

SafeStitch Medical, Inc.
Form 10-Q
August 07, 2009

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, 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
(State or other jurisdiction of
incorporation or organization)

11-2962080
(I.R.S. employer identification no.)

4400 Biscayne Blvd., Suite A-100, Miami, Florida
(Address of principal executive offices)

33137
(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.

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

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

17,962,718 shares of the Company's common stock, par value \$0.001 per share, were outstanding as of August 7, 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)

	June 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 39	\$ 561
Other receivable – related-party	10	13
Prepaid expenses	132	151
Total Current Assets	181	725
FIXED ASSETS		
Property and equipment, net	177	168
OTHER ASSETS		
Security deposits	2	2
Deferred financing costs, net	511	851
Total Other Assets	513	853
LONG-TERM INVESTMENT, net of valuation adjustment of \$1,754	–	–
TOTAL ASSETS	\$ 871	\$ 1,746
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 409	\$ 273
Stockholder loans	800	–
Total Current Liabilities	1,209	273
Commitments and contingencies (Note 9)		
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred Stock, \$.01 par value per share, 25,000,000 shares authorized, no shares issued and outstanding	–	–
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	10,905	10,817
Deficit accumulated during the development stage	(11,261)	(9,362)
Total Stockholders' (Deficit) Equity	(338)	1,473
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	\$ 871	\$ 1,746

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

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in 000s, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,		September 15, 2005 (Inception) to June 30,
	2009	2008	2009	2008	2009
REVENUES	\$ -	\$ -	\$ -	\$ -	\$ -
COSTS AND EXPENSES					
Research and development	449	804	798	1,618	6,385
General and administrative	417	390	748	806	3,421
Total Costs and Expenses	866	1,194	1,546	2,424	9,806
LOSS FROM OPERATIONS	(866)	(1,194)	(1,546)	(2,424)	(9,806)
INTEREST INCOME	-	7	-	12	77
AMORTIZATION OF DEBT ISSUANCE EXPENSE	(128)	(212)	(340)	(425)	(1,474)
INTEREST EXPENSE	(13)	(18)	(13)	(24)	(58)
LOSS BEFORE INCOME TAX	(1,007)	(1,417)	(1,899)	(2,861)	(11,261)
PROVISION FOR INCOME TAX	-	-	-	-	-
NET LOSS	\$ (1,007)	\$ (1,417)	\$ (1,899)	\$ (2,861)	\$ (11,261)
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	17,963	16,843	17,963	16,468	
NET LOSS PER BASIC AND DILUTED SHARE	\$ (0.06)	\$ (0.08)	\$ (0.11)	\$ (0.17)	

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

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY

FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH JUNE 30, 2009

(in 000s)

	Preferred Stock		Common Stock		Additional	Deficit	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Accumulated During the Development Stage	
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 per share

			8	—	10	—	10
Stock-based compensation	—	—	—	—	239	—	239
Net loss	—	—	—	—	—	(5,185)	(5,185)
Balance at December 31, 2008	—	\$	—	17,963	\$	18	\$ 10,817
						\$	(9,362)
							\$ 1,473
Stock-based compensation	—	—	—	—	88	—	88
Net loss	—	—	—	—	—	(1,899)	(1,899)
Balance at June 30, 2009 -							
Unaudited	—	\$	—	17,963	\$	18	\$ 10,905
							\$ (11,261)
							\$ (338)

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

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in 000s)

	Six Months Ended June 30,		September 15, 2005 (Inception) to June 30, 2009
	2009	2008	
OPERATING ACTIVITIES			
Net loss	\$ (1,899)	\$ (2,861)	\$ (11,261)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	340	425	1,474
Stock-based compensation expense	88	171	392
Stock-based compensation expense related to Share Exchange	—	—	77
Depreciation and amortization	27	25	86
Changes in operating assets and liabilities			
Other current assets	22	(26)	(122)
Other assets	—	(1)	(2)
Accounts payable and accrued liabilities	136	72	124
NET CASH USED IN OPERATING ACTIVITIES	(1,286)	(2,195)	(9,232)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of equipment	(36)	(25)	(263)
Payment received under Rule 16b	—	—	4
NET CASH USED IN INVESTING ACTIVITIES	(36)	(25)	(259)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net cash provided in connection with the acquisition of SafeStitch LLC	—	—	3,192
Issuance of common stock, net of offering costs	—	3,990	3,988
Capital contributions	—	—	1,431
Proceeds from stockholder loans	800	1,000	2,760
Repayment of stockholder loans	—	(1,000)	(1,876)
Exercise of options	—	—	35
NET CASH PROVIDED BY FINANCING ACTIVITIES	800	3,990	9,530
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(522)	1,770	39
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	561	631	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 39	\$ 2,401	\$ 39
Supplemental disclosures:			
Cash paid for interest	\$ —	\$ 24	\$ 45
Non cash activities:			

