



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-KSB

(Mark One)

Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the fiscal year ended **December 31, 2007**

OR

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_ to \_\_\_

Commission File Number **0-19437**

**SAFESTITCH MEDICAL, INC.**  
(formerly CELLULAR TECHNICAL SERVICES COMPANY, INC.)

(Name of Small Business Issuer as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**11-2962080**

(I.R.S. Employer Identification No.)

**4400 Biscayne Blvd. Suite 670 Miami, Florida, 33137**

(Address of Principal Executive Offices) (Zip Code)

Issuer's Telephone Number, Including Area Code: **(305) 575-6000**

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:

**Common Stock, \$0.001 par value per share**

(Title of Class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act

Check whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days.

Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein in any form, and, no disclosure will be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes  No

The Issuer had no revenue for the fiscal year ended December 31, 2007

The aggregate market value of the Registrant's common stock, par value \$0.001 per share, held by non-affiliates is approximately \$13,278,656, based upon the February 6, 2008 closing price of \$3.95 per share as reported on the over-the-counter bulletin board.

As of March 20, 2008 there were 16,093,016 shares of Common Stock, \$0.001 par value outstanding.

Transitional Small Business Disclosure Format

Yes  No

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-KSB contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (“PSLRA”), Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”), about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those set forth below as well as those contained in “Item 1A — Risk Factors” of this Annual Report on Form 10-KSB. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safeharbor 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.

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- 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.

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- 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.

\* \* \* \* \*

The Company files its periodic reports with the U.S. Securities and Exchange Commission (the “SEC”) in compliance with the “small business issuer” provisions of Regulation S-B promulgated under the Exchange Act. Generally, a small business issuer cannot file under Regulation S-B if its annual revenues or public float exceed \$25.0 million for two consecutive years. Because neither the Company’s annual revenues or public float exceeded \$25.0 million for the fiscal years ended December 31, 2006 and 2007, the Company qualifies as a Regulation S-B filer. Regulation S-B is tailored for the small business issuer, and although it requires accurate and complete disclosure, it does not require certain specific disclosures which are required under Regulation S-K and Regulation S-X.

## **PART I**

### **Item 1. Description of Business**

Unless the context otherwise requires, all references in this Annual Report on Form 10-KSB to the “Company”, “SafeStitch”, “we”, “our”, “ours”, and “us” refer to SafeStitch Medical, Inc., a Delaware corporation (formerly Cellular Technical Services Company, Inc.), including our wholly-owned subsidiaries, SafeStitch LLC, a Virginia limited liability company, and Isis Tele-Communications, Inc., a Delaware corporation with no operating business.

#### **General**

We were originally incorporated in August 1988 as NCS Ventures Corp. under laws of the State of Delaware, after which our name changed to Cellular Technical Services Company, Inc. (“CTS”). On September 4, 2007, we completed an acquisition of SafeStitch LLC, a privately held Virginia limited liability company (“LLC”), pursuant to a Share Transfer, Exchange and Contribution Agreement, dated as of July 25, 2007 (referred to as the “Share Exchange Agreement”), by and among us, LLC and the members of LLC. The Share Exchange Agreement provided for the exchange of all issued and outstanding membership interests of LLC for 11,256,369 shares of our common stock (the “Share Exchange”). We incurred customary acquisition related costs in connection with this transaction. In January 2008, we changed our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc., and, effective February 11, 2008, our trading symbol on the over-the-counter bulletin board changed from “CTSC” to “SFES”.

At the closing of the Share Exchange, we issued an aggregate of 11,256,369 shares of our common stock to the former members of SafeStitch in exchange for all of their membership interests in LLC. We also granted warrants to purchase a total of 805,521 shares of our common stock to The Frost Group, LLC and Jeffrey G. Spragens in connection with a line of credit of up to \$4 million that was provided to us simultaneously with the closing by The Frost Group, LLC and Jeffrey G. Spragens. The Warrants have a ten year term and an assumed exercise price of \$0.25 per share of common stock. Dr. Phillip Frost has a controlling interest in The Frost Group LLC and is the largest beneficial holder of our shares of common stock. Dr. Jane Hsiao and Steven D. Rubin, two of our directors, also are members of The Frost Group, LLC. Jeffrey G. Spragens is our Chief Executive Officer and President and a director. Frost Gamma Investments Trust, Dr. Phillip Frost, Dr. Jane Hsiao, Steven D. Rubin and Jeffrey G. Spragens were also beneficial owners of membership interests in LLC.

### **Accounting Treatment**

On September 4, 2007, the Company acquired LLC in a transaction accounted for as a recapitalization of LLC pursuant to an agreement dated July 25, 2007. For accounting purposes, LLC is treated as the continuing reporting entity. Since CTS did not have an operating business, the transaction is not accounted for as a business combination. Instead, the transaction is accounted for as a recapitalization of LLC and the issuance of stock by LLC (represented by the outstanding shares of SafeStitch) at the book values of assets and liabilities of SafeStitch, which approximates fair value with no goodwill or other intangibles recorded.

### **Treatment of Warrants and Options**

LLC did not have any outstanding warrants or options and no warrants or options were assumed by SafeStitch as a result of the Share Exchange, except warrants issued in connection with the line of credit described above.

### **Company Overview**

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

We have utilized our expertise in intraperitoneal surgery to test certain of our devices in *in vivo* and *ex vivo* animal trials and *ex vivo* human trials, and with certain products, in limited *in vivo* human trials, and we intend to rapidly, efficiently and safely move into clinical trials for our devices that are utilized in surgery for the treatment of obesity, GERD and esophageal obstructions and for the treatment and diagnosis of Barrett’s Esophagus. Clinical trials for certain product candidates should begin in 2008.

Our devices are designed to accomplish one or more of the following surgical goals:

- Increased effectiveness
- Safer
- Fewer complications
- Reduced costs

We believe that we can accomplish these goals by developing devices that, for example, allow surgery to be performed endoscopically that had previously been performed through an abdominal incision, including laparoscopically. Devices such as these reduce the need for inpatient hospital stay, as well as the likelihood of complications and their associated costs.

We plan to leverage our strengths to further develop a pipeline of surgical devices to be utilized in treating intraperitoneal abnormalities. These efforts may lead to our acquiring or developing products which aid in surgery for the treatment and diagnosis of gallstones, appendicitis, cancer of the intestinal tract, kidney cancer, trauma, reproductive disease tumors and liver conditions.

Dr. Charles Filipi, our Medical Director, has been a pioneer in laparoscopic surgery and endoluminal surgery at Creighton University and has been the lead physician responsible for the development of our product candidates. He has relationships with a number of physicians who are experts in this field and we believe that he will be able to utilize his expertise and these relationships to facilitate device development and the opportunities mentioned above. We are also working with leading hernia surgeons. Many of these experts are part of our medical advisory board.

## Market Opportunity

Obesity is the major factor leading to a number of operations which we intend for our product candidates to address. The incidence of obesity (defined as 100 pounds over ideal body weight) is increasing rapidly despite the diet industry and increased public awareness. According to a National Health and Nutrition Examination Survey, approximately two thirds of individuals living in the United States are overweight. Approximately 70 million Americans, roughly 25% of the U.S. population, are currently obese, and according to *Epidemiology Review 2007* estimates, in ten years, 100 million Americans, or approximately 35% of the anticipated U.S. population, will be obese. Obesity is not only growing in the U.S., but is becoming a problem in industrialized countries worldwide, including China and India. The most common causes of obesity include dietary behavior, physical inactivity, psychological issues such as anxiety and depression and socio-occupational factors. In addition, up to 40% of the American adult population has GERD symptoms monthly. GERD that is untreated over a long period of time can lead to complications, such as Barrett's Esophagus, a precancerous change to the thin layer of tissue lining the esophagus. Barrett's Esophagus can develop into a relatively rare, but often deadly type of cancer of the esophagus. Another common complication is scar tissue that blocks the movement of swallowed food and drink through the esophagus.

