

SafeStitch Medical, Inc.  
Form 10-Q  
May 13, 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 March 31, 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.

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(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

4400 Biscayne Blvd., Suite 670, Miami, Florida  
(Former name, former address and former fiscal year, if changed since last report)

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 May 12, 2009.

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SAFESTITCH MEDICAL, INC.  
(A Developmental Stage Company)

TABLE OF CONTENTS FOR FORM 10-Q

|                               |  |    |
|-------------------------------|--|----|
| PART I. FINANCIAL INFORMATION |  |    |
| ITEM 1.                       | FINANCIAL STATEMENTS   | 3  |
|                               | Condensed Consolidated Balance Sheets as of March 31, 2009<br>(unaudited) and December 31, 2008  | 3  |
|                               | Unaudited Condensed Consolidated Statements of Operations for the<br>Three Months ended March 31, 2009 and 2008, and for the period<br>from September 15, 2005 (inception) to March 31, 2009 | 4  |
|                               | Condensed Consolidated Statements of Stockholders' Equity for the<br>period from September 15, 2005 (inception) through March 31, 2009<br>(unaudited)  | 5  |
|                               | Unaudited Condensed Consolidated Statements of Cash Flows for the<br>Three Months ended March 31, 2009 and 2008, and for the period<br>from September 15, 2005 (inception) to March 31, 2009 | 6  |
|                               | Notes to unaudited condensed consolidated financial statements   | 7  |
| ITEM 2.                       | MANAGEMENT'S DISCUSSION AND ANALYSIS OF<br>FINANCIAL CONDITION AND RESULTS OF OPERATIONS   | 17 |
| ITEM 3.                       | QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT<br>MARKET RISK.   | 20 |
| ITEM 4T.                      | CONTROLS AND PROCEDURES  | 20 |
| PART II. OTHER INFORMATION    |  |    |
| ITEM 1.                       | LEGAL PROCEEDINGS  | 21 |
| ITEM 1A.                      | RISK FACTORS   | 21 |
| ITEM 2.                       | UNREGISTERED SALES OF EQUITY SECURITIES AND USE<br>OF PROCEEDS   | 21 |
| ITEM 3.                       | DEFAULTS UPON SENIOR SECURITIES  | 21 |
| ITEM 4.                       | SUBMISSION OF MATTERS TO A VOTE OF SECURITY<br>HOLDERS   | 21 |
| ITEM 5.                       | OTHER INFORMATION  | 21 |

|         |            |    |
|---------|------------|----|
| ITEM 6. | EXHIBITS   | 21 |
|         | SIGNATURES | 22 |

## SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in 000s, except share and per share data)

|  | March 31,<br>2009<br>(Unaudited) | December 31,<br>2008 |
|--|----------------------------------|----------------------|
| <b>ASSETS</b>  |                                  |                      |
| <b>CURRENT ASSETS</b>  |                                  |                      |
| Cash and cash equivalents  | \$ 218                           | \$ 561               |
| Other receivable – related-party   | 7                                | 13                   |
| Prepaid expenses   | 163                              | 151                  |
| Total Current Assets   | 388                              | 725                  |
| <b>FIXED ASSETS</b>  |                                  |                      |
| Property and equipment, net  | 158                              | 168                  |
| <b>OTHER ASSETS</b>  |                                  |                      |
| Security deposits  | 2                                | 2                    |
| Deferred financing costs, net  | 638                              | 851                  |
| Total Other Assets   | 640                              | 853                  |
| LONG-TERM INVESTMENT, net of valuation adjustment of \$1,754   | –                                | –                    |
| <b>TOTAL ASSETS</b>  | <b>\$ 1,186</b>                  | <b>\$ 1,746</b>      |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                  |                      |
| <b>CURRENT LIABILITIES</b>   |                                  |                      |
| Accounts payable and accrued liabilities   | \$ 270                           | \$ 273               |
| Total Current Liabilities  | 270                              | 273                  |
| Stockholder loans  | 300                              | –                    |
| Commitments and contingencies (Note 9)   | –                                | –                    |
| <b>STOCKHOLDERS' EQUITY</b>  |                                  |                      |
| Preferred Stock, \$.01 par value per share, 25,000,000 shares authorized,<br>no shares issued and outstanding        | –                                | –                    |
| Common Stock, \$.001 par value per share, 225,000,000 shares authorized,<br>17,962,718 shares issued and outstanding | 18                               | 18                   |
| Additional Paid-in Capital   | 10,853                           | 10,817               |
| Deficit accumulated during the development stage   | (10,255)                         | (9,362)              |
| Total Stockholders' Equity   | 616                              | 1,473                |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>  | <b>\$ 1,186</b>                  | <b>\$ 1,746</b>      |