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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.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

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 six months ended June 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, 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, 2009, the Company has accumulated a deficit of \$11.3 million and has not generated positive cash flows from operations. At June 30, 2009, the Company had a working capital deficit of \$1,028,000, including \$800,000 of stockholder loans, and a capital deficit of \$338,000. 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 16. 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 \$2.0 million gross proceeds from the July 2009 sale of Series A Preferred Stock; the commitment from private investors for an additional \$2.0

million of Series A Preferred Stock; 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 without meaningful revenues or additional financing at least through June 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. 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.

SAFESTITCH MEDICAL, INC.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Consolidation. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Isis Tele-Communications, Inc., which has no current operations, and SafeStitch LLC. All inter-company accounts and transactions have been eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with 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 follows Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share Based Payment", which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, 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 Company follows SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. 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. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of 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, as set forth in SFAS No. 109, "Accounting for Income Taxes" ("SFAS 109"). SFAS 109 prescribes an asset and liability approach, 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). SFAS No. 130, "Reporting Comprehensive Income (Loss)," requires companies to classify items of other comprehensive income (loss) in a financial statement. 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.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	Estimated Useful Lives	June 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		(86,000)	(59,000)
Property and equipment, net		\$ 177,000	\$ 168,000

Depreciation of fixed assets utilized in research and development activities is included in research and development expense. All other depreciation is included in general and administrative costs and expenses. Depreciation and amortization expense was \$14,000 and \$27,000, respectively, for the three and six months ended June 30, 2009, and was \$12,000 and \$25,000, respectively, for the three and six months ended June 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 six months ended June 30, 2009 was \$52,000 and \$88,000, respectively, and is included in general and administrative costs and expenses. Total stock-based compensation recorded for the three and six months ended June 30, 2008 was \$32,000 and \$171,000, 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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(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company granted zero and 358,500 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 Company granted zero and 148,500 options, respectively, under the 2007 Plan during the three and six months ended June 30, 2008. The options granted during the six months ended June 30, 2008 were issued at exercise prices between \$3.00 and \$3.10 per share and had an estimated aggregate grant date fair value of \$300,000. 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 six months ended June 30, 2009 and 2008 was estimated using the following assumptions.

	Six months ended June 30, 2009	Six months ended June 30, 2008
Expected volatility	74.59% - 86.43%	88.31% - 94.46%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.39% - 1.79%	1.96% - 2.61%
Expected life	4.0 - 5.5 years	3.5 - 5.5 years
Forfeiture rate	2.50%	0% - 2.50%

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	256,667	\$ 2.80	7.12	
Granted	358,500	\$ 0.80	6.62	
Exercised	—	—	—	
Canceled or expired	—	—	—	
Outstanding at June 30, 2009	615,167	\$ 1.63	6.48	\$ 107,550
Exercisable at June 30, 2009	143,834	\$ 2.93	5.88	\$ —
Vested and expected to vest at June 30, 2009	592,789	\$ 1.65	6.48	\$ 102,099

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

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	Stock Options	Weighted Average Grant Date Fair Value
Non-Vested at December 31, 2008	146,833	\$ 2.00
Options Granted	358,500	0.50
Options Vested	(34,000)	2.02
Non-Vested at June 30, 2009	471,333	\$ 0.86

At June 30, 2009, there was \$249,000 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 1.70 years.

No options were exercised during the six months ended June 30, 2009 and 2008. 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 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 the 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 \$128,000 and \$340,000, respectively, for the three and six months ended June 30, 2009 and \$212,000 and \$425,000, respectively, for the three and six months ended June 30, 2008.

The Company borrowed \$1.0 million under the Credit Facility during the six months ended June 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 \$800,000 under the Credit Facility during the six months ended June 30, 2009, which amount remained outstanding as of June 30, 2009 and was repaid with the proceeds of the 2009 issuance of Series A Preferred Stock described in Notes 7 and 16. 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 and approximately \$18,000 and \$24,000, respectively, for the three and six months ended June 30, 2008.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 the securities purchase agreements described in Note 16, pursuant to which the Company issued 2,000,000 shares of Series A Preferred Stock on July 22, 2009.