Alternatives available when considering obesity treatment include exercise and dieting, prescription drugs, bariatric surgical alternatives and gastric stimulators (not expected to be available until 2008 at the earliest). Exercise and dieting are often not successful, or, if successful, the results are often not permanent. In addition, although there are a number of drug alternatives currently in the market for the treatment of obesity, they often result in moderate weight loss (typically no more than 10% of body weight).

We believe the market for our product candidates is driven by:

- The aging and heavier population;
- An active and increased life expectancy among the aging baby-boomer generation;
- Painful and expensive surgical procedures with a moderate to high incidence of complications;
- Emerging technologies to treat obesity, GERD, Barrett's Esophagus and other surgical abnormalities; and
- An increased awareness of the benefits of minimally invasive surgery.

Initially, we have prioritized opportunities within gastroenterology that we believe combine attractive markets with an emerging understanding of intraluminal surgery. In that regard, our initial key product candidates focus on obesity and obesity-related conditions that often may be treated by bariatric surgery.

As a result of the foregoing, bariatric surgery has become more prevalent as an alternative. Approximately 350,000 — 400,000 bariatric surgical procedures are performed annually worldwide. Bariatric surgery is usually recommended for those people with a body mass index (BMI) of 35 or higher or for those who are approximately 100 pounds overweight. Currently the most common methods of surgery for the morbidly obese include gastric bypass, gastric banding and gastroplasty. By far, the leading and most successful type of bariatric surgery is gastric bypass. These operations combine the creation of a small stomach pouch to restrict food intake and the construction of bypasses of the duodenum and other segments of the small intestine to decrease the ability to absorb nutrients from food. Other types of bariatric surgery include gastric banding, in which a small inflatable/dilatable band (which allows the size of the opening between the pouch and the stomach to be adjusted) is placed around the upper part of the stomach, creating a small pouch, so that patients feel full sooner, and vertical banding gastroplasty, or stomach stapling, in which a band and staples are used to create a small stomach pouch. These procedures have a moderate to high level of complications and are expensive. In addition, they involve significant incisions.

In addition, there are approximately 200,000 — 250,000 GERD or acid reflux surgical or transoral procedures performed annually in the world. None of the currently available outpatient endoscopic procedures have proven effective in reversing inflammation of the esophagus or the amount of acid reflux. In addition, approximately 2 million esophageal dilations and 20 million endoscopies are performed annually worldwide. All endoscopies require a bite block.



## Product Candidates

The following describes our product candidates, all of which are in development or pre-development.

### **Intraluminal Gastroplasty Device for Obesity (“Obesity Device”)**

The Obesity Device is designed to perform incision-less, endoscopic bariatric surgery by introduction through the mouth and esophagus. Bariatric surgery is generally performed through an external abdominal incision, and sometimes laparoscopically. The traditional surgery has the potential for significant complications, requires an in-patient hospital stay and is expensive.

Our gastroplasty devices are the most tested of our devices. These tests have established the effectiveness of these devices. In animal tests and *ex vivo* human testing, the Obesity Device has been successful in suturing and excising tissue and reducing stomach size by approximately 95%. We presently expect to conduct the first *in vivo* human testing of this device in 2008. We believe that this device will result in significantly less complications and expense, both because of the less-invasive manner in which the procedure will be performed and the reduced recuperation time. We believe this device to be a Class II 510k device that will require IDE (investigational device exemption) clinical data for FDA approval.

### **Intraluminal Gastroplasty Device for GERD (the “GERD Device”)**

The GERD Device contains the same features as the Obesity Device and is designed to promote healing at the gastroesophageal junction to prevent acid reflux. In GERD patients, the esophageal junction does not close completely and acid or bile from the stomach enters the esophagus. Both the hydrochloric acid or bile from the stomach can damage the esophagus. Typically, surgery is performed through either an external abdominal incision, or laparoscopically. The traditional surgery has the potential for significant complications, requires a two-three day inpatient hospital stay and is expensive. Like the obesity device, the GERD Device is inserted through the mouth and esophagus. The benefits are similar to those of the Obesity Device. We believe that this device will result in significantly more effective treatment and less complications and expense and will permit the procedure to be performed on an outpatient basis.

We have successfully tested a prototype of this device in two patients with Creighton University Institutional Review Board (IRB) permission. We presently expect to continue *in vivo* human testing of this device in 2008. We believe this device to be a Class II 510k device that will require IDE clinical data for FDA approval.

### **Barrett’s Excision and Ablation Device for Treatment and Diagnosis (“Barrett’s Device”)**

The Barrett’s Device is the only device we are aware of designed to assist in both diagnosis of and treatment of Barrett’s Esophagus. Barrett’s Esophagus is the lining of the esophagus that imitates the stomach mucosa, beginning at the esophageal junction and migrating upward. Barrett’s esophageal tissue is pre-cancerous and can result in difficulty in swallowing, spreading malignancy and death.

Existing treatments include medication, laparoscopic surgery and cauterization. The Barrett’s Device allows the mucosa to be suctioned, sliced off and tested. The device also allows for cauterization of the affected area. If the Barrett’s Esophagus covers all four quadrants of the esophagus, at least two procedures are necessary, each covering up to one half of the circumference, as a 360° excision would create a stricture that would cause difficulty swallowing. We expect that the procedures will be done two months apart. No incision is required, and the procedure will be an outpatient procedure. We expect this device to be more effective and less costly than existing procedures.

In over ten *in vivo* and *ex vivo* animal tests and five *ex vivo* human tests, the Barrett’s Device has been successful in excision width, length, depth and contour. We presently expect to conduct the first human testing of the Barrett’s Device by the end of 2008. We believe this device to be a Class II 510k device that will require IDE clinical data for FDA approval.

### **Smart Dilator**

Dilators are used when an endoscopy demonstrates the narrowing of the esophagus. Narrowing may be treated by medication for GERD or by using a dilator to expand the esophagus. Studies indicate that there are approximately 10,000 perforations of the esophagus per year resulting from dilation. According to peer-reviewed literature, dilation results in a 0.5-1.0% perforation rate. Approximately 800,000 dilations are performed in the United States each year. Untreated perforation of the esophagus is fatal; usually within two days. Our testing has shown that there should be no greater than two pounds of pressure on the dilator. The Smart Dilator signals the physician as to how close he or she is to this amount of pressure through change in the color of the dilator handle from green to yellow to red. The Smart Dilator handle also locks in place when the pressure exceeds 2.5 pounds. While there are numerous dilators on the market, none provide a safety mechanism similar to what will be provided by the Smart Dilator.

Limited *ex vivo* and *in vivo* animal tests and *ex vivo* human tests were performed to assist us in simulating the use of this product in patients and to develop specifications. We have received Creighton University IRB approval to perform a study on the Smart Dilator. We anticipate that this study will commence mid-2008. We believe this device to be a Class II 510k device that will require IDE clinical data for FDA approval.

