UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 22, 2008

SafeStitch Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-19437	11-2962080
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

4400 Biscayne Blvd., Suite 670, Miami, Florida	33137
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 305-575-6000

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Top of the Form

Item 1.01 Entry into a Material Definitive Agreement.

Item 3.02 to this Current Report on Form 8-K is hereby incorporated by reference.

Item 3.02 Unregistered Sales of Equity Securities.

During the period beginning May 22, 2008 and ended May 28, 2008, SafeStitch Medical, Inc. ("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, par value $0.001 per share, at a purchase price of $2.15 per share. The Pricing Committee of 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 over-the-counter bulletin board 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 $4,002,000. Among the Investors acquiring a portion of the Shares were Dr. Jane Hsiao, the Company& #x2019;s Chairman of the Board, Jeffrey G. Spragens, the Company's Chief Executive Officer, President and a director, and some of his relatives, Dr. Kenneth Heithoff, a director, Kevin Wayne, 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.

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 "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) of the Act and that the Shares were being acquired for investment purposes. The Shares have not been registered under the Act and are "restricted securities" as that term is defined by Rule 144 under the Act. The Company has not undertaken to register the Shares and no registration rights have been granted to the I nvestors in respect of the Shares.

The form of Subscription Agreement is attached as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On May 29, 2008, the Company issued a press release announcing the consummation of the private placement described in Item 3.02 to this Current Report on Form 8-K. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01.

The press release attached as an exhibit to this report contains various "forward looking statements" within the meaning of Section 27A of the Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which represent the Company's expectations or beliefs concerning future events. When used in the press release and this report, the terms "anticipate," "believe," "estimate," "expect" and "intend" and words or phrases of similar import, as they relate to the Company or its subsidiaries or its management, are intended to identify forward-looking statements. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, the Company's ability to protect its intellectual property, dedication of substantial resources towards research and development efforts, product liability risks and the effects of governmental regulation. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors, including those factors discussed under "Risk Factors" set forth in Item 1A to the Company's Annual Report on Form 10-KSB, as amended, for the year ended December 31, 2007. The Company undertakes no obligation to update, and the Company does not have a policy of updating or revising, these forward-looking statements.

The information in this report will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD. The furnishing of this informatio n is not intended to, and does not, constitute a determination or admission by the Company that such information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Act.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number Description

10.1 Form of Subscription Agreement.

99.1 Press Release dated May 29, 2008.

Top of the Form

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SafeStitch Medical, Inc.

May 29, 2008

By: /s/ Adam S. Jackson

Name: Adam S. Jackson
Title: Chief Financial Officer

Top of the Form

Exhibit Index

Exhibit No.	Description
10.1	Form of Subscription Agreement
99.1	Press release dated May 29, 2008

SAFESTITCH MEDICAL, INC.

Offering of up to

$10,000,000 Aggregate Amount

of

Common Stock, par value $0.001 per share,

of

SafeStitch Medical, Inc.

SUBSCRIPTION AGREEMENT

May __, 2008

SafeStitch Medical, Inc.
4400 Biscayne Blvd.
Suite 670
Miami, FL 33137
Attn: Jeffrey G. Spragens, CEO & President

Re: Subscription Agreement (the "Agreement") to Purchase Shares of Common Stock, par value $0.001 per share ("Common Stock"), and Disclosure for SafeStitch Medical, Inc., a Delaware corporation (the "Company" or "SFES").

NOTE TO PURCHASER: Please check the appropriate box:

I/We have selected 4.2(a) on Page 5; or

I/We have selected 4.2(b) on Page 5.

Ladies and Gentlemen:

The undersigned (the "Purchaser") hereby tenders this Agreement, subject to the terms and conditions set forth herein. If the Agreement is acceptable to you, kindly indicate your acceptance by executing this instrument in the space provided and returning a fully executed counterpart to the Company at the address set forth above.

NOTICES:

THE SECURITIES OFFERED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR THE SECURITIES LAWS OF ANY STATE OR ANY OTHER JURISDICTION, NOR IS SUCH REGISTRATION CONTEMPLATED, AND ARE BEING OFFERED AND SOLD IN RELIANCE UPON EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH LAWS.

FURTHERMORE, THE SECURITIES OFFERED HEREBY HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES REGULATORY AUTHORITY OF ANY STATE OR OF ANY OTHER JURISDICTION, NOR HAS ANY OF THE FOREGOING AUTHORITIES PASSED UPON THE ACCURACY OR ADEQUACY OF THIS DOCUMENT OR ENDORSED THE MERITS OF THIS OFFERING. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

FLORIDA RESIDENTS:

ANY SALE HEREUNDER IN FLORIDA IS VOIDABLE BY THE PURCHASER EITHER WITHIN THREE DAYS AFTER THE FIRST TENDER OF CONSIDERATION BY SUCH PURCHASER TO THE ISSUER, OR AN AGENT OF THE ISSUER, OR AN ESCROW AGENT, OR WITHIN THREE DAYS AFTER THE AVAILABILITY OF THAT PRIVILEGE IS COMMUNICATED TO THE PURCHASER, WHICHEVER OCCURS LATER.

NEW YORK RESIDENTS:

THE ATTORNEY GENERAL OF THE STATE OF NEW YORK HAS NOT PASSED ON OR ENDORSED THE MERITS OF THIS OFFERING. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

1. Purchase.

The offering price per share of Common Stock shall be $2.15 (the "Offering Price"). The Purchaser hereby agrees to purchase from the Company the number of shares (the "Shares") of Common Stock equal to $___(the "Investment Amount") divided by the Offering Price, rounded down to the nearest whole number. The Investment Amount shall be paid in full in cash on the date this Agreement is accepted and signed by an officer of the Company (such date, the "Closing Date"). The Company, in its sole discretion, may accept additional investments at the Offering Price at a second closing to be held no later than the thirtieth (30th) day after the Closing Date.

Under the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue up to 225,000,000 Shares of Common Stock and 25,000,000 shares of Preferred Stock, par value $0.01 per share. A copy of the Certificate of Incorporation is contained in its Definitive Information Statement on Schedule 14C, filed with the SEC on December 7, 2007 (the "Information Statement"), which is attached hereto as Exhibit A, and a copy of Company's Bylaws is attached as an exhibit to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2007, a copy of which is attached hereto as Exhibit B. The Purchaser understands that the Company will use reasonable efforts to sell up to an aggregate amount of $10,000,000 of Common Stock during the offering period (the "Offering Period"), which will end on or about May 15, 2008, but may be extended by the Company on one or more occasions until as late as June 30, 2008.

