the nine months ended September 30, 2009, and repaid all outstanding amounts with the proceeds of the 2009 issuance of Series A Preferred Stock described in Note 7. The Company recognized interest expense related to the outstanding borrowings of \$6,000 and \$19,000, respectively, for the three and nine months ended September 30, 2009 and approximately \$0 and \$24,000, respectively, for the three and nine months ended September 30, 2008.

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**NOTE 7 CAPITAL TRANSACTIONS**

*2008 Private Placement of Common Stock.* During the period beginning May 22, 2008 and ended May 28, 2008, the Company entered into stock purchase subscription agreements (the "Subscription Agreements") with certain private investors (the "Investors"), pursuant to which the Company agreed to issue an aggregate of 1,861,505 shares (the "Shares") of its Common Stock at a purchase price of \$2.15 per share. The Company's Board of Directors established the \$2.15 purchase price based on an approximately 10% discount to the average closing price of the Common Stock on the OTCBB during the five trading days beginning April 23, 2008 and ended April 29, 2008. The Company closed on the issuance of the Shares during the period beginning May 22, 2008 and ended May 28, 2008. The Company received aggregate consideration for the Shares of approximately \$4.0 million and incurred \$14,000 of costs related to the offering, which were recorded as a reduction of paid-in-capital. Among the Investors acquiring a portion of the Shares were Dr. Hsiao, Jeffrey G. Spragens and some of his relatives, Dr. Kenneth Heithoff, a former director, Kevin Wayne, a director, and Frost Gamma Investments Trust. The Company issued the 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 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 Shares were being acquired for investment purposes. The 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 Shares and no registration rights have been granted to the Investors in respect of the Shares.

*2009 Issuance of Series A Preferred Stock.* On July 21, 2009, the Company entered into a securities purchase agreement (the "Current Purchase Agreement") with a private investor (the "Current Investor"), pursuant to which the Current Investor agreed to purchase an aggregate of up to 2,000,000 shares (the "Current Shares") of the Company's newly-designated 10.0% Series A Cumulative Convertible Preferred Stock, par value \$0.01 per share ("Series A Preferred Stock"), at a purchase price of \$1.00 per share. On July 22, 2009, the Company closed on the issuance of 2,000,000 Current Shares under the Current Purchase Agreement 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 6.

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

Additionally, 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"), pursuant to which the Future Investors agreed to purchase an aggregate of up to 2,000,000 shares of Series A Preferred Stock (the "Future Shares") at a purchase price of \$1.00 per share. The Company is not obligated to consummate the sale of the Future Shares under the Future Purchase Agreement, and the Company may elect, in its sole discretion, to consummate such sale on any date on or prior to June 30, 2010, subject to providing the Future Investors ten days written notice of such closing date. Among the Future Investors who have obligated themselves to potentially acquire a portion of the Future Shares are Hsu Gamma Investment, L.P., an entity of which Dr. Jane Hsiao, the Company's Chairman of the Board, is general partner, Jeffrey G. Spragens, the Company's Chief Executive Officer, President and a director, and Frost Gamma Investments Trust, a trust controlled by Dr. Phillip Frost, who is the largest beneficial owner of the Company's Common Stock (collectively, the "Related Party Investors"). Each of the Related Party Investors is the beneficial owner of more than 10% of the Company's Common 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"). Upon the occurrence of a Liquidation Event (as defined in the Certificate of Designation of the Powers, Preferences and Relative, Participating, Optional and Other Special Rights of 10.0% Series A Cumulative Convertible Preferred Stock, and Qualifications, Limitations and Restrictions Thereof), 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, the Common Stock.

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The Series A Preferred Stock is presently convertible by the holders into shares of Common Stock on a one-for-one basis. The Series A Preferred Stock may be converted by the Company at any time after September 5, 2009 at the then-current conversion rate if the aggregate market value of the Common Stock equals or exceeds \$150 million over a specified period. The holders of Series A Preferred Stock 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. Except as otherwise expressly set forth in the Company's Restated Certificate of Incorporation, as amended from time to time, the holders of Series A Preferred Stock will vote on each matter submitted to them with the holders of Common Stock and all other classes and series of the Company's capital stock entitled to vote on such matter, taken together as a single class. 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.

The closing price of the Common Stock on the over-the-counter bulletin board was \$1.10 on July 22, 2009, resulting in a beneficial conversion feature of \$0.10 per share of Series A Preferred Stock on the issue date. The \$200,000 aggregate beneficial conversion feature of the Series A Preferred Stock on the issue date was deemed a discount on the issuance of the shares and was recorded as an increase to additional paid in capital in the unaudited consolidated financial statements. Because the Series A Preferred Stock was immediately convertible to Common Stock, the \$200,000 aggregate intrinsic value is deemed a dividend paid to the investors on such closing date. Such deemed dividend has been recorded as an increase in losses attributable to common stockholders and, in the absence of retained earnings, as a reduction of additional paid in capital.