### **Standard Bite Block**

A bite block is used to protect the endoscope used in transoral gastrointestinal procedures and is required in all such procedures. A number of bite blocks are on the market. Our Standard Bite Block provides a higher level of protection as it is less easily expelled from the mouth. The Standard Bite Block is designed with a bigger lip and slightly different aperture than other bite blocks. Because this is a Class I device, it has not been necessary to do significant testing; however, Creighton University Medical Center has approved a bite block study which will commence mid-2008. See “-FDA Regulation of the Design, Manufacture and Distribution of Medical Devices”. This product candidate was tested for comfort in *in vivo* human patients. Endoscopic procedures have not yet been attempted with this device. We believe this to be a Class I 510k exempt device.

### **Airway Bite Block**

The Airway Bite Block has an airway built into the bite block to assist patients with larger tongues or smaller throats, usually because of obesity, in breathing during an endoscopic procedure. The Airway Bite Block will also be tested under IRB approval at Creighton University, which will commence mid-2008. The Airway Bite Block will come in two sizes. This product candidate has only been tested in a human cadaver. We believe this to be a Class I 510k exempt device.

### **T Fasteners for Upper GI Bleeding (“T Fastener Gun”)**

The T Fastener Gun delivers small metal fasteners at the end of an endoscope. We believe that our T Fastener Gun can provide full-thickness stomach wall suturing for control of gastric bleeding. Existing devices apply energy or clips that are often too superficial, resulting in rebleeding. The T Fastener suture end is tightened, and because it is full thickness bite, a larger amount of tissue will compress the bleeding vessel.

The T Fastener Gun is in an early stage of development and has undergone *in vivo* and *ex vivo* animal studies. These tests have established the feasibility of the T Fastener Gun.

### **Novel Surgical Fasteners for Hernia Repairs and Other Surgical Procedures (“Surgical Fasteners”)**

This Surgical Fastener is an absorbable or non-absorbable staple with a stapler for the repair of inguinal or groin hernias. The staples are utilized to fix mesh in place. The mesh helps prevent the recurrence of a hernia. The absorbable nature of the staples may reduce the incidence of chronic postoperative pain, which affects approximately 20% of patients. The staples will also decrease operative time as they are easier and faster to apply. We are continuing to develop these devices.

## **Novel Devices for Natural Orifice Transluminal Endoscopic Surgery (“NOTES”)**

Natural Orifice Transluminal Endoscopic Surgery or NOTES is a new method of operating in the abdominal cavity without making an incision in the abdominal wall. This surgery is also referred to as NO SCAR surgery. The natural orifices used in this type of procedure are the mouth and the rectum and, in females, the vagina. If the mouth is used, instruments are passed through this natural orifice out of the stomach and into the abdominal cavity.

NOTES includes surgeries for gallbladder removal, appendectomy, tubal ligation, removal of intestinal and reproductive organ cancer and hernia repair, all through the gastric, rectal or vaginal walls as indicated above. Surgery utilizing the NOTES approach requires stabilization of long flexible instruments and the organs to be operated upon. SafeStitch has received a license from Creighton University for a patent application for a magnetic gallbladder retractor that would enable improved operative exposure for gallbladder removal, as well as other devices to assist in NOTES procedures.

## **Intellectual Property**

We have exclusively licensed technology, know-how and patent applications from Creighton University for all of our product candidates. These applications include systems and techniques for minimally invasive gastrointestinal procedures, a dilator for use with an endoscope, bite blocks for use with an endoscope and for preserving airways of patients during endoscopy, surgical fasteners, a T-Fastener Gun and NOTES. In addition, we have certain rights to other Creighton University intellectual property that we have not yet defined as product candidates.

In total, we have exclusively licensed from Creighton University seven patent applications in the United States and four foreign patent applications.

Pursuant to our exclusive license and development agreement with Creighton University, we own all inventions conceived of and reduced to practice solely by our employees and agents, and all patent applications and patents claiming such inventions developed without the use of any licensed patent rights or associated know-how and Creighton University owns all inventions conceived of and reduced to practice solely by Dr. Filipi, or any university employees or agents who work directly with Dr. Filipi in the course of performing duties for us, and all patent applications and patents claiming such inventions, which inventions, patent applications and all resulting licensed patent rights are subject to the exclusive license and development agreement. Together with the university we jointly own all inventions conceived of and reduced to practice jointly by Dr. Filipi, and/or any university employees or agents who work directly with him and our employees or agents. Notwithstanding, the university owns all inventions conceived of or reduced to practice under the research and development budget, and all patent applications and patents claiming such inventions, even if conceived of solely by our employees or agents, and such inventions, patent applications and all resulting licensed patent rights are subject to the exclusive license and development agreement.

Creighton University is obligated to file, prosecute and maintain all licensed patents and all patent applications and patents disclosing and claiming inventions made in whole or in part by university employees, agents or contractors resulting from the research and development the university engages in on our behalf in such countries as we designate. We have the right, but not the obligation, at our sole expense, to enforce our licensed patent rights and associated know-how under the exclusive license and development agreement against any infringer, including the right to file suit for patent infringement naming Creighton University as a party, and the right to settle such suit with the university’s consent, which shall not be unreasonably withheld. The University is entitled to 1.5% of any amount collected as a result of such judgment or settlement. In the event that we choose not to file suit for patent infringement within 180 days after becoming aware of infringement, Creighton University shall have the right, but not the obligation, at its sole expense, to enforce the licensed patent rights and associated know-how against any infringer, including the right to file suit for patent infringement naming us as a party, and the right to settle such suit with our consent, which shall not be unreasonably withheld. The university shall pay us 1.5% of any amount collected as a result of such judgment or settlement.

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We believe that technological innovation is driving breakthroughs in the surgical markets that we intend to service. We intend to adopt a comprehensive intellectual property strategy which will blend our efforts toward focused innovation with our business development activities designed to strategically in-source intellectual property rights.

We intend to develop, protect and defend our own intellectual property rights as dictated by the developing competitive environment. We value our intellectual property assets and believe we have benefited from our relationship with Creighton University and Dr. Filipi.

### **Licenses and Collaborative Relationships; Research and Development**

Our strategy is to develop a portfolio of product candidates through a combination of internal development and external partnerships. Collaborations are key to our strategy, and, on May 26, 2006, we entered into an exclusive worldwide license and development agreement with Creighton University granting us the rights to license and sublicense all of our product candidates and associated know-how, including the exclusive right to manufacture, use and sell the product candidates. The foregoing license is exclusive even with respect to Creighton University. In addition, for 36 months, we have an option to accept or reject for continued development any additional devices, materials and methods used in the practice of bariatric medicine and treatment of GERD, transoral surgical techniques and all alimentary and gastrointestinal components associated therewith, including but not limited to the esophagus, stomach, intestines and digestive tract, as well as such abnormalities as gastric bleeding, hernias and other medical conditions that may benefit from such technologies.

During such time as we sell any product licensed under this agreement, we are obligated to pay Creighton University, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from such sales, less certain amounts, including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The agreement does not provide for minimum royalties.