As of March 31, 2008, the Company has outstanding 16,093,016 shares of Common Stock.

The Purchaser understands that none of the funds tendered for the Shares will be held in escrow and, such funds will, in the Company's sole discretion, be immediately deposited in the Company's bank account for immediate use in the Company's business. There is no required minimum amount to be raised in this offering for the Company in order to accept any subscriptions. The Company reserves the right, in its sole discretion, to reject or accept any subscription in whole or in part.

The expenses of this offering are estimated to be approximately $12,500.

2. Use of Proceeds; Financing.

The Purchaser understands that the proceeds of this offering are to be used by the Company for working capital and to pay the expenses of this offering.

3. The Company.

The Purchaser acknowledges that he, she or it has been provided with an opportunity to ask any questions and to conduct any other investigations he, she or it desires about the Company and its business and its, his or her rights and obligations as a Company stockholder. The Purchaser acknowledges that he, she or it has received and reviewed the exhibits attached hereto and any other information Purchaser has requested and has been further advised of the following summary:

3.1. Incorporation by Reference. The information contained (i) in Sections 1 and 2 hereinabove and (ii) in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") is incorporated herein by reference. The Company's SEC filings may be obtained at http://www.sec.gov/edgar/searchedgar/companysearch.html.

3.2. Name Change. Effective January 8, 2008, the Company changed its name to SafeStitch Medical, Inc. from Cellular Technical Services Company, Inc.

3.3. Corporate Information. The Company's business address is 4400 Biscayne Blvd., Suite 670 Miami, Florida 33137. The Company has one wholly-owned subsidiary, SafeStitch LLC, a Virginia limited liability company.

3.4. Execution of Existing Agreements. The Purchaser hereunder is required to fund 100% of his, her or its capital contribution to the Company in cash upon the later of the execution of this Agreement by the Purchaser or the Company. The Company will not be liable for the return of any part of the capital contributions of the Purchaser.

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

3.6. Market for Company Products. The Company has not yet fully assessed the market for the Company's products. Please see the documents incorporated by reference in Section 3.1.

3.7. Financial Information. The Company is a pre-clinical-stage medical device company with a limited operating history, and its SafeStitch LLC subsidiary is not profitable and has incurred losses since its inception. The Company does not anticipate that it will generate revenue from the sale of products for the foreseeable future, nor has it submitted any products for clearance or approval by regulatory authorities, and the Company does not currently have rights to any product candidates that have been cleared or approved for marketing in our territory. The Company continues to incur research and development and general and administrative expenses related to its operations. The Company's net losses for the years ended December 31, 2007 and 2006 and for the partial year from September 15, 2005 until December 31, 2005 were ($3,041,000), $(1,060,000) and $(76,000), respectively. As of December 31, 2007, we had an accumulated deficit of ($4,177,000). The Company's (i) Annual Report on Form 10-KSB for the year ended December 31, 2007; (ii) Amendment No. 1 to its Annual Report on Form 10-KSB/A; (iii) Current Report on Form

8-K, filed with the SEC on April 4, 2008; and (iv) Current Report on Form 8-K, filed with the SEC on April 24, 2008 are attached hereto as Exhibit B, Exhibit C, Exhibit D and Exhibit E, respectively.

3.8. Management. The executive officers and directors of the Company are as follows:

Name	Age	Title
Jane H. Hsiao, Ph.D., MBA	61	Director and Chairman of the Board of Directors
Jeffrey G. Spragens	66	Chief Executive Officer, President and Director
Dr. Stewart B. Davis	28	Chief Operating Officer and Secretary
Dr. Charles Filipi	66	Medical Director and Director
Adam S. Jackson	45	Vice President, Finance and Chief Financial Officer
Dr. Kenneth Heithoff	64	Director
Richard Pfenniger, Jr.	52	Director
Steven D. Rubin	47	Director
Kevin Wayne	44	Director

3.9. Employees3.10. As of March 31, 2008, the Company has twelve (12) full-time employees.

3.10. Certificate of Incorporation and Bylaws. The Certificate of Incorporation and the Bylaws of the Company are the governing instruments which contain the rules under which the Company operates. The Purchaser acknowledges that he, she or it has reviewed the Certificate of Incorporation and Bylaws in full before executing this Agreement.

3.11. Option Plan. The Company has in place the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan (the "2007 Plan"). Under the 2007 Plan, the Company is authorized to grant options to purchase an aggregate of up to 2,000,000 shares of Common Stock. Options may be either incentive stock options or non-qualified options. The price of options under the 2007 Plan and the number of options granted, as well as any other terms not required by the 2007 Plan, shall be determined by the Company's Compensation Committee. The Purchaser acknowledges reviewing the 2007 Plan, a copy of which is contained in the Information Statement attached hereto as Exhibit A.

3.12. Property. The Company's principal corporate office is located at 4400 Biscayne Blvd., Suite 670, Miami, Florida 33137. The Company rents this space, approximately 2,900 square feet, from Frost Real Estate Holdings, LLC which is a company controlled by Dr. Phillip Frost, the Company's largest beneficial stockholder. Additionally, the Company leases approximately 462 square feet of office space in Omaha, Nebraska, which includes one administrative office. Dr. Filipi is based in Omaha, Nebraska. We also have a prototype lab, which is located in a leased warehouse in Miami, Florida.