NOTE 8 – BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss 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. In computing diluted net loss per share for the three and six months ended June 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 is anti-dilutive.

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

	June 30, 2009	June 30, 2008
Stock options	615,167	237,167
Stock warrants	805,521	805,521
Total	1,420,688	1,042,688

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 \$53,000 for the three and six months ended June 30, 2009, respectively, and \$30,000 and \$78,000 for the three and six months ended June 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 June 30, 2009, the Company has contributed approximately \$81,000 in cash and has incurred additional liabilities of approximately \$129,000. 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.

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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 2nd 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 \$20,000, respectively, for the three and six months ended June 30, 2009, and \$81,000 and \$147,000, respectively, for the three and six months ended June 30, 2008.

NOTE 11 – INCOME TAXES

The Company accounts for income taxes using the asset and liability method described in SFAS No. 109, "Accounting For Income Taxes," 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 adopted the provisions of FASB interpretation No. 48 “Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109.” 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 June 30, 2009 and December 31, 2008.

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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 \$500,000 and \$800,000 for the three and six months ended June 30, 2009, respectively, and zero and \$1.0 million for the three and six months ended June 30, 2008, respectively. \$800,000 was outstanding under the Credit Facility as of June 30, 2009. The Company recognized interest expense related to the Credit Facility of approximately \$13,000 and \$13,000 for the three and six months ended June 30, 2009, respectively, and approximately \$18,000 and \$24,000 for the three and six months ended June 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 \$19,000 and \$40,000 of rent expense related to the Miami lease for the three and six months ended June 30, 2009, respectively, and \$24,000 and \$61,000 for the three and six months ended June 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 June 30, 2009, the Company had approximately \$23,000 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 six months ended June 30, 2009 of approximately \$20,000 and \$39,000, respectively, and \$15,000 and \$15,000 for the three and six months ended June 30, 2008, respectively, to account for the sharing of costs under this arrangement. Accounts receivable from NIMS and Aero were approximately \$7,000 and \$3,000, respectively, as of June 30, 2009.

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 \$37,000 to general and administrative costs and expenses for the three and six months ended June 30, 2008 to account for the provision of these services. No such services have been provided to OPKO in the six months ended June 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.

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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 \$5,000 and \$11,000 for the three and six months ended June 30, 2009, respectively, and approximately \$8,000 and \$8,000, respectively, for the three and six months ended June 30, 2008.

NOTE 14 – FINANCIAL INSTRUMENTS

Effective January 1, 2008, the Company adopted SFAS 157, which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. In accordance with FASB Staff Position 157-2, “Effective Date of the FASB Statement No. 157,” the Company deferred adoption of SFAS 157 for its nonfinancial assets and nonfinancial liabilities, except those items recognized or disclosed at fair value on an annual or more recurring basis, until January 1, 2009. SFAS 157 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 June 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, and therefore the adoption of the respective provisions of SFAS 157 did not have a material impact on the Company’s consolidated financial statements.

NOTE 15 – RECENT ACCOUNTING PRONOUNCEMENTS

Effective January 1, 2009, the Company adopted SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51” (“SFAS 160”). SFAS 160 establishes 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 SFAS 160 has not had a material impact on the Company’s consolidated financial statements.

Effective January 1, 2009, the Company adopted SFAS No. 141 R “Business Combinations” (“SFAS 141R”). SFAS 141R establishes 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. SFAS 141R also provides guidance for recognizing and measuring the goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. The adoption of SFAS 141R has not had a material impact on the Company’s consolidated financial statements. In April 2009, the FASB issued FSP No. FAS 141(R)-1, “Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies” (“FSP 141(R)-1”), to amend and clarify the initial recognition and measurement, subsequent measurement and accounting,

and related disclosures arising from contingencies in a business combination under SFAS 141R. Under the new 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. FSP 141(R)-1 is effective January 1, 2009. As such, the adoption applies to business combinations for which the acquisition date is on or after January 1, 2009.

Effective January 1, 2009, the Company adopted Emerging Issues Task Force Issue No. 07-1, "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property" ("EITF 07-1").

EITF 07-1 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 EITF 07-1 has not had a material impact on the Company's consolidated financial statements.