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<br>March 31, |            | September 15,<br>2005<br>(Inception) to<br>March 31, 2009 |
|---|---------------------------------|------------|---|
|   | 2009                            | 2008       |   |
| REVENUES  | \$ —                            | \$ —       | \$ —  |
| COSTS AND EXPENSES                                      |                                 |            |   |
| Research and development                                | 349                             | 814        | 5,936   |
| General and administrative                              | 331                             | 416        | 3,004   |
| Total Costs and Expenses                                | 680                             | 1,230      | 8,940   |
| LOSS FROM OPERATIONS                                    | (680)                           | (1,230)    | (8,940)   |
| INTEREST INCOME   | —                               | 5          | 77  |
| AMORTIZATION OF FINANCE COSTS                           | (213)                           | (213)      | (1,347)   |
| INTEREST EXPENSE  | —                               | (6)        | (45)  |
| LOSS BEFORE INCOME TAX                                  | (893)                           | (1,444)    | (10,255)  |
| PROVISION FOR INCOME TAX                                | —                               | —          | —   |
| NET LOSS  | \$ (893)                        | \$ (1,444) | \$ (10,255)   |
| WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED | 17,963                          | 16,093     |   |
| NET LOSS PER BASIC AND DILUTED SHARE                    | \$ (0.05)                       | \$ (0.09)  |   |

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' EQUITY

FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH MARCH 31, 2009

(in 000s)

|  | Preferred Stock |        | Common Stock |        | Additional         | Deficit   | Total    |
|--|-----------------|--------|--------------|--------|--------------------|---|----------|
|  | Shares          | Amount | Shares       | Amount | Paid-in<br>Capital | Accumulated<br>During the<br>Development<br>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<br>(CTS)-September 23, 2007 at<br>\$0.79 per share                                       | –               | –      | 42           | –      | 35                 | –   | 35       |
| Stock-based<br>compensation-September 4,<br>2007   | –               | –      | –            | –      | 77                 | –   | 77       |
| Issuance of shares in<br>recapitalization - September 4,<br>2007 at \$0.64 per share                         | –               | –      | 4,795        | 5      | 3,078              | –   | 3,083    |
| SafeStitch expenses associated<br>with recapitalization  | –               | –      | –            | –      | (156)              | –   | (156)    |
| Stock-based compensation   | –               | –      | –            | –      | 65                 | –   | 65       |
| Warrants issued in connection<br>with credit facility-September<br>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<br>private offering – May 2008 at<br>\$2.15 per share, net of offering<br>costs | –               | –      | 1,862        | 2      | 3,986              | –   | 3,988    |
| Issuance of common shares as<br>repayment of stockholder   | –               | –      | 8            | –      | 10                 | –   | 10       |

note-December 30, 2008 at  
\$1.22 per share

|  |   |    |   |        |     |         |                               |
|--|---|----|---|--------|-----|---------|-------------------------------|
| Stock-based compensation                 | – | –  | – | –      | 239 | –       | 239                           |
| Net loss                                 | – | –  | – | –      | –   | (5,185) | (5,185)                       |
| Balance at December 31, 2008             | – | \$ | – | 17,963 | \$  | 18      | \$ 10,817 \$ (9,362) \$ 1,473 |
| Stock-based compensation                 | – | –  | – | –      | 36  | –       | 36                            |
| Net loss                                 | – | –  | – | –      | –   | (893)   | (893)                         |
| Balance at March 31, 2009 -<br>Unaudited | – | \$ | – | 17,963 | \$  | 18      | \$ 10,853 \$ (10,255) \$ 616  |