4. Representations of the Purchaser.

The Purchaser hereby warrants, covenants and represents as follows:

4.1. The Purchaser is a U.S. citizen or resident alien.

4.2. **The Purchaser hereby represents either (a) or (b), below (please select):**

(a) or (b)

(a) He, she or it is a sophisticated investor by virtue of his, her or its education, training and/or numerous prior investments made on the Purchaser's own behalf or through entities which the Purchaser, alone or with others, controls. The Purchaser is knowledgeable and experienced in financial and business matters which have risks similar to those which may be encountered by the Company. The Purchaser is capable of evaluating the merits and risks of an investment in the Company. The Purchaser is an accredited investor because he, she or it is **(please indicate by checking the appropriate box at left)**:

(1) Either (a) a bank as defined in section 3(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), or a savings and loan association or other institution as defined in Section 3(a)(5)(A) of the Securities Act whether acting in its individual or fiduciary capacity, (b) any broker or dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); (c) an insurance company as defined in Section 2(13) of the Securities Act, (d) an investment company registered under the Investment Company Act of 1940 or a business development company as defined in Section 2(a)(48) of that act, (e) a Small Business Investment Company licensed by the U.S. Small Business Administration under Section 301(c) or 301(d) of the Small Business Investment Act of 1958, (f) an employee benefit plan within the meaning of Title I of the Employee Retirement Income Security Act of 1974, if the investment decision is made by a plan fiduciary, as defined in Section 3(21) of such act, which plan fiduciary is either a bank, savings and loan association, insurance company or registered investment advisor, or if the employee benefit plan has total assets in excess of $5,000,000 or if a self-directed plan, with investment decisions made solely by persons that are accredited investors, or (g) an employee benefit plan established and maintained by a state government and their political subdivisions and agencies if the employee benefit plan has assets in excess of $5,000,000;

(2) A private business development company as defined in Section 202(a)(22) of the Investment Advisors Act of 1940;

(3) Any organization described in section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000;

(4) Any director, executive officer, or general partner of the issuer of the securities being offered or sold, or any director, executive officer, or general partner of a general partner of that issuer;

(5) Any natural person whose individual net worth, or joint net worth with that person's spouse, at the time of his purchase exceeds $1,000,000;

(6) Any natural person who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and has a reasonable expectation of reaching the same income level in current year;

(7) Any trust, with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in Rule 506(b)(2)(ii) under the Securities Act;

(8) Any entity in which all of the equity owners are accredited investors.

(b) He, she or it, either alone or together with the purchaser representative named below, (x) is a sophisticated investor by virtue of his, her or its education, training and/or numerous prior investments made on the Purchaser's own behalf or through entities which the Purchaser, alone or with others, controls, (y) is knowledgeable and experienced in financial and business matters which have risks similar to those which may be encountered by the Company and (z) is capable of evaluating the merits and risks of an investment in the Company, and has appointed the following person as his, her or its purchaser representative in connection with the Purchaser's acquisition of the Shares under this Agreement**:___(If making this representation instead of the representation set forth in (a), above, then fill in name of purchaser representative)**

4.3. The Purchaser has been furnished or otherwise obtained all information necessary to enable him to evaluate the merits and risks of his prospective investment in the Company and has received and reviewed this Agreement and the exhibits hereto. **The Purchaser is aware of the risk factors identified in Section 5 hereof and various other risks inherent in this investment, including those set forth in the Company's Form 10-KSB, filed with the SEC on March 26, 2008, as amended by the Company's Amendment No. 1 to its Annual Report on Form 10-KSB/A, filed with the SEC on April 24, 2008.**

4.4. The Purchaser has been furnished or has had access to any and all material documents and information regarding the Company and its intended business that the Purchaser has sought to review. The Purchaser has had an opportunity to question individuals involved in the management of the Company. The Purchaser hereby acknowledges that the Company has made available to the Purchaser prior to any investment in the Company all information (i) requested by the Purchaser and (ii) reasonably necessary to enable the Purchaser to evaluate the risks and merits of an investment in the Company. The Purchaser, after a review of this information and other information he has obtained, is aware of the speculative nature of any investment in the Company.

4.5. The Purchaser has reviewed the Company's filings with the SEC, which are incorporated by reference in this Agreement under Section 3.1, above.

4.6. The Purchaser is aware that the Purchaser will have to make the cash payment the number of Shares set forth above. The Purchaser can bear the economic risk of the investment in the Company (including the possible loss of his entire investment) without impairing the Purchaser's ability to provide for himself and/or his family in the same manner that the Purchaser would have been able to provide prior to making an investment in the Company. The Purchaser understands that he must continue to bear the economic risk of the investment in the Company for an indefinite period of time.

4.7. The Purchaser understands that the Shares have not been registered under the Securities Act or related laws or regulations or under any other applicable securities laws of any State or other jurisdiction (collectively, the "Securities Laws"), inasmuch as the Offering is being made to a limited group of potential investors. The Purchaser understands that he, she or it has no rights whatsoever to request, and that the Company is under no obligation whatsoever to furnish, a registration under the Securities Laws of the Shares purchased hereunder.

4.8. The Shares that the Purchaser is acquiring are solely for his, her or its account and are not being purchased with a view to, or for resale in connection with, any distribution within the meaning of the Securities Act or any other applicable Securities Laws. The Purchaser will not resell or offer to resell any Shares except in accordance with the terms of this Agreement and in compliance with all applicable Securities Laws.

4.9. The Purchaser understands that the Shares being purchased hereunder will be "restricted securities" as that term is defined in Rule 144 under the Securities Act, and the certificate(s), if any, representing the Shares will bear restrictive legends thereon as follows:

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED DIRECTLY OR INDIRECTLY FROM THE ISSUER WITHOUT BEING REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY OTHER APPLICABLE SECURITIES LAWS, AND ARE RESTRICTED SECURITIES AS THAT TERM IS DEFINED UNDER RULE 144 PROMULGATED

UNDER THE ACT. THESE SHARES MAY NOT BE SOLD, PLEDGED, TRANSFERRED, DISTRIBUTED OR OTHERWISE DISPOSED OF IN ANY MANNER ("TRANSFER") UNLESS THEY ARE REGISTERED UNDER THE ACT AND ANY APPLICABLE SECURITIES LAWS, OR UNLESS THE REQUEST FOR TRANSFER IS ACCOMPANIED BY A FAVORABLE OPINION OF COUNSEL, REASONABLY SATISFACTORY TO THE ISSUER, STATING THAT THE TRANSFER WILL NOT RESULT IN A VIOLATION OF THE ACT OR ANY APPLICABLE SECURITIES LAWS."