**NOTE 8 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 nine months ended September 30, 2009 and 2008, 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:

	September 30, 2009	September 30, 2008
Stock options	615,167	243,167
Stock warrants	805,521	805,521
Series A Preferred Stock	2,000,000	
<b>Total</b>	<b>3,420,688</b>	<b>1,048,688</b>



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**NOTE 9 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 \$78,000 for the three and nine months ended September 30, 2009, respectively, and \$32,000 and \$105,000 for the three and nine months ended September 30, 2008, respectively. The Company is presently a plaintiff in securities fraud and appraisal actions in respect of its ownership of 191,118 shares of common stock of TruePosition (See Note 4). The securities fraud action was filed November 13, 2007 in the United States District Court for the District of Connecticut, whereby SafeStitch and other plaintiffs seek damages and other relief totaling \$80 million. The related appraisal action was filed in the Chancery Court of the State of Delaware on August 31, 2007. In August 2007, the Company was informed that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of TruePosition's outstanding capital stock, was being merged into TruePosition. Pursuant to the terms of the merger, TruePosition's minority stockholders, including the Company, became entitled to receive \$3.5116 in cash in exchange for each share held, which the Company and certain other minority stockholders considered insufficient compensation. The Company and other minority stockholders brought forth the aforementioned securities fraud and appraisal action, and, on August 10, 2007, the Company entered into a joint stockholder litigation governance and funding agreement (the "Funding Agreement") with such other stockholders. Under the Funding Agreement, the Company has agreed to fund a portion of the litigation expenses in connection with the appraisal and securities fraud action. Through September 30, 2009, the Company has contributed approximately \$81,000 in cash and has incurred additional liabilities of approximately \$144,000. Management anticipates that the Company will be called upon to fund additional amounts during the next twelve months. The Company may elect to terminate its participation in the Funding Agreement, whereby the Company would no longer be required to contribute funds; however, the Company would lose all rights under the Funding Agreement, including access to any work-product created after the date of termination. Additionally, the Company's portion of any proceeds from a favorable disposition of the litigation may be reduced if the Company terminates its participation. In February 2009, the United States District Court for the District of Connecticut granted the defendants' motion to dismiss the securities fraud action described above. In March 2009, the Company, together with the other plaintiffs filed an appeal of the District Court's dismissal with the United States<sup>2</sup> Circuit Court of Appeals. The outcomes of the appeal and the appraisal action are not now known, nor can they be reasonably predicted at this time.

**NOTE 10 AGREEMENT WITH CREIGHTON UNIVERSITY**

On May 26, 2006, our wholly-owned subsidiary, SafeStitch LLC ("LLC") entered into an exclusive license and development agreement (the "License Agreement") with Creighton University ("Creighton") granting LLC a worldwide exclusive (even as to Creighton) license, with rights to sublicense, to all of LLC's product candidates and associated know-how, including the exclusive right to manufacture, use and sell the product candidates. Pursuant to the License Agreement, LLC is entitled to exercise its own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion and other commercial exploitation of any licensed products, provided that, if LLC has not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the License Agreement or the date such technology is disclosed to and accepted by LLC, then the licensed patent and associated know-how shall revert back to Creighton, with no rights retained by LLC, and Creighton will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless LLC purchases one or more one-year extensions.

Pursuant to the License Agreement, LLC 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 License Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The License Agreement does not provide for minimum royalties. Also pursuant to the License Agreement, LLC 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 excludes the first \$150,000 of costs related to the prosecution of

patents, which LLC invested outside of the License Agreement. LLC is further obligated to pay to Creighton an amount equal to 20 percent of certain of LLC'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, LLC 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 \$10,000 and \$30,000, respectively, for the three and nine months ended September 30, 2009, and \$14,000 and \$161,000, respectively, for the three and nine months ended September 30, 2008.

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**NOTE 11 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 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 September 30, 2009 and December 31, 2008.

The tax years 2004 through 2008 remain open to examination by the major tax jurisdictions in which the Company operates.