Pursuant to the agreement, Creighton University shall provide all necessary facilities, including animal research laboratories, to accommodate Dr. Filipi's research and development of any licensed product and shall be compensated by us for use of such facilities as provided in the research and development agreement, which is updated annually. In 2006 and 2007, we recorded an expense of \$112,016 and \$321,733, respectively, in satisfaction of the indirect cost allowance equal to 20% of the direct and personnel costs for services conducted at the university or company facilities. Pursuant to the agreement, the university has agreed that Dr. Filipi shall devote at least 90% of his working time during the four-year period that began May 26, 2006, and at least 50% of his time during the two years thereafter, towards the research and development of any licensed product under the agreement, including the development of any such product to a final design and prototype as a commercially viable product. The agreement further provides that Dr. Filipi shall assist us with the prosecution of any and all patent applications related to any such products developed under the agreement.

We have agreed to invest in the aggregate, at least \$2.5 million over 36 months towards development of any licensed product, not including the first \$150,000 of costs related to the prosecution of patents, which we have done. Our failure to do so would have resulted in all rights in the licensed patents and know-how reverting back to the university. Through December 31, 2007, we had invested \$2,709,183 in the licensed products, inclusive of our costs to date relating to prosecution of patents. Pursuant to the agreement, we are entitled to exercise our own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion, or other commercial exploitation of any licensed products, provided that if we have not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the agreement or the date such technology is disclosed to and accepted by us, then the licensed patent and associated know-how shall revert back to the university, with no rights retained by us, and the university will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless we purchase one year extensions. In addition to the expenses in connection with our agreement with Creighton University, we have incurred research and development expenses of \$1,636,000 and \$748,000 for the years ended December 31, 2007 and 2006, respectively.

## **Competition**

The market for our products is highly competitive due to the large number of products competing for market share and significant levels of commercial resources being utilized to promote those products. Competitors include USGI Medical, TOGa devices from Satiety and StomaphyX and EsophyX from Endo Gastric Solutions, Inc. with respect to our Obesity Device; USGI Medical, NDO Surgical, Inc. and Medigus, Ltd. with respect to our GERD Device, Olympus Medical Equipment Services America, Inc. and BARRX Medical, Inc. with respect to our Barrett's Device, Olympus and Wilson Cook with respect to gastrointestinal bleeding; Bard, LLC, ConMed Corporation, U.S. Endoscopy, Omni Medical Supply, Inc. and Olympus with respect to our bite blocks and Boston Scientific Corporation, Cook Medical Supply, Inc., Miller Medical Specialties, U.S. Endoscopy and The Rush Incorporated with respect to our dilator. There are also a significant number of bite blocks on the market. In addition, our ability to compete may be affected because of the failure to educate physicians or the level of physician expertise. This may have the effect of making our product less attractive to buyers. Among the products with which we will directly compete, we expect to differentiate on the basis of enhanced safety, effectiveness and efficiency, as well as lower cost, in most cases. Several medical device companies are actively engaged in research and development of treatments for gastrointestinal abnormalities similar to the gastrointestinal abnormalities that are targeted by our product candidates. We cannot predict the basis upon which we will compete with new products marketed by others. Many of our competitors have substantially greater financial, operational, sales and marketing and research and development resources than we have.

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 (Helioscopic) or gastric sleeves to reduce food intake.

## **Government Regulation of our Medical Device Development Activities**

Healthcare is heavily regulated by the federal government and by state and local governments. The federal laws and regulations affecting healthcare change constantly thereby increasing the uncertainty and risk associated with any healthcare-related venture.

The federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA which administers the Food, Drug, and Cosmetic Act ("FD&C Act"), as well as other relevant laws; (ii) the Centers for Medicare & Medicaid Services ("CMS") which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General ("OIG"), which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude health care providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). All of the aforementioned are agencies within the Department of Health and Human Services ("HHS"). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs under, among other laws, the Veterans Health Care Act of 1992, the Public Health Service within HHS under the Public Health Service Act, the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under the Medicaid program and their internal laws regulating all healthcare activities.

## **FDA Regulation of the Design, Manufacture and Distribution of Medical Devices**

The testing, manufacture, distribution, advertising and marketing of medical devices are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory clearances or approvals, as the case may be, before it may be marketed in a particular country. Under United States law, a "medical device" ("device") is an article, which, among other things, is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. See FD&C Act § 201(h). Substantially all of the devices being developed by SafeStitch are classified as medical devices and subject to regulation by numerous agencies and legislative bodies, including the FDA and comparable foreign counterparts.

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Devices are subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution. The FDA classifies medical devices into one of three classes. Class I devices are relatively simple and can be manufactured and distributed with general controls. Class II devices are somewhat more complex and require greater scrutiny. Class III devices are new and frequently help sustain life.

In the United States, a company generally can obtain permission to distribute a new device in two ways. The first applies to any device that is substantially equivalent to a device first marketed prior to May 1976 or to another device marketed after that date, but which was substantially equivalent to a pre-May 1976 device. These devices are either Class I or Class II devices. To obtain FDA permission to distribute our devices, we generally must submit a pre-market notification application (a section 510(k) submission), and receive an FDA order finding substantial equivalence to a predicate device (pre-May 1976 or post-May 1976 device that was substantially equivalent to a pre-May 1976 device) and permitting commercial distribution of that device for its intended use. A 510(k) submission must provide information supporting its claim of substantial equivalence to the predicate device. FDA permits certain low risk medical devices to be marketed without requiring the manufacturer to submit a premarket notification. In other instances, FDA may require that a premarket notification not only be submitted, but also be accompanied by clinical data. If clinical data from human experience are required to support the 510(k) submission, these data must be gathered in compliance with investigational device exemption (“IDE”) regulations for investigations performed in the United States. The FDA review process for premarket notifications submitted pursuant to section 510(k) takes on average about 90 days, but it can take substantially longer if the agency has concerns, and there is no guarantee that the agency will “clear” the device for marketing, in which case the device cannot be distributed in the United States. Nor is there any guarantee that the agency will deem the article subject to the 510(k) process, as opposed to the more time-consuming, resource intensive and problematic, premarket approval (“PMA”) process described below.

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a pre-1976 product or to one that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices and can only be marketed following approval of a PMA. For example, most implantable devices are subject to the approval process. Two steps of FDA approval generally are required before a company can market a product in the U.S. that is subject to approval as opposed to clearance. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device, however, those regulations permit a company to undertake a clinical study of a “non-significant risk” device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. If there is any doubt as to whether a device is a “non-significant risk” device, companies normally seek prior approval from the FDA. Second, the FDA must review SafeStitch’s PMA application, which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds there is reasonable assurance the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process.

We believe that our Obesity Device and other of the products we have licensed are “substantially equivalent,” as that term is used by the FDA, to devices that have been cleared for marketing by the FDA under the 510(k) process. However, it is uncertain at this time whether the licensed Obesity Device or any other licensed product that we propose to manufacture and distribute would be subject to the 510(k) process or the more elaborate PMA process, and it is also unclear the types of clinical data, if any, that FDA might require as part of a premarket notification under the 510(k) process or a PMA application under section 515, as the case may be. It is also unclear whether the FDA would view the Obesity Device as a “significant risk device,” requiring prior FDA approval to conduct a clinical study involving that Device. We have not yet sought FDA approval to conduct any clinical studies of any of our licensed products in the United States and no such studies have been conducted domestically. There is no assurance that the FDA would permit us to conduct such clinical studies and no assurance that the FDA would agree with our study design, statistical methods or endpoints.