5. Information Regarding Forward-Looking Statements.

This Agreement and other information, if any, provided to Purchaser by the Company, contain "forward-looking statements," as that term is defined under Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Forward-looking statements include statements 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 activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described under the caption "Risk Factors" in Section 7, below. We do not undertake any obligation to update forward-looking statements. 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.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

- We have a history of operating losses and we do not expect to become profitable in the near future.
- Our technologies are in an early stage of development and are unproven.
- Our research and development activities may not result in commercially viable products.
- We are highly dependent on the success of our product candidates, and we cannot give any assurance that they will receive regulatory clearance, or approval, if necessary, or be successfully commercialized.
- The results of previous clinical experience with devices similar to the devices that we have licensed may not be predictive of results with our licensed products, and any clinical trials that the U.S. Food and Drug Administration (the "FDA") may require us to undertake may not satisfy FDA requirements or the requirements of other non-U.S. regulatory authorities.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.
- Our product development activities could be delayed or stopped.
- The regulatory clearance or approval process is expensive, time-consuming and uncertain and may prevent us or our collaboration partners from obtaining clearance, or approval, if necessary, for the commercialization of some or all of our product candidates.
- Even if we obtain regulatory clearances or approvals for our product candidates, the terms thereof and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.
- Even if we receive regulatory clearances or approvals to market our product candidates, the market may not be receptive to our products.
- If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.
- As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.
- If we fail to acquire and develop other products or product candidates at all or on commercially reasonable terms, we may be unable to diversify or grow our business.
- We will rely on third parties to manufacture and supply our product candidates.
- We currently do not have a marketing staff or sales or distribution organization. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

- Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.
- The success of our business may be dependent on the actions of our collaborative partners.
- All of our current product plans are licensed to us by Creighton University. Any loss of our rights under the agreement with Creighton University or any failure by Creighton University to properly maintain or enforce the patents under such licenses would materially adversely affect our business prospects.
- An inability to find additional or other sources for our products could materially and adversely affect us.
- If we or Creighton University are unable to obtain and enforce patent protection for our product candidates, our business could be materially harmed.
- If we or Creighton University are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.
- Future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.
- Failure to obtain regulatory clearance or approval outside the United States will prevent us from marketing our product candidates abroad.
- Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.
- Our business may become subject to economic, political, regulatory and other risks associated with international operations.
- The market price of our common stock may fluctuate significantly.
- Trading of our common stock is limited and trading restrictions imposed on us by applicable regulations and by lockup agreements we have entered into with our principal stockholders may further reduce our trading, making it difficult for our stockholders to sell their shares.
- Because our common stock may be a "penny stock," it may be more difficult for investors to sell shares of our common stock, and the market price of our common stock may be adversely affected.
- Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interests or in the best interests of our stockholders.
- Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

6. Certain Federal Income Tax Considerations.

The following discussion summarizes certain U.S. federal income tax consequences to a purchaser of a share of Common Stock that is a U.S. Holder, as defined below. This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), the applicable Treasury regulations promulgated or proposed thereunder, administrative pronouncements of the Internal Revenue Service ("IRS") and judicial decisions, in each case as of the date hereof, all of which are subject to change at any time, possibly retroactively. There can be no assurance that the IRS will not take a view contrary to that set forth herein which may be upheld by a court. No ruling from the IRS or opinion of counsel has been or will be sought as to any of the matters discussed below.

This summary is for general information purposes only and applies only to an initial purchaser who acquires shares of Common Stock as a capital asset within the meaning of section 1221 of the Code. It does not purport to address all tax consequences that may be relevant to any particular investor or to an investor subject to special tax rules (including, for example, a financial institution, broker-dealer, insurance company, regulated investment company, personal holding company, S corporation, tax-exempt organization, a person who holds Common Shares in a hedging transaction or as part of a "straddle", "conversion transaction" or other risk reduction transaction or a person subject to the alternative minimum tax). In addition, the discussion does not address any aspect of state, local or foreign taxation.

EACH PROSPECTIVE PURCHASER OF COMMON STOCK IS URGED TO CONSULT THE PURCHASER'S TAX ADVISER CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES TO THE PURCHASER OF ACQUIRING, OWNING AND DISPOSING OF SHARES OF COMMON STOCK, AS WELL AS THE APPLICATION OF STATE, LOCAL AND FOREIGN INCOME AND OTHER TAX LAWS.

As used herein, the term "U.S. Holder" means a beneficial owner of a share of Common Stock that for U.S. federal income tax purposes is:

- a citizen or individual resident of the United States;

- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the law of the United States or of any political subdivision thereof;

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust, and one or more United States persons have the authority to control all substantial decisions of the trust, or (ii) the trust was in existence on August 20, 1996 and properly elected to continue to be treated as a United States person.

Distributions

A distribution on a share of Common Stock will be includible in the gross income of the holder as ordinary income to the extent the distribution is out of the Company's current or accumulated earnings and profits (as computed for U.S. federal income tax purposes). To the extent distributions with respect to a share of Common Stock in any taxable year are not paid out of current or accumulated earnings and profits, they will be treated as a non-taxable return (and reduction) of basis in that share of Common Stock to the extent thereof, and if and to the extent they exceed earnings and profits and basis, they will be treated as gain from the sale of the share of Common Stock.

The rate of federal income tax that a non-corporate taxpayer generally pays on dividends is 15 percent for taxable years beginning before January 1, 2011, after which dividends are taxable as ordinary income. To qualify for the reduced rate, the non-corporate shareholder must satisfy certain holding period and other requirements. Dividends received by a corporation are generally eligible for the dividends received deduction, subject to the limitations under section 1059 of the Code relating to extraordinary dividends.

Disposition of Shares of Common Stock

Upon a sale or other taxable disposition of a share of Common Stock, the holder generally will recognize capital gain or loss equal to the difference between the amount realized and the holder's tax basis in the share of Common Stock. That gain or loss will be long-term capital gain or loss if the holding period for that share of Common Stock was more than one year on the date of sale or other disposition. The maximum rate of federal income tax applicable to a long-term capital gain of a non-corporate taxpayer in a taxable year beginning before January 1, 2011 is generally 15%. In later taxable years, that 15% reverts to 20%.

Backup Withholding

A U.S. Holder may be subject to backup withholding in respect of dividends on Common Stock and the proceeds from a sale, exchange or redemption of Common Stock unless the holder (a) is a corporation or other exempt recipient or (b) provides, when required, the U.S. Holder's taxpayer identification number to the payer, certifies that the U.S. Holder is not subject to backup withholding and otherwise complies with the backup withholding rules. Backup withholding is not an additional tax; any amount so withheld is creditable against the U.S. Holder's U.S. federal income tax liability or is refundable, provided the required information is furnished to the IRS.

7. Risk Factors.

The Purchaser understands that in addition to the various risks ordinarily attendant upon equity investments in companies, certain unique factors make an investment in the Company subject to a high degree of risk. The Purchaser has been cautioned that an investment in the Company is speculative and involves significant risks, and that it is probably not possible to foresee and describe all of the business, economic and financial risk factors which may affect the Company. The Purchaser acknowledges that he has been advised to seek independent professional advice in order to carefully analyze the risks and merits of an investment in the Company.