**NOTE 12 CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

As more fully described in Note 6, 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, a Florida limited liability company whose members include Chairman of the Board Dr. Jane H. Hsiao, director Steven D. Rubin and Frost Gamma Investments Trust, a trust controlled by Dr. Phillip Frost, the Company's largest beneficial stockholder. Advances under the Credit Facility totaled \$100,000 and \$900,000 for the three and nine months ended September 30, 2009, respectively, and zero and \$1.0 million for the three and nine months ended September 30, 2008, respectively. There were no outstanding balances under the Credit Facility as of September 30, 2009. The Company recognized interest expense related to the Credit Facility of approximately \$6,000 and \$19,000 for the three and nine months ended September 30, 2009, respectively, and approximately \$0 and \$24,000 for the three and nine months ended September 30, 2008, respectively.

The Company entered into a five year lease for office space in Miami, Florida with a company controlled by Dr. Frost. The initial rental payments under the Miami office lease, which commenced January 1, 2008, were approximately \$8,000 per month for the first year and escalate 4.5% annually over the life of the lease. Pursuant to a lease amendment effective February 2009, the Company relocated its corporate office to an alternate space within the same building for annual rental payments of approximately \$68,000. All other terms and conditions of the Company's corporate office lease remain unchanged. The Company recorded approximately \$20,000 and \$60,000 of rent expense related to the Miami lease for the three and nine months ended September 30, 2009, respectively, and \$24,000 and \$85,000 for the three and nine months ended September 30, 2008, respectively.

Dr. Hsiao is 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 September 30, 2009, the Company had approximately \$56,000 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, and of Aero Pharmaceuticals, Inc. ( Aero ), a privately-held pharmaceutical distribution company. Director Richard Pfenniger is also a shareholder of NIMS. Commencing in March 2008, 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. The Company has recorded reductions to general and administrative costs and expenses for the three and nine months ended September 30, 2009 of approximately \$18,000 and \$57,000, respectively, and \$9,000 and \$24,000 for the three and nine months ended September 30, 2008, respectively, to account for the sharing of costs under this arrangement. Accounts receivable from NIMS and Aero were approximately \$2,000 and \$3,000, respectively, as of September 30, 2009.



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Dr. Hsiao, Dr. Frost, Mr. Rubin and Mr. Pfenniger are each significant stockholders, officers and/or directors of OPKO Health, Inc. ( OPKO ), a publicly-traded specialty healthcare company. Certain of the Company's employees from time to time during the year ended December 31, 2008 provided consulting services to OPKO on a cost-plus basis. The Company recorded reductions totaling \$8,000 and \$45,000 to general and administrative costs and expenses for the three and nine months ended September 30, 2008 to account for the provision of these services. No such services have been provided to OPKO in the nine months ended September 30, 2009. The amounts charged may not be representative of those that would have been charged in an arms-length transaction. The 2008 transactions were ratified by the Audit Committee of the Board of Directors.

**NOTE 13 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 will contribute 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 \$6,000 and \$17,000 for the three and nine months ended September 30, 2009, respectively, and approximately \$13,000 and \$21,000, respectively, for the three and nine months ended September 30, 2008.

**NOTE 14 FINANCIAL INSTRUMENTS**

Recent authoritative accounting guidance defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. This guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. As of September 30, 2009, the Company did not hold any assets or liabilities that were required to be measured at fair value on a recurring basis and did not hold any non-financial assets or liabilities that were required to be re-measured at fair value.

**NOTE 15 RECENT ACCOUNTING PRONOUNCEMENTS**

Effective January 1, 2009, the Company adopted authoritative guidance which established accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Effective January 1, 2009, the Company adopted authoritative guidance which established principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree. This guidance also established principles for recognizing and measuring the goodwill acquired in a business combination and determining what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. In April 2009, the FASB amended and clarified this guidance regarding the initial recognition and measurement, subsequent measurement and accounting, and related disclosures arising from contingencies in a business combination. Under the amended guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value cannot be determined, acquired contingencies should be accounted for using existing guidance. The adoption of this guidance applies to business combinations for which the acquisition date is on or after January 1, 2009, and has not had a material impact on the Company's consolidated financial statements.



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Effective January 1, 2009, the Company adopted authoritative guidance which defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Effective January 1, 2009, the Company adopted authoritative guidance for determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in previously issued guidance regarding derivative accounting. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted authoritative guidance which provides guidelines for making fair value measurements when the volume and level of activity for an asset or liability have significantly decreased and identifying transactions that are not orderly. This guidance establishes guidelines for determining whether a market is active or inactive and whether a transaction is distressed. This guidance is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted authoritative guidance which requires disclosures about fair value of financial instruments in interim, as well as in annual, financial statements. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted authoritative guidance which provides additional guidance to enhance clarity about the credit and noncredit components of an other-than-temporary impairment event and to improve presentation and disclosure of other-than-temporary impairments in the financial statements. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

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. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

In June 2009, the FASB established the FASB Accounting Standards Codification (Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in accordance with GAAP. All existing accounting standard documents are superseded by the Codification and any accounting literature not included in the Codification will not be authoritative. However, rules and interpretive releases of the SEC issued under the authority of federal securities laws will continue to be sources of authoritative GAAP for SEC registrants. The Codification became effective beginning with the Company's third fiscal quarter of 2009. The Codification does not change or alter existing GAAP and, therefore, has not had any impact on the Company's consolidated financial statements.