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)

|   | Three Months Ended<br>March 31, |               | September 15,<br>2005<br>(Inception) to<br>March 31, |
|---|---------------------------------|---------------|--|
|   | 2009                            | 2008          | 2009   |
| <b>OPERATING ACTIVITIES</b>   |                                 |               |  |
| Net loss  | \$ (893)                        | \$ (1,444)    | \$ (10,255)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |               |  |
| Amortization of deferred finance costs                                      | 213                             | 213           | 1,347  |
| Stock-based compensation expense  | 36                              | 139           | 340  |
| Stock-based compensation expense related to Share Exchange                  | —                               | —             | 77   |
| Depreciation and amortization   | 13                              | 13            | 72   |
| Changes in operating assets and liabilities                                 |                                 |               |  |
| Other current assets  | (6)                             | (3)           | (150)  |
| Other assets  | —                               | —             | (2)  |
| Accounts payable and accrued liabilities                                    | (3)                             | 112           | (15)   |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>                                | <b>(640)</b>                    | <b>(970)</b>  | <b>(8,586)</b>                                       |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                 |                                 |               |  |
| Purchase of equipment   | (3)                             | (3)           | (230)  |
| Payment received under Rule 16b   | —                               | —             | 4  |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>                                | <b>(3)</b>                      | <b>(3)</b>    | <b>(226)</b>   |
| <b>CASH FLOWS FROM 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  |
| Capital contributions   | —                               | —             | 1,431  |
| Proceeds from stockholder loans   | 300                             | 1,000         | 2,260  |
| Repayment of stockholder loans  | —                               | —             | (1,876)  |
| Exercise of options   | —                               | —             | 35   |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                            | <b>300</b>                      | <b>1,000</b>  | <b>9,030</b>   |
| <b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>                 | <b>(343)</b>                    | <b>27</b>     | <b>218</b>   |
| <b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>                     | <b>561</b>                      | <b>631</b>    | <b>—</b>   |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                           | <b>\$ 218</b>                   | <b>\$ 658</b> | <b>\$ 218</b>  |
| Supplemental disclosures:   |                                 |               |  |
| Cash paid for interest  | \$ —                            | \$ —          | \$ 45  |
| Non cash activities:  |                                 |               |  |
| Stockholder loans contributed to capital                                    | \$ —                            | \$ —          | \$ 84  |
| Warrants issued in connection with credit facility                          | \$ —                            | \$ 1,985      | \$ 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 months ended March 31, 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 Exchange Commission 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 March 31, 2009, the Company has accumulated a deficit of \$10.3 million and has not generated positive cash flows from operations. The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain its operations. 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; 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 revenues or additional financing at least through May 2010. 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.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

**Use of estimates.** The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions, 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 an original 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 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 | March 31, 2009 | December 31, 2008 |
|---|------------------------|----------------|-------------------|
| Machinery and equipment                   | 5 years                | \$ 156,000     | \$ 153,000        |
| Furniture and fixtures                    | 3-5 years              | 37,000         | 37,000            |
| Software                                  | 3-5 years              | 37,000         | 37,000            |
|   |                        | 230,000        | 227,000           |
| Accumulated depreciation and amortization |                        | (72,000)       | (59,000)          |
| Property and equipment, net               |                        | \$ 158,000     | \$ 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 \$13,000 and \$13,000, respectively for the three months ended March 31, 2009 and 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, 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 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 plan may have a term exceeding ten years.



## SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Total stock-based compensation recorded for the three months ended March 31, 2009 and 2008 was \$36,000 and \$139,000, respectively, and is included in general and administrative costs and expenses. 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.