The specific risks set forth below have been described in detail to the Purchaser. They are not, however, to be considered exhaustive or definitive of all of the risks involved in an investment in the Shares.

We have a history of operating losses and we do not expect to become profitable in the near future.

We are a pre-clinical stage medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. We do not anticipate that we will generate revenue from the sale of products for the foreseeable future. We have not yet submitted any products for clearance or approval by regulatory authorities and we do not currently have rights to any product candidates that have been cleared or approved for marketing in our territory. We continue to incur research and development and general and administrative expenses related to our operations. Our net losses for the years ended December 31, 2007 and 2006 and for the partial year from September 15, 2005 until December 31, 2005 were ($3,041,000), $(1,060,000) and $(76,000), respectively. As of December 31, 2007, we had an accumulated deficit of ($4,177,000). We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research activities and conduct development of, and seek regulatory clearances and approvals for, our product candidates, and prepare for and begin to commercialize any cleared or approved products. If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our technologies are in an early stage of development and are unproven.

We are engaged in the research and development of intraluminal medical devices that manipulate tissues for the treatment of intraperitoneal abnormalities, including obesity, GERD, Barrett's Esophagus, esophageal obstructions, upper gastrointestinal bleeding and hernia formation. The effectiveness of our technologies is not well-known in, or accepted generally by, the clinical medical community. There can be no assurance that we will be able to successfully employ our technologies as surgical, therapeutic or diagnostic solutions for any intraperitoneal abnormalities. Our failure to establish the efficacy and safety of our technologies would have a material adverse effect on our business.

Our product research and development activities may not result in commercially viable products.

Our product candidates are all in very early stages of development and are prone to the risks of failure inherent in medical device product development; but none of our products has been studied in clinical trials. We will likely be required to undertake significant clinical trials to demonstrate to the FDA that our licensed devices are either safe and effective for their intended uses or are substantially equivalent in terms of safety and effectiveness to an existing, lawfully marketed non-PMA device. We may also be required to undertake clinical trials by non-U.S. regulatory agencies. Clinical trials are expensive and uncertain processes that may take years to complete. Failure can occur at any point in the process, and early positive results do not ensure that the entire clinical trial will be successful. Product candidates in clinical trials may fail to show desired efficacy and safety traits despite early promising results. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results at earlier points.

The results of previous animal trials and pre-clinical trials may not be indicative of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

The results of previous animal trials and pre-clinical and clinical trials of similar devices may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

Positive results from limited in vivo and ex vivo animal trials we have conducted or from pre-clinical studies and early clinical experience with similar devices should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates either (i) are safe and effective for their intended uses or (ii) are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under Section 510(k).

Further, our product candidates may not be cleared or approved, as the case may be, even if the clinical data are satisfactory and support, in our view, clearance or approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of the clinical data. In addition, any of these regulatory authorities may change requirements for the clearance or approval of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA approval. In addition, any of these regulatory authorities may also clear or approve a product candidate for fewer or more limited uses than we request or may grant clearance or approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-U.S. regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates.

We are highly dependent on the success of our initial product candidates, especially the Obesity Device, the GERD Device and the Barrett's Device, and we cannot give any assurance that any of them will receive regulatory clearance or be successfully commercialized.

We are highly dependent on the success of our initial product candidates, especially the Obesity Device, the GERD Device and the Barrett's Device. We cannot give any assurance that the FDA will permit us to clinically test the devices, nor can we give any assurance that these products will receive regulatory clearance or approval or be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts, or our failure to obtain positive coverage determinations or reimbursement. Any failure to obtain clearance or approval of our products or to successfully commercialize them would have a material and adverse effect on our business.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We intend to advance multiple product candidates through clinical and pre-clinical development. We will need to raise substantial additional capital to engage in our clinical and pre-clinical development and commercialization activities.

Our future funding requirements will depend on many factors, including but not limited to:

- our need to expand our research and development activities;
- the rate of progress and cost of our clinical trials;
- the costs associated with establishing a sales force and commercialization capabilities;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals;

- the economic and other terms and timing of our existing licensing arrangement and any collaboration, licensing or other arrangements into which we may enter in the future;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- our ability to maintain, expand and defend the scope of our intellectual property portfolio.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our product candidates or grant licenses on terms that may not be favorable to us.

If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address the intraperitoneal abnormalities we are endeavoring to address. We are currently developing medical devices that will compete with other medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other medical devices and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical devices companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than we do. As indicated, there are also other methods to treat obesity, such as diet, exercise and medicine. Other competitors have developed products such as medical implants that occupy volume in the stomach to promote the feeling of satiety (Helioscopie) or gastric sleeves to reduce food intake. Some of the medical device companies we expect to compete with include USGI Medical, TOGa Devices from Satiety, StomaphyX and EsophyX from EndoGastric Solution, Inc., NDO Surgical, Inc., Medigus, Ltd., Bard, LLC, Olympus Medical Equipment Services America, Inc., BARRX Medical, Inc., Boston Scientific Corporation, ConMed Corporation, Cook Medical Supply, Inc., Miller Medical Specialties, U.S. Endoscopy, The Rush Incorporated and a number of bite block manufacturers. In addition, many other universities and private and public research institutions are or may become active in research involving surgical devices for gastrointestinal abnormalities and minimally invasive surgery.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to commercialize and market any of our product candidates that may receive regulatory clearance or approval;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory clearances or approvals;
- appropriate coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of future product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than our future product candidates, if any, or that reach the market sooner than our future product candidates, if any, we may not achieve commercial success. In addition, the medical device industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive.

Our product development activities could be delayed or stopped.