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Effective January 1, 2009, the Company adopted EITF 07-05, "Determining whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-05"). EITF 07-05 provides guidance on 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 paragraph 11(a) of SFAS 133. The adoption of EITF 07-05 has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted FASB Staff Position FAS-157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly" ("FSP FAS 157-4"). FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. FSP FAS 157-4 is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of FSP FAS 157-4 has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted FASB Staff Positions FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments" ("FSP FAS 115-2") and ("FSP FAS 124-2"). FSP FAS 115-2 and FSP FAS 124-2 provide additional guidance to provide greater clarity about the credit and noncredit component 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 FSP FAS 115-2 and FSP FAS 124-2 has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted FASB Staff Position FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments" ("FSP FAS 107-1") and ("APB 28-1"). FSP FAS 107-1 amends FASB Statement No. 107, "Disclosures about Fair Value of Financial Instruments", to require disclosures about fair value of financial instruments in interim as well as in annual financial statements and amends APB Opinion No. 28 "Interim Financial Reporting", to require those disclosures in interim financial statements. The adoption of FSP FAS 107-1 and APB 28-1 has not had a material impact on the Company's consolidated financial statements.

Effective June 30, 2009 the Company adopted SFAS 165, "Subsequent Events," which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or available to be issued. The adoption of SFAS 165 has not had a material impact on the Company's consolidated financial statements. The Company has evaluated subsequent events through August 7, 2009, which is the date the financial statements were available to be issued.

In June 2009, the FASB issued FAS No. 168, "The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles - a replacement of FASB Statement No. 162" ("FAS No. 168"). FAS No. 168 replaces FAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" and establishes 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.

FAS No. 168 will be effective beginning with the Company's third fiscal quarter of 2009. Therefore, all references made by it to GAAP in its consolidated financial statements will use the new Codification numbering system. The Codification does not change or alter existing GAAP and, therefore, it is not expected to have any impact on the Company's consolidated financial statements.

NOTE 16 – SUBSEQUENT EVENTS

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.

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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 outstanding 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 Company’s common stock, par value \$0.001 per share (“Common Stock”).

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.

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 acquisition of SafeStitch LLC, a privately held Virginia limited liability company, on September 4, 2007, 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.

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 believe our Intraluminal Gastroplasty Device for Obesity and GERD (the “Gastroplasty Device”), which is still in development, will require IDE (investigational device exemption) clinical data for FDA approval as a Class II 510k device. We expect to commence the necessary clinical trials for this device in 2010. We have completed principal development of the AMID Stapler™, and we expect to submit applications during the third quarter of 2009 for approval to market the AMID Stapler™ to both United States and European Economic Community regulatory agencies.

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

Our losses totaled \$11.3 million for the period commencing September 15, 2005 (inception) and ended June 30, 2009. Such losses included \$1.9 million and \$2.9 million for the six months ended June 30, 2009 and 2008, respectively. At June 30, 2009, we had an accumulated deficit of \$11.3 million. Since we do not currently generate revenue from any of our product candidates, including those approved for commercial marketing by the FDA, we expect to continue to generate losses in connection with the initial commercial launch of such FDA-approved products and the development of our other products and technologies. Our research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe our operating losses are likely to be substantial over the next several years. 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 to commence commercialization activities and further the development of our product candidates.

Three and Six Months ended June 30, 2009 Compared to Three and Six Months Ended June 30, 2008

Research and development costs and expenses were \$449,000 and \$798,000, respectively, for the three and six months ended June 30, 2009 as compared to \$804,000 and \$1.6 million, respectively, for the same periods in 2008. These \$355,000 and \$820,000 respective decreases resulted primarily from the reduction in R&D staffing discussed above and from completion of development activities related to certain of our products. We expect research and development costs and expenses in 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.

General and administrative costs and expenses were \$417,000 for the three months ended June 30, 2009, as compared to \$390,000 for the three months ended June 30, 2008. This \$27,000 increase was primarily due to a \$50,000 increase in legal and professional fees, related in part to the TruePosition litigation, partially offset by reductions in travel expenses. General and administrative costs and expenses were \$748,000 for the six months ended June 30, 2009, as compared to \$806,000 for the six months ended June 30, 2008. This \$58,000 decrease was primarily the result of \$83,000 lower stock-based compensation expense and reductions in rent and travel expense, partially offset by increases in accounting and administrative payroll costs and legal and professional fees. 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 increase during 2009 as compared to 2008 as we commence commercialization activities for our SMART DilatorTM and bite block products, as well as for the AMID StaplerTM, which we expect will be cleared for marketing before the end of 2009. 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 six months ended June 30, 2009 as compared to \$7,000 and \$12,000, respectively, for the comparable 2008 periods, primarily due to lower invested cash balances resulting from the use of cash in our operating activities. Interest expense was \$13,000 and \$13,000, respectively, for the three and six months ended June 30, 2009 as compared to \$18,000 and \$24,000, respectively, for the comparable 2008 periods, due to lower balances outstanding under the Credit Facility. We expect interest expense to decrease due to the repayment of balances outstanding under the Credit Facility with the proceeds of the July 2009 issuance of Series A Preferred Stock described below.