Even when a clinical study has been approved by the FDA or deemed approved, the study is subject to factors beyond a manufacturer’s control, including, but not limited to the fact that the institutional review board at a given clinical site might not approve the study, might decline to renew approval which is required annually, or might suspend or terminate the study before the study has been completed. Also, the interim results of a study may not be satisfactory, leading the sponsor to terminate or suspend the study on its own initiative or the FDA may terminate or

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suspend the study. There is no assurance that a clinical study at any given site will progress as anticipated; there may be an insufficient number of patients who qualify for the study or who agree to participate in the study, or the investigator at the site may have priorities other than the study. Also, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA that the product is safe and effective, a prerequisite for FDA approval of a PMA, or substantially equivalent in terms of safety and effectiveness to a predicate device, a prerequisite for clearance under 510(k). Even if the FDA approves or clears a device, it may limit its intended uses in such a way that manufacturing and distributing the device may not be commercially feasible.

After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval or require changes to a device, its manufacturing process or its labeling or additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the PMA is not permitted to make changes to the device which affect its safety or effectiveness without first submitting a supplement application to its PMA and obtaining FDA approval for that supplement. In some instances, the FDA may require clinical trials to support a supplement application. A manufacturer of a device cleared through the 510(k) must submit another premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Any change in the intended uses of a PMA device or a 510(k) device requires an approval supplement or cleared premarket notification. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

A company that intends to manufacture medical devices is required to register with the FDA before it begins to manufacture the device for commercial distribution. As a result, we and any entity that manufactures products on our behalf will be subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation requirements and other regulations. In the European Community, we will be required to maintain certain International Organization for Standardization ("ISO") certifications in order to sell products and we or our manufacturers undergo periodic inspections by notified bodies to obtain and maintain these certifications. These regulations require us or our manufacturers to manufacture products and maintain documents in a prescribed manner with respect to design, manufacturing, testing and control activities. Further, we are required to comply with various FDA and other agency requirements for labeling and promotion. The Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. In addition, the FDA prohibits us from promoting a medical device for unapproved indications.

The FDA in the course of enforcing the FD&C Act may subject a company to various sanctions for violating FDA regulations or provisions of the Act, including requiring recalls, issuing Warning Letters, seeking to impose civil money penalties, seizing devices that the agency believes are non-compliant, seeking to enjoin distribution of a specific type of device or other product, seeking to revoke a clearance or approval, seeking disgorgement of profits and seeking to criminally prosecute a company and its officers and other responsible parties.

### **Third-Party Payments, Especially Payments by Medicare and Medicaid**

#### **A. Medicare Coverage**

Inasmuch as a percentage of the projected patient population that could potentially benefit from our devices are elderly, Medicare would likely be a potential source of reimbursement. Medicare is a federal program that provides certain hospital and medical insurance benefits to persons age 65 and over, certain disabled persons, persons with end-stage renal disease and those suffering from Lou Gehrig's Disease. In contrast, Medicaid is a medical assistance program jointly funded by federal and state governments and administered by each state pursuant to which benefits are available to certain indigent patients. The Medicare and Medicaid statutory framework is subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare and Medicaid.

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Medicare reimburses for medical devices in a variety of ways depending on where and how the device is used. However, Medicare only provides reimbursement if CMS determines that the device should be covered and that the use of the device is consistent with the coverage criteria. A coverage determination can be made at the local level (“Local Coverage Determination”) by the Medicare administrative contractor (formerly called carriers and fiscal intermediaries), a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a National Coverage Determination. There are new statutory provisions intended to facilitate coverage determinations for new technologies under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”) §§ 731 and 942, but it is unclear how these new provisions will be implemented. Coverage presupposes that the device has been cleared or approved by the FDA and, further, that the coverage will be no broader than the approved intended uses of the device (i.e., the device’s label) as cleared or approved by the FDA, but coverage can be narrower. In that regard, a narrow Medicare coverage determination may undermine the commercial viability of a device.

CMS has issued a National Coverage Determination with respect to bariatric surgery under which CMS will cover the surgery only for treatment of co-morbidities associated with morbid obesity, and only under the following conditions:

- Medicare beneficiary has a body-mass index of 35 or greater,
- Medicare beneficiary has at least one co-morbidity related to obesity such as diabetes or hypertension,
- Medicare beneficiary has been previously unsuccessful with medical treatment for obesity, and
- Procedure is performed in an approved facility listed at <http://www.cms.hhs.gov>

It is unclear whether the type of bariatric surgery that would rely on our primary device would be covered under the National Coverage Determination noted above.

Seeking to modify a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for respective devices. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations. Our inability to obtain a favorable coverage determination may adversely affect our ability to market our products and thus, the commercial viability of our products.

### **B. Medicare Reimbursement Levels**

Even if Medicare covers the procedure that uses our devices the level of reimbursement may not be sufficient for commercial success. The Medicare reimbursement levels for covered procedures are determined annually through two sets of rulemakings, one for outpatient departments of hospitals under the Outpatient Prospective Payment System (“OPPS”) and the other, for procedures in physicians’ offices under the Resource-Based Relative Value Scales (“RBRVS”) (the Medicare fee schedule). If the use of a device is covered by Medicare, a physician’s ability to bill a Medicare patient more than the Medicare allowable amount is significantly constrained by the rules limiting balance billing. For covered services in a physician’s office, Medicare normally pays 80% of the Medicare allowable amount and the beneficiary pays the remaining 20%, assuming that the beneficiary has met his or her annual Medicare deductible and is not also a Medicaid beneficiary. For services performed in an outpatient department of a hospital, the patients co-payment under Medicare may exceed 20%, depending on the service and depending on whether CMS has set the co-payment at greater than 20%. Usually, Medicaid pays less than Medicare, assuming that the state covers the service. In addition, private payors, including managed care payors, increasingly are demanding discounted fee structures and the assumption by healthcare providers of all or a portion of the financial risk. Efforts to impose greater discounts and more stringent cost controls upon healthcare providers by private and public payors are expected to continue.



Significant limits on the scope of services covered or on reimbursement rates and fees on those services that are covered could have a material adverse effect on our ability to commercialize our devices and therefore, on our liquidity and financial condition.

### **Anti-Fraud and Abuse Rule**

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties that can materially affect us. These federal laws include, by way of example, the following:

- The anti-kickback statute (Section 1128B(b) of the Social Security Act) prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other governmental programs;
- The physician self-referral prohibition (Ethics in Patient Referral Act of 1989, as amended, commonly referred to as the Stark Law, Section 1877 of the Social Security Act), which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians (or their immediate family members) have ownership interests or with which they have certain other financial arrangements.
- The anti-inducement law (Section 1128A(a)(5) of the Social Security Act), which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program;
- The False Claims Act (31 U.S.C. § 3729 et seq.), which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment to the federal government (including the Medicare and Medicaid programs); and
- The Civil Monetary Penalties Law (Section 1128A of the Social Security Act), which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from the Medicare and other government programs.

Many states have adopted or are considering legislative proposals similar to the federal fraud and abuse laws, some of which extend beyond the Medicare and Medicaid programs, to prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted or are considering legislative proposals to increase patient protections, such as limiting the use and disclosure of patient specific health information. These state laws also impose criminal and civil penalties similar to the federal laws.

In the ordinary course of their business, medical device manufacturers and suppliers have been and are subject regularly to inquiries, investigations and audits by federal and state agencies that oversee these laws and regulations. Recent federal and state legislation has greatly increased funding for investigations and enforcement actions, which have increased dramatically over the past several years. This trend is expected to continue. Private enforcement of healthcare fraud also has increased due in large part to amendments to the civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. These whistleblower suits by private persons, known as qui tam relators, may be filed by almost anyone, including present and former patients or nurses and other employees, as well as competitors. HIPAA, in addition to its privacy provisions, created a series of new healthcare-related crimes.