The Company granted 358,500 options under the 2007 Plan during the three months ended March 31, 2009 at an exercise price of \$0.80 per share and an estimated aggregate grant date fair value of \$180,000. The Company granted 148,500 options under the 2007 Plan during the three months ended March 31, 2008 at exercise prices between \$3.00 and \$3.10 per share and an estimated aggregate grant date fair value of \$300,000. The fair values of options granted are estimated on the date of their grant using the Black-Scholes option pricing model based on the assumptions included in the table below. Expected volatility is based on the historical volatility of the 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 the United States Securities and Exchange Commission ("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 three months ended March 31, 2009 and 2008 was estimated using the following assumptions.

|                         | Three months ended<br>March 31, 2009 | Three months ended<br>March 31, 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 three months ended March 31, 2009:

|   | Shares  | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic<br>Value |
|---|---------|--|---|---------------------------------|
| Outstanding at December 31, 2008              | 256,667 | \$ 2.80                                  | 7.12  |                                 |
| Granted                                       | 358,500 | \$ 0.80                                  | 6.87  |                                 |
| Exercised                                     | —       | —  | —   |                                 |
| Canceled or expired                           | —       | —  | —   |                                 |
| Outstanding at March 31, 2009                 | 615,167 | \$ 1.63                                  | 6.87  | \$ 71,700                       |
| Exercisable at March 31, 2009                 | 143,834 | \$ 2.93                                  | 6.74  | \$ —                            |
| Vested and expected to vest at March 31, 2009 | 592,789 | \$ 1.65                                  | 6.88  | \$ 68,066                       |

None of the 358,500 options granted during the first quarter of the Company's 2009 fiscal year were vested as of March 31, 2009. A summary of the status of the Company's non-vested options and changes during the three months ended March 31, 2009 is presented below.

## SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

|                                 | Stock Options | Weighted Average Grant<br>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 March 31, 2009    | 471,333       | \$ 0.86                                   |

At March 31, 2009, there was \$301,000 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 1.85 years.

No options were exercised during the three months ended March 31, 2009 and 2008. The \$36,000 of stock-based compensation recorded in the three months ended March 31, 2009 is net of an approximately \$15,000 credit related to the modification of stock option awards for certain former employees. The Company's Compensation Committee accelerated the vesting of the former employees' options, which originally vested on various dates through 2012, to be fully vested on the modification date, and extended the expiration of the options to one year from 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 \$213,000 and \$213,000, respectively, for the three months ended March 31, 2009 and 2008.

The Company borrowed \$1.0 million under the Credit Facility during the three months ended March 31, 2008 and repaid the entire outstanding balance in June 2008 using the proceeds of the private placement described in Note 7. The Company borrowed \$300,000 under the Credit Facility during the three months ended March 31, 2009, which

amount remained outstanding as of March 31, 2009. The Company recognized interest expense related to the outstanding borrowings of less than \$1,000 for the three months ended March 31, 2009 and approximately \$6,000 for the three months ended March 31, 2008.

## SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 7 – CAPITAL TRANSACTIONS:

2008 Private Placement. 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 has 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 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.

## 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 months ended March 31, 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:

|                | March 31, 2009 | March 31, 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 \$28,000 and \$48,000 for the three months ended March 31, 2009 and 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 March 31, 2009, the Company has contributed approximately \$81,000 in cash and has incurred additional liabilities of approximately \$69,000. 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.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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. For the three months ended March 31, 2009 and 2008, the Company paid Creighton \$10,000 and \$66,000, respectively, in satisfaction of the 20% facility reimbursement obligation.

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 March 31, 2009 and December 31, 2008.



SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 \$300,000 and \$1.0 million for the three months ended March 31, 2009 and 2008, respectively, and \$300,000 was outstanding as of March 31, 2009. The Company recognized interest expense related to the Credit Facility of less than \$1,000 for the three months ended March 31, 2009 and approximately \$6,000 for the three months ended March 31, 2008.

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 \$21,000 and \$36,000 of rent expense related to the Miami lease for the three months ended March 31, 2009 and 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 March 31, 2009, the Company had approximately \$17,000 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. 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 months ended March 31, 2009 and 2008 of \$19,000 and \$0, respectively, to account for the sharing of costs under this arrangement. Accounts receivable from NIMS and Aero were approximately \$3,000 and \$3,000, respectively, as of March 31, 2009.