Liquidity and Capital Resources

As a result of our significant research and development expenditures and the lack, until February 2009, of any products approved for sale, we have not been profitable and have generated operating losses since inception. Additionally, in connection with our involvement as a plaintiff in the TruePosition litigation, we spent approximately \$81,000 during the two years since the litigation began, which reduced our available cash and will continue to do so for so long as we stay involved in the litigation. We do not expect to generate any meaningful revenues before the beginning of 2010, and we expect to incur losses from operations for the foreseeable future. Beginning in 2010, we expect to incur increasing research and development costs and expenses, including expenses related to hiring new personnel and conducting clinical trials for our Gastroplasty Device. We expect that general and administrative costs and expenses will also increase 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.

To date, we have funded our operations primarily with proceeds from the private placement of stock and credit facilities available to us, including the July 2009 issuance of Series A Preferred Stock described in Note 16 to the accompanying unaudited condensed consolidated financial statements. Our ability to sell additional shares of our stock and/or borrow cash under existing or new credit facilities could be materially adversely affected by the recent and continuing economic turmoil in the world's equity and credit markets. There can therefore be no assurance that we will be able to raise funds on acceptable terms or at all, which may materially adversely affect our ability to continue our operations. Additionally, the current economic turmoil could also reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our product candidates. Such delay could have a material adverse impact on our expected cash flows, liquidity, results of operations and financial position. In order to address this uncertainty, our management has taken steps to reduce our near-term cash requirements by focusing our product

development efforts primarily on the significant product candidates, including the Gastroplasty Device and AMID Stapler™, which are expected to have the most promising market potential and the shortest remaining development time.

As a result of these actions, our management has budgeted expenditures through June 2010 to fund the final development of the AMID Stapler™ and the initial marketing of the AMID Stapler™ and the three other product candidates already developed, as well as to continue research and development of our Gastroplasty Device. Our management believes that our \$39,000 cash balance as of June 30, 2009, the \$2.0 million gross proceeds from the July 2009 sale of Series A Preferred Stock, the commitment from private investors for an additional \$2.0 million of Series A Preferred Stock, together with the \$3.2 million availability remaining under our Credit Facility, which expires in June 2010, will be sufficient to fund our cash flow requirements through at least June 2010. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the precise amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials.

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 will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Our Credit Facility expires in June 2010, and we are continuing to evaluate longer-term financing alternatives. Under the second of the two securities purchase agreements we entered into in July 2009, we obtained commitments from private investors to purchase from us an additional \$2 million of Series A Preferred Stock on a date selected by our Board of Directors on or before June 30, 2010. We may need to raise additional funds more quickly if one or more of our budgeting assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our 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 merge or otherwise enter into business combination transactions. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our 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.

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 4T. Controls and Procedures.

We maintain a system of disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) that is designed to provide reasonable assurance that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to management in a timely manner. Our Chief Executive Officer and Chief Financial Officer evaluated this system of disclosure controls and procedures as of the end of the period covered by this quarterly report, and have concluded that the system is operating effectively to ensure appropriate disclosure.

There were no significant changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act that occurred during period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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, members of Congress have proposed a single-payer healthcare system, 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.

None.

Item 3. Defaults Upon Senior Securities.

None.

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

At our Annual Meeting of Stockholders held on June 10, 2009, our stockholders voted to re-elect each of the Director nominees named in our Definitive Proxy Statement on Schedule 14A as filed with the SEC on April 30, 2009. The number of votes cast for or withheld, with respect to each of the nominees, were as follows:

Nominee	For	Withheld
Jane H. Hsiao, Ph.D., MBA	11,910,332	13,857
Jeffrey G. Spragens	11,843,732	80,457
Charles J. Filipi, M.D.	11,843,832	80,357
Kenneth Heithoff, M.D.	11,840,334	83,855
Richard C. Pfenniger, Jr.	11,840,234	83,955
Steven D. Rubin	11,840,134	84,055
Kevin Wayne, DBA	11,916,340	7,849

No other matters were submitted to a vote of our stockholders at the Annual Meeting.

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

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 7, 2009

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

Date: August 7, 2009

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