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As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on a suppliers' liquidity and financial condition. A investigation into the use of a device by physicians may dissuade physicians from either purchasing or using the device. This could have a material adverse effect on our ability to commercialize our devices.

### **The Privacy Provisions of HIPAA**

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities," such as healthcare providers, insurers and clearinghouses, and indirectly regulates "business associates," with respect to the privacy of patients' medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA and it is unlikely that we, based on our current business model, would be a business associate. Nevertheless, we will likely be contractually required to physically safeguard the integrity and security of any patient information that we receive, store, create or transmit. If we fail to adhere to our contractual commitments, then our physician or hospital customers may be subject to civil monetary penalties, which could adversely affect our ability to market our devices.

### **Manufacturing**

We have no commercial manufacturing facilities and we currently do not intend to build commercial manufacturing facilities of our own in the foreseeable future. We intend to enter into agreements with various third parties for the formulation and manufacture of our products. We have entered into agreements with several third party manufacturers for the manufacture of prototypes for certain of our products. These suppliers and their manufacturing facilities must comply with FDA regulations, current quality system regulations (referred to as QSRs), which include current good manufacturing practices, or cGMPs, and to the extent laboratory analysis is involved, current good laboratory practices, or cGLPs. We have recently acquired our own prototype lab located in Miami, Florida, where we make prototypes for testing, including for limited use in animal or human clinical testing.

### **Sales & Marketing**

We currently do not have sales or marketing personnel. In order to commercialize any products that are approved for commercial sale, we must either build a sales and marketing infrastructure or collaborate with third parties with sales and marketing experience. We may build our own sales and marketing infrastructure to market some of our product candidates targeting gastrointestinal specialists in certain regions or collaborate with companies established in this industry to market and sell certain of our products, if cleared or approved, as the case may be. Such collaborations could take the form of joint ventures or sales, marketing or distribution agreements. We intend to distribute our products through companies established in the industry.

### **Employees**

As of December 31, 2007, we had eight full-time employees, four of whom hold advanced degrees. We plan to add to our headcount in key functional areas that will allow us to further the development of our product candidates. None of our employees are represented by a collective bargaining agreement.

### **Glossary of Terms**

"**Barrett's Esophagus**" is a complication of severe chronic GERD involving changes in the cells of the tissue that line the bottom of the esophagus. These cells become irritated when the contents of the stomach back up (refluxes), resulting in a small, but definite, increased risk of cancer of the esophagus. The diagnosis results upon seeing (through endoscopy) an orange esophageal lining (mucosa) that extends a short distance (usually less than 2.5 inches) up the esophagus from the gastroesophageal junction and findings of intestinal type cells (goblet cells) seen on histological examinations of biopsy tissue.

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“**Bariatric**” relates to the branch of medicine that deals with the treatment of obesity and allied diseases.

“**Endoscopic**” is a procedure utilizing an illuminated, usually fiber-optic flexible or rigid tubular instrument, for visualizing the interior of a hollow organ or part (such as the esophagus) for diagnostic or therapeutic purposes that typically has one or more channels to enable passage of instruments.

“**Ex vivo**” means outside of a living animal or human.

“**Gastroplasty**” is surgical treatment of the stomach used to decrease the size of the stomach.

“**GERD**” is gastrointestinal reflux disease, a highly variable chronic condition that is characterized by periodic episodes of acid reflux usually accompanied by heartburn and that may result in histopathologic changes in the esophagus.

“**Histological**” relates to the tissue changes characteristic of disease or that affect a part of or accompany a disease.

“**Intraluminal**” within the lumen of a hollow organ. Hollow organs include the esophagus, stomach and small and large intestines, as well as the heart, arteries, veins, ureter and urethra.

“**Intraperitoneal**” refers to within the abdominal cavity.

“**In vivo**” means inside of a living animal or human.

“**Laparoscopic**” is surgery utilizing a small incision to examine the abdominal cavity.

“**Lumen**” is the central opening in a hollow organ.

“**Medical device**” is an article, which, among other things, is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals.

“**Transoral**” refers to procedures originating through the mouth.

“**Transluminal**” is the egress of instrumentation through the intestinal wall.

### **Item 1A. Risk Factors.**

An investment in our company involves a significant level of risk. Investors should carefully consider the risk factors described below together with the other information included in this Annual Report on Form 10-KSB. If any of the risks described below occurs, or if other risks not identified below occur, our business, financial condition, and results of operations could be materially adversely affected.

***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), \$(1,059,000) and \$(75,000), respectively. As

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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

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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.

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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

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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.

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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.

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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 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 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”.

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 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.

## **Item 2. Description of Property**

Our principal corporate office is located at 4400 Biscayne Blvd, Suite 670, Miami, Florida. We rent this space from Frost Real Estate Holdings, LLC, which is a company controlled by Dr. Phillip Frost, our largest beneficial stockholder. We lease approximately 2,900 square feet under the lease agreement, which is for a five-year term that began on January 1, 2008, and requires annual rent of approximately \$91,000, which amount increases by approximately 4.5% per year.

We currently lease approximately 462 square feet of office space in Omaha, Nebraska. This facility includes one administrative office. Dr. Filipi, our Medical Director and one of the members of our Board of Directors, is based in Omaha, Nebraska.

We have leased a warehouse in Miami, Florida, which is used as our prototype lab. The lease term began on January 1, 2008 and extends for a period of twelve months.

## **Item 3. Legal Proceedings**

We are presently a plaintiff in a securities fraud and appraisal action in respect of our ownership of 191,118 shares of common stock of True Position, Inc., a Delaware corporation (referred to as “True Position”). This action was filed November 13, 2007 in the United States District Court for the District of Connecticut, and we and other plaintiffs party to the suit seek damages and other relief totaling \$80 million.

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In August 2007, we were informed that that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of True Position's outstanding capital stock, was being merged into True Position. As a result of the merger, all of the issued and outstanding shares of common stock of True Position were cancelled, and True Position's minority stockholders, including ourselves, became entitled to receive \$3.5116 in cash in exchange for each share held. We and other minority stockholders considered that the consideration payable in respect of our shares under the merger was not representative of the true value of our shares of True Position stock.

We have joined with certain other minority stockholders of True Position in bringing the aforementioned appraisal and securities fraud action, and, on August 10, 2007, we entered into a joint shareholder litigation governance and funding agreement (referred to as the funding agreement) with such stockholders. Under the funding agreement, we have agreed to fund a portion of the litigation expenses in connection with the appraisal and securities fraud action. To date, we have contributed approximately \$45,000, and we anticipate that we will be called upon to fund at least a similar, and possibly significantly greater, amount during our 2008 fiscal year. The extent to which we will be called upon to contribute additional funds is determined in part by the majority vote of those stockholders party to the funding agreement. We may elect to terminate our participation in the funding agreement upon ten days' written notice to the administrative agent under the agreement. Upon termination, we would no longer be required to fund any amounts not already paid by us under the funding agreement, but we would lose all rights to participate under the funding agreement, including access to any additional work-product created after the date of termination. Additionally, if we elect to terminate our participation under the funding agreement, our portion of any proceeds from a favorable disposition of the litigation may be reduced. The outcome of this litigation is not now known, nor can it be reasonably predicted at this time.