We do not know whether our other planned clinical trials will be completed on schedule, or at all, and we cannot guarantee that our planned clinical trials will begin on time or at all. The commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients that meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- limited number of, and competition for, suitable sites to conduct our clinical trials, and delay or failure to obtain FDA approval, if necessary, to commence a clinical trial;
- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;
- requirements to provide the medical device required in our clinical trial at cost, which may require significant expenditures that we are unable or unwilling to make;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval or renewal to conduct a clinical trial at a prospective or accruing site, respectively.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB for any given site, or us. Any failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive a clearance letter under the 510(k) process or approval of a PMA from the FDA, depending on the nature of the device. We have not submitted an application or premarket notification for or received marketing clearance or approval for any of our product candidates. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews and clears a premarket notification in three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, that even if a device is reviewed under the premarket notification process (510(k) process), that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. In addition, failure to comply with FDA, non-U.S. regulatory authorities or other applicable U.S. and non-U.S. regulatory requirements may, either before or after product clearance or approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters or non-warning letters incorporating inspectional observations;
- civil and criminal penalties;
- injunctions;

- suspension or withdrawal of regulatory clearances or approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.

Regulatory approval of a PMA, PMA supplement or clearance pursuant to a premarket notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive and, may, especially in the case of the PMA application, take several years. The FDA also has substantial discretion in the medical device clearance process or approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA clearance or approval varies depending on the medical device candidate, the disease or condition that the medical device candidate is designed to address, and the regulations applicable to any particular medical device candidate. The FDA can delay, limit or deny clearance or approval of a medical device candidate for many reasons, including:

- a medical device candidate may not be deemed safe or effective, in the case of a PMA application;
- a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed non-PMA device in the case of a premarket notification;
- FDA officials may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturer's processes or facilities; or
- the FDA may change its clearance or approval policies or adopt new regulations.

Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.

We may encounter delays if we are unable to recruit and enroll and retain enough patients to complete clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Delays in patient enrollment are not unusual. Any such delays in planned patient enrollment may result in increased costs, which could harm our ability to develop products.

Even if we obtain regulatory clearances or approvals for our product candidates, the terms of clearances or approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

Once regulatory clearance or approval has been granted, the cleared or approved product and its manufacturer are subject to continual review. Any cleared or approved product may only be promoted for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities clear or approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with the FDA's Quality System Regulation, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing with the FDA Medical Device Reports, which are publicly available. Further, regulatory agencies must approve our manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters, non-warning letters incorporating inspectional observations;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory clearances or approvals;

- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.

In addition, the FDA and other non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future product candidates and we may not achieve or sustain profitability.

Even if we receive regulatory clearance or approval to market our product candidates, the market may not be receptive to our products.

Even if our product candidates obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- safety and efficacy of our product;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our future product candidates, both in absolute terms and relative to alternative treatments; and
- availability of coverage and reimbursement from government and other third-party payors.

If our future product candidates fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.

The coverage and reimbursement status of newly cleared or approved medical devices is uncertain, and failure to obtain adequate coverage and adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be cleared or approved.

There is significant uncertainty related to the third-party coverage and reimbursement of newly cleared or approved medical devices. Normally, surgical devices are not directly covered; instead, the procedure using the device is subject to a coverage determination by the insurer. The commercial success of our existing and future product candidates in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our existing and future product candidates. These payors may conclude that our product candidates are not as safe or effective as existing devices or that procedures using our devices are not as safe or effective as the existing procedures using other devices. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our product candidates for coverage and adequate reimbursement. The failure to obtain coverage and adequate reimbursement for our existing and future product candidates or health care cost containment initiatives that limit or restrict reimbursement for our existing and future product candidates may reduce any future product revenue.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our senior management, particularly Jeffrey G. Spragens, Dr. Stewart B. Davis and Dr. Charles Filipi, could delay or prevent the development or commercialization of our product candidates. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. We employ these individuals on an at- will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing function.

We have scientific and clinical advisors who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may

limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among medical device and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance our product candidates through research and development, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

Furthermore, we may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If we fail to acquire and develop other products or product candidates at all or on commercially reasonable terms, we may be unable to diversify or grow our business.

We intend to continue to rely on in-licensing as the source of our products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select and acquire medical device product candidates. Proposing, negotiating and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with other medical device companies and academic research institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with such third parties. In addition, even if we find promising product candidates, and generate interest in a partnering or strategic arrangement to acquire such product candidates, we may not be able to acquire rights to additional product candidates or approved products on commercially reasonable terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require additional development efforts prior to commercial sale, including extensive clinical testing and clearance or approval by the FDA and other non-U.S. regulatory authorities. All product candidates are subject to the risks of failure inherent in medical device product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates are cleared or approved, we cannot be sure that they would be capable of economically feasible production or commercial success.

We rely on third parties to manufacture and supply our product candidates.

We do not own or operate manufacturing facilities for clinical or commercial production of our product candidates, other than a prototype lab. We have no experience in medical device manufacturing, and we lack the resources and the capability to manufacture any of our product candidates on a commercial scale. If our future manufacturing partners are unable to produce our products in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require. We expect to depend on third-party contract manufacturers for the foreseeable future.

Our product candidates require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and other non-U.S. regulatory authorities to ensure strict compliance with quality system regulation (referred to as QSR), including current Good Manufacturing Practice, or cGMP, and other applicable government regulations and corresponding standards. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our future product candidates, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our product candidates. Such approval would require additional non-clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

We currently have no marketing staff and no sales or distribution organization. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. If our product candidates are approved, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future product candidates. If we are not successful in commercializing our existing and future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.

We will depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the clinical trials, or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations could adversely affect the clinical development of our product candidates and harm our business.

The success of our business may be dependent on the actions of our collaborative partners.

An element of our strategy may be to enter into collaborative arrangements with established multinational medical device companies which will finance or otherwise assist in the development, manufacture and marketing of products incorporating our technology. We anticipate deriving some revenues from research and development fees, license fees, milestone payments and royalties from collaborative partners. Our prospects, therefore, may depend to some extent upon our ability to attract and retain collaborative partners and to develop technologies and products that meet the requirements of prospective collaborative partners. In addition, our collaborative partners may have the right to abandon research projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms. There can be no assurance that we will be successful in establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before completion of projects, that our collaborative arrangements will result in successful product commercialization or that we will derive any revenues from such arrangements. To the extent that we are not able to develop and maintain collaborative arrangements, we would need substantial additional capital to undertake research, development and commercialization activities on our own.

If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. At present, we do not hold any patents and none of the technology we license has been patented. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third party patent or otherwise circumvent the third party patent.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. In addition, we will rely on third-party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time-consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, unenforceable or circumvented. Moreover, the United States Patent and Trademark Office (the "USPTO") may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by medical device companies.

Our pending patent applications may not result in issued patents. The patent position of medical device companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties, including Creighton University.