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

*This Quarterly Report on Form 10-Q contains certain forward-looking statements 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 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 regulatory environments of the United States and other countries in which we intend to operate; our ability to attract and retain key management 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 obesity, 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 SMART Dilator™, standard and airway bite blocks and AMID Stapler™. 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. Clinical trials for certain of these product candidates are anticipated to begin in 2010.

Immediately prior to our September 2007 acquisition of SafeStitch LLC, a privately held Virginia limited liability company, we had no business operations. Under the name Cellular Technical Services Company, Inc. ( "CTSC" ), we had previously developed, marketed, distributed and supported a diversified mix of products and services for the telecommunications industry. In 2002, CTSC ceased its product development efforts and adopted a plan to wind down all operations related to its historical business, which process it completed in December 2005. Between that time and the 2007 consummation of our acquisition of SafeStitch LLC described below, all of CTSC's staff and administrative positions were eliminated. As such, CTSC was a company with primarily cash and cash equivalents and no operations.

On September 4, 2007, we completed our acquisition of SafeStitch LLC pursuant to a Share Transfer, Exchange and Contribution Agreement, dated as of July 25, 2007, by and among us, SafeStitch LLC and the members of SafeStitch LLC. The acquisition was accounted for as a recapitalization of SafeStitch, LLC, which has been treated as the continuing reporting entity.

In January 2008, we changed our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc., and, on February 11, 2008, our trading symbol on the OTCBB changed from CTSC to SFES. We intend to apply for the listing of our Common Stock on the NYSE Amex Equities at such time as we meet the initial listing requirements



set by the exchange.

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### ***Products***

Three of our products may currently be marketed in the United States without further FDA clearance. We received FDA clearance to market our SMART Dilator™ in February 2009, and 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 have completed development of the AMID Stapler™, and in October 2009 and November 2009 submitted applications to United States and European Economic Community regulatory agencies for clearance to market the AMID Stapler™ in those jurisdictions. While we expect to receive such clearances during the first quarter of 2010, there can be no assurance that such clearances will be granted in a timely manner or at all. We expect to begin marketing the AMID Stapler™ upon receipt of the necessary FDA and European Economic Community clearances, and anticipate commencing commercialization activities for the SMART Dilator™ and standard and airway bite blocks upon successful launch of the AMID Stapler™. We believe our Intraluminal Gastroplasty Device for Obesity and GERD (the Gastroplasty Device), which is still in development, will require investigational device exemption (IDE) clinical data for FDA approval as a Class II 510k device. We expect to commence the necessary clinical trials for this device in 2010.

### ***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 those related to investments, 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, 2008. Actual results may differ from these estimates.

### ***Results of Operations***

We incurred losses of \$2.6 million and \$4.0 million for the nine months ended September 30, 2009 and 2008, respectively, and we had an accumulated deficit of \$12.0 million at September 30, 2009. We expect to continue to generate losses as we continue the development of our products and technologies and prepare the initial commercial launch of our FDA-cleared and exempt products. 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. In January 2009, we reduced our research and development staff by five full-time employees to reduce costs as we completed development of three products and refocused our development efforts on our most promising product candidates. We plan to add to our headcount in key functional areas as required during the fourth quarter of 2009 and first quarter of 2010 to commence commercialization activities and further the development of our product candidates.

### ***Three and Nine Months ended September 30, 2009 Compared to Three and Nine Months Ended September 30, 2008***

Research and development costs and expenses were \$258,000 and \$1.1 million, respectively, for the three and nine months ended September 30, 2009 as compared to \$494,000 and \$2.1 million, respectively, for the same periods in 2008. These \$236,000 and \$1.0 million respective decreases resulted primarily from the reduction in R&D staffing discussed above and from decreased consulting fees as a result of the completion of certain third-party development activities related to our Gastroplasty Device, offset in part by increased consulting fees related to third-party development of the AMID Stapler™. We expect research and development costs and expenses for the remainder of 2009 to remain below 2008 levels, but such costs and expenses should increase in 2010 and beyond as we enter into more advanced stages of development for our Gastroplasty Device and other surgical product candidates, including the commencement of clinical trials.