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) matching expense of approximately \$6,000 and \$0, respectively, for the three months ended March 31, 2009 and 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 March 31, 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.

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED 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.

In May 2008, the FASB issued SFAS No. 162, “The Hierarchy of Generally Accepted Accounting Principles” (“SFAS 162”). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements that are presented in conformity with GAAP. SFAS 162 will become effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, “The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.” The Company does not expect the adoption of SFAS 162 to have a material impact on its consolidated financial statements.

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.



SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In April 2009, the FASB issued 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. FSP FAS 157-4 is required to be adopted no later than the periods ending after June 15, 2009. The Company is currently evaluating the potential impact of the adoption of FSP FAS 157-4 on its consolidated financial statements.

In April 2009, the FASB issued 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. FSP FAS 115-2 and FSP FAS 124-2 are required to be adopted no later than the periods ending after June 15, 2009. The Company is currently evaluating the potential impact of the adoption of FSP FAS 115-2 on its consolidated financial statements.

In April 2009, the FASB issued 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. FSP FAS 107-1 and APB 28-1 are required to be adopted no later than the periods ending after June 15, 2009. The Company is currently evaluating the potential impact of the adoption of FSP FAS 107-1 on its consolidated financial statements.

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 hernia 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 our standard and airway bite blocks to be 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 expect to complete principal development of the Amid Hernia Stapler in the fall of 2009, and we expect to submit to the FDA a 510(k) premarket approval application for the Amid Hernia Stapler in the second half of 2009.

## 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 \$10.3 million for the period commencing September 15, 2005 (inception) and ended March 31, 2009. Such losses included \$0.9 million and \$1.4 million for the three months ended March 31, 2009 and 2008, respectively. At March 31, 2009, we had an accumulated deficit of \$10.3 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 Months ended March 31, 2009 Compared to Three Months Ended March 31, 2008

Research and development costs and expenses were \$349,000 for the three months ended March 31, 2009 as compared to \$814,000 for the same period in 2008. This \$465,000 decrease resulted primarily from the reductions 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 and 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 \$331,000 for the three months ended March 31, 2009, as compared to \$416,000 for the three months ended March 31, 2008. This \$85,000 decrease was primarily the result of lower stock-based compensation expense, partially offset by an increase in accounting and administrative staffing and related operating 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 increase during 2009 as we commence commercialization activities for our SMART Dilator™ and bite block products, as well as for the Amid Hernia Stapler, which we expect will be cleared for marketing before the end of 2009. Additionally, we expect increased costs in connection with our reporting and other obligations incident to our being a public company.

Interest income was negligible for the three months ended March 31, 2009 as compared to \$5,000 in the comparable 2008 period, primarily due to lower invested cash balances resulting from the use of cash in our operating activities. Interest expense was negligible for the three months ended March 31, 2009 as compared to \$6,000 in the comparable 2008 period, due to lower balances outstanding under the Credit Facility. Interest expense is expected to increase as we draw down additional funds under the Credit Facility to fund our operating activities.

#### Liquidity and Capital Resources

As a result of our significant research and development expenditures and the lack, until February 2009, of any approved products to generate product sales revenue, 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 eighteen months 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 have any source of revenues before the second half of 2009, 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 additional 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. 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 Hernia 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 currently budgeted expenditures of approximately \$2.4 million for our 2009 fiscal year to fund the final development of our hernia stapler and the initial marketing of the hernia 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 \$218,000 cash balance as of March 31, 2009, together with the \$3.7 million availability remaining under our Credit Facility, will be sufficient to fund our current cash flow requirements through at least the next twelve months. 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 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 currently evaluating longer-term financing alternatives. We do not have any commitments for such future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our 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.

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.

None.

### 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.

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| Date: May 12, 2009 | By: | /s/ Jeffrey G. Spragens<br>Jeffrey G. Spragens<br>President and Chief Executive Officer |
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| Date: May 12, 2009 | By: | /s/ Adam S. Jackson<br>Adam S. Jackson<br>Chief Financial Officer |
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