We cannot assure you that any patents that will issue, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our product candidates or our future products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

We will rely heavily on licenses from third parties.

All of the patent applications in our patent portfolio are not owned by us, but are licensed from one third party. Presently, we rely solely on technology licensed from Creighton University for all of our products and may license additional technology from other third parties in the future. Such license agreements give us rights for the commercial exploitation of the patents resulting from the patent applications, subject to certain provisions of the license agreements. Failure to comply with these provisions could result in the loss of our rights under these license agreements. Our inability to rely on these patent applications which are the basis of our technology would have a material adverse effect on our business.

We presently license patent rights to all of our technology from one third party owner. If we or this third party owner does not properly maintain or enforce the patent applications underlying any such licenses, our competitive position and business prospects will be harmed.

We have obtained licenses from Creighton University for all of our current products in development. In addition, we hope to enter into additional licenses of third party intellectual property in the future.

Our success will depend in part on the ability of us or our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights in our field. We or our licensors may not successfully prosecute the patent applications which are licensed to us. Even if patents issue in respect of these

patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Some jurisdictions may require us or Creighton University to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third party patent or circumvent the third party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third-party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Medicare legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.

In the United States, there have been a number of legislative and regulatory proposals, at both the federal and state government levels, to change the healthcare system in ways that could affect our ability to sell our products profitably, if approved. To the extent that our products are deemed to be "durable medical equipment" or DME they may be subject to distribution under the new Competitive Acquisition regulations, this could adversely affect the amount that we can seek from payors. Non-DME devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage.

We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. Any cost containment measures or other health care system reforms that are adopted could have a material adverse effect on our ability to commercialize our existing and future product candidates successfully.

Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates in non-U.S. markets. In order to market our existing and future product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market certain of our existing and future product candidates in both the U.S. and in non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our existing and future product candidates to other available products. If reimbursement of our future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally, in part due to a number of our suppliers being located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country’s or region’s political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws; and
- difficulties associated with staffing and managing foreign operations, including differing labor relations.

The market price of our common stock may fluctuate significantly.

The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors’ results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the medical device industry;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for medical device companies in particular, has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock might be worse if the trading volume of our common stock is low.

Some or all of the "restricted" shares of our common stock issued to former stockholders of SafeStitch in connection with the Share Exchange or held by other of our stockholders may be offered from time to time in the open market pursuant to an effective registration statement or Rule 144, and these sales may have a depressive effect on the market for our common stock.

We have identified material weaknesses in our internal control over financial reporting that may prevent us from being able to accurately report our financial results or prevent fraud, which could harm our business and operating results, the trading price of our stock and our access to capital.

Our management, with the participation of our Chief Executive Officer and our then current, but now former, Chief Financial Officer evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) or 15d-15(e)) as of December 31, 2007. Based upon that evaluation, the Chief Executive Officer and our former Chief Financial Officer concluded that, as of that date, the Company's disclosure controls and procedures were not effective at a reasonable assurance level because of the identification of the material weakness in our internal control over financial reporting described above and in more detail in "Item 8A(T) — Controls and Procedures" contained in our Annual Report on Form 10-KSB, which is attached hereto as Exhibit B, as amended by our Amendment No. 1 to our Annual Report on Form 10-KSB/A, which is attached hereto as Exhibit C.

Upon identification of the material weakness, management advised our Audit Committee of the issues encountered and management's key decisions relating to remediation efforts. Under the direction of our Chief Executive Officer and former Chief Financial Officer, we developed a plan to remediate the material weakness. Our Audit Committee reviewed, advised and concurred with management's plan of remediation, which includes the addition of employees who are trained in the preparation of financial statements in accordance with GAAP and who have the experience necessary to ensure that we have in place appropriate internal control over financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we establish and maintain an adequate internal control structure and procedures for financial reporting and assess on an on-going basis the design and operating effectiveness of our internal control structure and procedures for financial reporting. We are committed to continuously improving our internal control over financial reporting, in order that we fully satisfy the requirements of Section 404 of the Sarbanes-Oxley Act.

In connection with the audits of, and the issuance of a report on, our consolidated financial statements for the years ended December 31, 2007 and 2006, our independent registered public accounting firm, Eisner LLP, also communicated to our management and Audit Committee that certain matters involving our internal controls amounted to a "material weakness", as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (referred to as the Exchange Act). Eisner LLP was not engaged to perform an audit of our internal control over financial reporting. Eisner LLP's audits include consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of our internal control over financial reporting. Accordingly, Eisner LLP did not express such an opinion. This material weakness derived from our failure to maintain a sufficient complement of personnel with the appropriate level of knowledge, experience and training in the application of accounting principles generally accepted in the U.S. (referred to as GAAP) and in internal control over financial reporting commensurate with our financial reporting obligations under the Exchange Act. We did not maintain effective controls over the presentation of our consolidated financial statements and related disclosures in preparing our consolidated financial statements

If we are unable to conclude that our internal control over financial reporting is effective at any such time that we are required to attest to them, our ability to obtain additional financing on favorable terms could be materially and adversely affected, which, in turn, could materially and adversely affect our business, our financial condition and the market value of our securities.

Trading of our common stock is limited and trading restrictions imposed on us by applicable regulations and by lockup agreements we have entered into with our principal stockholders may further reduce our trading, making it difficult for our stockholders to sell their shares.

Trading of our common stock is currently conducted on the National Association of Securities Dealers, Inc.'s, OTC Bulletin Board, or "OTC BB." The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all.

Approximately 70% of the outstanding shares of our common stock are subject to lockup agreements which limit sales for a two-year period ending September 4, 2009. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock. In addition, without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future.

Future sales of common stock could reduce our stock price.

Sales by stockholders of substantial amounts of our shares of common stock, the issuance of new shares of common stock by us or the perception that these sales may occur in the future, could materially and adversely affect the market price of our common stock. As described herein, substantially all of the former members of SafeStitch LLC, who received an aggregate of 11,256,369 shares of our common stock in connection with our acquisition of SafeStitch LLC, entered into lock-up agreements with respect to such shares. Under the lock-up agreements, these former members of SafeStitch LLC may not directly or indirectly sell or otherwise transfer the shares of our common stock issued to them in connection with our acquisition of SafeStitch LLC during the two-year period ending September 4, 2009.