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

On November 13, 2007, certain of our stockholders holding an aggregate of approximately 79% of our issued and outstanding common stock, approved an amendment to our Restated Certificate of Incorporation to (i) change our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc., (ii) increase the number of authorized shares of all classes of our capital stock, (iii) eliminate the classification and staggering of our Board of Directors, (iv) delete the provision restricting our ability to acquire common stock from certain of our stockholders holding 5% or more of our outstanding voting securities, (v) delete all supermajority voting requirements, (vi) delete the provision setting forth compromise procedures in the event of insolvency and (vii) delete immaterial provisions. Additionally, the same stockholders approved the adoption by our Board of Directors of the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan. In accordance with the relevant provisions of the Delaware General Corporation Law, the foregoing actions were approved by the stockholders pursuant to a written consent in lieu of a special meeting of stockholders.

The foregoing is merely a summary of those matters submitted to a stockholder vote during the fourth quarter of our fiscal year ended December 31, 2007, and is qualified in its entirety by the full text of our Definitive Information Statement on Schedule 14C, filed with the SEC on December 7, 2007, which is incorporated by reference in this Item 4 to our Annual Report on Form 10-KSB.

**PART II****Item 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities**

The following table sets forth the reported high and low sales prices of our common stock, for the fiscal quarters indicated, as reported on the on the over-the-counter bulleting board (“OTCBB”). During the indicated periods, our trading symbol on the OTCBB was “CTSC”, but it has since changed to “SFES”, effective February 11, 2008.

	Prices	
	High	Low
<b>2007</b>		
First Quarter	\$ 1.95	\$ 1.28
Second Quarter	2.20	1.55
Third Quarter	3.25	1.60
Fourth Quarter	5.00	2.95
<b>2006</b>		
First Quarter	\$ 2.70	\$ 2.00
Second Quarter	2.87	2.48
Third Quarter	2.65	1.72
Fourth Quarter	1.92	1.20

As of March 20, 2008, there were 172 record holders of our common stock, and we estimate that there are in excess of 3,000 beneficial owners of our common stock.

We paid no dividends or made any other distributions in respect of our common stock during our fiscal years ended December 31, 2007 and 2006, and we have no plans to pay any dividends or make any other distributions in the future.

In connection with our acquisition of SafeStitch LLC, we entered into a Note and Security Agreement with both The Frost Group, LLC, a Florida limited liability company whose members include Frost Gamma Investments Trust, a trust indirectly controlled by Dr. Phillip Frost, the largest beneficial holder of our common stock, as well as Dr. Jane H. Hsiao and Steven D. Rubin, two of our directors, and Jeffrey G. Spragens, our Chief Executive Officer and President and a director for \$4.0 million in total available borrowings. Under this credit facility, we may distribute stock dividends in respect of our common stock, but we may not pay cash dividends in respect of our common stock.

**EQUITY COMPENSATION PLAN INFORMATION**

Our 1996 Stock Option Plan authorized the grant of both incentive (“ISO”) and non-qualified stock options up to a maximum of 335,000 shares of our common stock to employees of SafeStitch (including officers and directors who are employees) and consultants to SafeStitch. The exercise price, term and vesting provision of each option grant was fixed by our Compensation Committee with the provision that the exercise price of an ISO may not be less than the fair market value of our common stock on the date of grant, and the term of an ISO may not exceed ten years. We did not grant any options under this plan during the years ended December 31, 2007 and 2006. As of December 31, 2007, there are no options available under the plan. This plan has been terminated, and no additional awards will be made under our 1996 Stock Option Plan.

Our Board of Directors and a majority of our stockholders approved the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan (the “2007 Plan”) on November 13, 2007, which is now our only compensation plan in effect. We have reserved a total of 2,000,000 shares of our common stock for issuance under the 2007 Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or our capital structure. As of December 31, 2007, no options to purchase shares of common stock had yet been granted under the 2007 Plan. A more detailed summary of the 2007 Plan is contained in Note D to our consolidated financial statements set forth under Item 7 to this Annual Report on Form 10-KSB. The full text of the 2007 Plan was filed with the SEC on December 7, 2007 as Annex B to our Definitive Information Statement on Schedule 14C, and is incorporated herein by reference.

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The following table provides information about our equity compensation plans as of December 31, 2007:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders(1)	—	—	2,000,000
Equity compensation plans not approved by security holders	88,667(2)	\$2.60(2)	—
Total	88,667(3)(4)	\$2.60	2,000,000

(1) SafeStitch Medical, Inc. 2007 Incentive Compensation Plan.

(2) On September 11, 2007, we issued to Dr. Stewart Davis, our COO and Secretary, an aggregate of 88,667 options (outside the 2007 Plan) to purchase our common stock at a strike price of \$2.60 per share. This grant was made in accordance with that certain employment letter agreement, dated May 16, 2007, by and between Dr. Davis and SafeStitch LLC, which we have since acquired, and in consideration for Dr. Davis' continued service as our COO and Secretary. 25% of such options were immediately exercisable with another 25% becoming exercisable on September 11th of each of 2008, 2009 and 2010; provided, however, that all options shall become immediately exercisable in the event of a change of control of SafeStitch.

(3) On March 18, 2008, we issued an aggregate of 95,500 options to purchase our common stock under the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, each at a strike price of \$3.10 per share. These options were issued as follows: each of our independent and non-employee directors, Kevin Wayne, Kenneth Heithoff, Dr. Jane Hsiao, Steven Rubin and Richard Pfenninger, received 10,000 options, except that Dr. Hsiao, Mr. Rubin and Mr. Pfenninger received an additional 5,000, 1,000 and 1,000 options, respectively, for their respective service as chairman of our Board of Directors, Compensation Committee and Audit Committee; and the remaining 33,500 options were issued to new and existing employees and consultants, including 5,000 to Jeffrey G. Spragens, our President and Chief Executive Officer, and 10,000 to Dr. Stewart B. Davis, our Chief Operating Officer and Secretary.

(4) On March 24, 2008, we issued to new employees an aggregate of 53,000 options to purchase our common stock under the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, each at a strike price of \$3.00 per share.

### Item 6. Management's Discussion and Analysis or Plan of Operation.

*This Annual Report on Form 10-KSB contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those set forth below as well as those contained in "Item 1A — Risk Factors" of this Annual Report on Form 10-KSB. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safeharbor provisions of PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.*

#### Overview

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

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We have utilized our expertise in intraperitoneal surgery to test certain of our devices in *in vivo* and *ex vivo* animal trials and *ex vivo* human trials, and with certain products, in limited *in vivo* human trials, and we intend to rapidly, efficiently and safely move into clinical trials for our devices that are utilized in surgery for the treatment of obesity, GERD and esophageal obstructions and for the treatment and diagnosis of Barrett's Esophagus. Clinical trials for certain product candidates should begin in 2008.

Immediately prior to the consummation of our acquisition of SafeStitch LLC, a privately held Virginia limited liability company, on September 4, 2007, we had no business operations. Under the name Cellular Technical Services Company, Inc. (the Company, during the time so named, "CTSC"), we previously developed, marketed, distributed and supported a diversified mix of products and services for the telecommunications industry. On November 9, 2002, CTSC ceased its product development efforts, and on December 11, 2002 adopted a plan to wind down all operations related to its historical business, which process it completed in December 2005. Between that time and the consummation of our acquisition of SafeStitch LLC, all of our staff and administrative positions were eliminated. As such, immediately prior to the Share Exchange, we were a company with primarily only cash and cash equivalents and no operations.