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General and administrative costs and expenses were \$324,000 for the three months ended September 30, 2009, as compared to \$405,000 for the three months ended September 30, 2008. This \$81,000 decrease was primarily due to a \$75,000 decrease in legal and professional fees and a \$35,000 decrease in payroll costs, offset in part by an \$18,000 increase in stock-based compensation expense and increased office expenses. General and administrative costs and expenses were \$1.1 million for the nine months ended September 30, 2009, as compared to \$1.2 million for the nine months ended September 30, 2008. This \$139,000 decrease was primarily the result of \$62,000 lower stock-based compensation expense, a \$55,000 decrease in legal and professional fees, a \$30,000 decrease in travel and trade show expenses and a \$13,000 decrease in rent expense, partially offset by increases in employee benefit and liability insurance costs. General and administrative costs and expenses consist primarily of salaries and other related costs, including stock-based compensation expense. Other general and administrative costs and expenses include facility-related costs not otherwise included in research and development costs and expenses, and professional fees for legal and accounting services. We expect that our general and administrative costs and expenses will begin to increase in the fourth quarter of 2009 and continue to expand in 2010 as we establish the infrastructure required to launch commercialization and marketing activities for our current products and the AMID Stapler™, which we expect will be cleared for marketing in the first quarter of 2010. Additionally, we expect increased costs as we expand our finance and administrative staff, add infrastructure and incur continuing costs related to being a public company, including the costs of directors and officers insurance, investor relations programs and increased professional fees.

Interest income was negligible for the three and nine months ended September 30, 2009 as compared to \$7,000 and \$19,000, respectively, for the comparable 2008 periods. The decrease in interest income was primarily due to lower invested cash balances resulting from the use of cash in our operating activities. Interest expense was \$6,000 and \$19,000, respectively, for the three and nine months ended September 30, 2009 as compared to \$0 and \$24,000, respectively, for the comparable 2008 periods. We do not anticipate significant interest expense during the next 12 months as we expect to fund our operations with existing cash and proceeds from the issuance of the Series A Preferred Stock described below.

***Liquidity and Capital Resources***

We have not generated any revenues and have incurred operating losses since inception, and we expect to continue incurring losses from operations for the foreseeable future. We have funded our operations to date primarily with proceeds from the private placement of equity and advances under credit facilities available to us. Our management believes that our \$579,000 cash balance as of September 30, 2009, together with the \$2 million available to us under commitments from investors to purchase Series A Preferred Stock, will be sufficient to fund our cash flow requirements through the September 30, 2010. This estimate is subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development and commercialization of our 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.

We intend to finance our future cash needs through public or private equity offerings (including the sale of the remaining two million shares of Series A Preferred Stock described above), 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, if 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 debt securities may result in dilution to our shareholders. 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 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.

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We currently have \$4.0 million available under our existing Credit Facility, which expires in June 2010. We do not anticipate borrowing any additional funds under this Credit Facility, nor do we expect to extend or replace the Credit Facility upon its expiration, although the Credit Facility remains a potential source of funding to us until such expiration.

**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.

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

See Note 9 to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for a discussion of recent material developments related to our legal proceedings since the filing of our Annual Report on Form 10-K for the year ended December 31, 2008.

**Item 1A. Risk Factors.**

*Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may have a material adverse effect on us.*

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. Certain proposals, if passed, may impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a material adverse effect on our financial position and results of operations.

Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. In the Obama administration's fiscal year 2010 federal budget proposal, the administration emphasized maintaining patient choice, reducing inefficiencies and costs, increasing prevention programs, increasing coverage portability and universality, improving quality of care and maintaining fiscal sustainability. The Obama administration's fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, certain members of Congress have proposed a government health insurance option to compete with private plans and other expanded public healthcare measures. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

Except as set forth above, 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, 2008.

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

The information required by this Item 2 has been previously reported on our Current Report on Form 8-K, filed with the SEC on July 23, 2009.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Item 5. Other Information.**

None.

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**Item 6. Exhibits.**

**Exhibits:**

- 3.1 Certificate of Designation of Series A Preferred Stock, filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
- 4.1 Specimen Certificate for Series A Preferred Stock, filed as Exhibit 4.2 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
- 10.1 Form of Current Securities Purchase Agreement, filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
- 10.2 Form of Future Securities Purchase Agreement, filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
- 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



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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: November 10, 2009

By: /s/ Jeffrey G. Spragens

Jeffrey G. Spragens  
President and Chief Executive Officer

Date: November 10, 2009

By: /s/ Adam S. Jackson

Adam S. Jackson  
Chief Financial Officer