On September 4, 2009, the lock-up agreements entered into in connection with our acquisition of SafeStitch LLC will expire, which will allow an aggregate of 11,256,369 shares of our common stock, or approximately 70% of our currently outstanding shares of common stock, to be available for sale on the public market, subject in most cases to the limitations of Rule 144 under the Securities Act of 1933, as amended.

Because our common stock may be a "penny stock," it may be more difficult for investors to sell shares of our common stock, and the market price of our common stock may be adversely affected.

Our common stock may be a "penny stock" if, among other things, the stock price is below $5.00 per share, it is not listed on a national securities exchange or approved for quotation on the Nasdaq Stock Market or any other national stock exchange or it has not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the Securities and Exchange Commission ("SEC"). This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their shares of our common stock. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stocks and the market price of our common stock may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to resell their shares of our common stock publicly at times and prices that they feel are appropriate.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in the best interests of our stockholders.

As of the closing of the Share Exchange, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, over 80% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, new regulations promulgated by the SEC and rules promulgated by the American Stock Exchange ("AMEX"), the other national securities exchanges and the NASDAQ. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our directors, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board of directors members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed.

The Shares being purchased hereunder are not freely transferable.

The Shares being purchased hereunder are "restricted securities", as defined in Rule 144 promulgated under the Securities Act, and have no registration rights. As such, they are not freely transferable and will not be transferable for a significant period of time. Purchasers of the Shares must have the financial capacity to hold such shares for a significant period of time and should not expect to be able to transfer such shares for the next year and, perhaps longer.

8. Indemnification.

The Purchaser agrees to indemnify, defend and hold harmless the Company and its stockholders, directors, executive officers and affiliates from and against all liability, damage, losses, costs and expenses (including reasonable attorneys' fees) which they may incur by reason of the failure of the Purchaser to fulfill any of the terms and conditions of this Agreement, or by reason of any breach of the representations and warranties made by the Purchaser herein or in any document provided by the Purchaser to any executive officers, directors, the Company or any of their Affiliates.

9. Miscellaneous.

9.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Florida.

9.2. Construction. In construing this Agreement, the singular shall be held to include the plural, the plural shall include the singular, the use of any gender shall include every other and all genders, and captions and paragraph headings shall be disregarded. All of the parties to this Agreement have participated fully in the negotiation and preparation hereof; and, accordingly, this Agreement shall not be more strictly construed against any one of the parties hereto.

9.3. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses, sections or subsections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part hereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, sections or subsections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, section or sections, or subsection or subsections had not been inserted.

9.4. Benefit of Representations, Warranties and Statements. The representations, warranties and statements of the Purchaser set forth in this Agreement are also being made for the benefit of successors of the Company, the Company's stockholders, the Board and the executive officers of the Company and present and future controlling parties of the Company, and may be relied upon by them.

9.5. Section Headings. The section and other headings contained in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of any provisions of this Agreement.

9.6. Counterparts; Facsimile Signatures. This Agreement may be executed in any number of counterparts and by the several parties hereto in separate counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Facsimile signatures shall be deemed original signatures for all purposes of this Agreement.

9.7. Entire Agreement; Amendments. This Agreement constitutes the entire agreement among the parties hereto with respect to the transaction contemplated hereby and supersedes all prior agreements, understandings, negotiations and discussions, both written and oral, among the parties hereto with respect to the subject matter hereof. This Agreement may not be amended or modified in any way except by a written instrument executed by all of the parties hereto.

[Signatures follow on next page]

IN WITNESS WHEREOF, The Purchaser hereby subscribes for the purchase of the Shares of the Company described in this Agreement and is tendering herewith the full amount of the capital contribution described herein.

Date: ___, 2008

Purchaser

Signature

(name)(print)

(street)

(city, state, zip)

(country)

The foregoing Agreement has been accepted this ___day of ___, 2008.

SAFESTITCH MEDICAL, INC.

By:___
Jeffrey G. Spragens
Chief Executive Officer and President

EXHIBIT A

INFORMATION STATEMENT

EXHIBIT B

ANNUAL REPORT ON FORM 10-KSB

FOR THE YEAR ENDED DECEMBER 31, 2007

EXHIBIT C

AMENDMENT NO. 1
TO
ANNUAL REPORT ON FORM 10-KSB/A

EXHIBIT D

CURRENT REPORT ON FORM 8-K

AS FILED WITH THE SEC ON APRIL 4, 2008

EXHIBIT E

CURRENT REPORT ON FORM 8-K

AS FILED WITH THE SEC ON APRIL 24, 2008

SAFESTITCH MEDICAL, INC. COMPLETES PRIVATE PLACEMENT

Raises $4 million for product development and clinical trials

MIAMI—(BUSINESS WIRE)—On May 29, 2008, SafeStitch Medical, Inc. (OTCBB:SFES — News) (the “Company” or “SafeStitch”) announced that it had completed the sale of 1,861,505 shares of the Company’s common stock to a number of private investors for an aggregate of approximately $4.0 million. The Company intends to use the funds for general working capital purposes, including the continued development and testing of its products.

“We are excited that these investors have shown their confidence in our research and management teams and our product candidates by investing in SafeStitch,” said Jeffrey G. Spragens, the Company’s President and Chief Executive Officer.

Dr. Stewart B. Davis, SafeStitch’s Chief Operating Officer, added that “this infusion of capital will help us to continue the expansion of our in-house R&D capabilities. Our current product development is progressing on track, and our gastroplasty device could be in human clinical trials as early as the end of this year.”

SafeStitch Medical, Inc. is a medical device company developing endoscopic and minimally invasive surgical devices. The Company is headquartered in Miami, Florida, and also has a research and development office in Omaha, Nebraska. SafeStitch’s product portfolio includes a gastroplasty device for endoscopic bariatric surgery (obesity surgery) and endoscopic repair of gastroesophageal reflux disorder (GERD), as well as an endoscopic device for excision and diagnosis of Barrett’s esophagus. The Company also plans to market a standard bite block, as well as the first airway bite block, to be used during endoscopy, and is pioneering the Smart Dilator for esophageal strictures. SafeStitch is also developing products for hernia repair and natural orifice transluminal endoscopic surgery (NOTES). Information about the Company may be found on its website at www.safestitch.com.

This press release contains “forward-looking statements,” as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, and patent positions and litigation, among other factors. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Contact:

SafeStitch Medical, Inc., Miami

Dr. Stewart B. Davis, 305-575-6000