After the termination of CTSC's operations, the Company's board of directors and management focused on redeploying the remaining residual assets of CTSC and the board of directors had been studying the potential strategic directions for and identifying potential business opportunities. The Company's objective was to redeploy its assets and actively pursue new business opportunities.

On April 12, 2005, CTSC completed its sale of 2.1 million shares of our common stock, constituting approximately 45% our then issued and outstanding shares of capital stock, on a fully diluted basis, to a small group of investors led by Frost Gamma Investments Trust, a trust controlled by Dr. Phillip Frost, a director of CTSC until the Share Exchange. Dr. Jane Hsiao and Richard C. Pfenniger, Jr., directors of CTSC both before and after the Share Exchange, also led the investment. The stock sale was made pursuant to the terms of a securities purchase agreement and letter agreement, each dated April 12, 2005. The investors paid CTSC an aggregate purchase price of \$1.575 million, or \$0.75 per share. CTSC also agreed to appoint three designees of the investors to its board of directors.

On September 4, 2007, we completed the acquisition of SafeStitch LLC pursuant to a Share Transfer, Exchange and Contribution Agreement, dated as of July 25, 2007 (referred to as the "Share Exchange Agreement"), by and among us, SafeStitch LLC and the members of SafeStitch LLC.

At the closing of the transaction contemplated by the Share Exchange Agreement (the "Share Exchange"), we issued an aggregate of 11,256,369 shares of our common stock to the former members of SafeStitch LLC in exchange for all of their membership interests in SafeStitch LLC. We also granted warrants to purchase a total of 805,521 shares of our common stock to The Frost Group, LLC and Jeffrey G. Spragens in connection with a line of credit of up to \$4 million that was provided to us simultaneously with the closing by The Frost Group, LLC and Jeffrey G. Spragens. The warrants have a ten year term and an assumed exercise price of \$0.25 per share of common stock. Dr. Phillip Frost has a controlling interest in The Frost Group LLC and is the largest beneficial holder of our shares of common stock. Dr. Jane Hsiao and Steven D. Rubin, two of our directors, are also members of The Frost Group, LLC. Jeffrey G. Spragens is our Chief Executive Officer and President and a director. Frost Gamma Investments Trust, Dr. Phillip Frost, Dr. Jane Hsiao, Steven D. Rubin and Jeffrey G. Spragens were also beneficial owners of membership interests in SafeStitch LLC. We incurred customary acquisition related costs in connection with the share exchange.

In January 2008, we changed our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc., and, on February 11, 2008, our trading symbol on the OTCBB changed from "CTSC" to "SFES". We intend to apply for the listing of our common stock on the American Stock Exchange during our 2008 fiscal year.



***Critical Accounting Policies and Estimates***

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, product returns, bad debts, inventories, investments, including the carrying value of our long term investment, property and equipment, intangible assets, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note B in the Notes to the Consolidated Financial Statements set forth in Item 7 of this Annual Report on Form 10-KSB for the year ended December 31, 2007. Actual results may differ from these estimates under different assumptions or conditions.

***Accounting Treatment***

Our acquisition of SafeStitch in accordance with the Share Exchange Agreement has been accounted for as a recapitalization of SafeStitch. For accounting purposes, SafeStitch is treated as the continuing reporting entity. Because we did not have an operating business, the transaction is not accounted for as a business combination. Instead, the transaction is accounted for as a recapitalization of SafeStitch and the issuance of stock by SafeStitch (represented by our outstanding shares of common stock) at the book values of our assets and liabilities, which approximates fair value with no goodwill or other intangibles recorded.

***Treatment of Warrants and Options***

SafeStitch did not have any outstanding warrants or options and no warrants or options were assumed by CTS as a result of the Share Exchange, except warrants issued in connection with the line of credit described above.

***Amendment to Certificate of Incorporation***

On January 8, 2008, we filed our Amended and Restated Certificate of Incorporation (our "Certificate of Incorporation") with the Secretary of State of the State of Delaware. The following summarizes the amendments to our Certificate of Incorporation, which became effective on January 8, 2008:

- we changed our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc., which more appropriately describes our business;
- we increased the aggregate number of shares of all classes of capital stock that we may issue from 35,000,000 to 250,000,000, which is composed of 225,000,000 shares of common stock, par value \$0.001 per share, and 25,000,000 shares of preferred stock, par value \$0.01 per share;
- we eliminated the staggering of our Board of Directors with the effect that all directors on the Board comprise a single class; therefore, all positions on our Board of Directors may be subject to an election in any given year;
- we provided that any vacancy occurring on our Board of Directors, including any vacancy created by reason of an increase in the number of directors, shall be filled for the unexpired term by the concurring vote of a majority of the directors then in office, whether or not a quorum, and any director so chosen shall hold office for the remainder of the full term of the director whose departure caused the vacancy and until such director's successor shall have been elected and qualified;

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- in order that we have maximum flexibility to acquire our own capital stock, we eliminated the restrictive provision that had been contained in our Certificate of Incorporation that required the affirmative vote of the holders of a majority of the total number of the outstanding shares of our common stock prior to our purchase of any common stock from (i) any person who or which is the beneficial owner, directly or indirectly, of five percent (5%) or more of the voting power of our outstanding common stock and (ii) who or which has beneficially owned such common stock for less than two years;
- we eliminated all supermajority voting provisions contained in our Certificate of Incorporation, which required a two-thirds vote of stockholders to change the structure of the Board of Directors, remove a Director, amend our bylaws or amend those provisions set forth in our Certificate of Incorporation which require such supermajority approval. Following the amendment, a simple majority is now sufficient to take the foregoing actions;
- in an attempt to address instances of financial hardship, our Certificate of Incorporation contained a provision providing for certain compromise procedures in the event it became necessary for us to reorganize or restructure. This provision, which would have involved the intervention of a Delaware court of equity, could have potentially bound the Company or otherwise limited our options in the event of financial difficulty. As amended, our Certificate of Incorporation no longer contains such a provision, which allows us maximum flexibility should financial hardship ever arise; and
- we deleted non-material provisions from our Certificate of Incorporation, including the name of our original incorporator.

Overall, we believe that our Certificate of Incorporation, as amended, including the authorization of additional share capital, will enhance our ability to grow our business and respond to potential mergers and acquisitions. We cannot assure you, however, that the several amendments to our Certificate of Incorporation will result in our effecting a merger or acquisition or otherwise make us more attractive to acquisition candidates or potential investors.

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

Our losses totaled \$4,177,000 from September 15, 2005 (inception) through December 31, 2007. Such losses included \$3,041,000 and \$1,059,000 for the years ended December 31, 2007 and 2006, respectively. At December 31, 2007, we had an accumulated deficit of \$4.2 million. Since we do not generate revenue from any of our product candidates, we expect to continue to generate losses in connection with the continual clinical development of our products and development activities relating to our technologies. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe our operating losses are likely to be substantial over the next several years.

### ***Year Ended December 31, 2007 Compared to Year Ended December 31, 2006***

Research and Development expenses were \$1,636,000 for the year ended December 31, 2007 an increase of \$888,000 compared with the same period in 2006, resulting from an increase in the amount of research being performed, as we moved further into our research activities. We expect research and development expenses to continue to increase as we enter into a more advanced stage of clinical trials for our product candidates.

General and Administrative costs were \$1,135,000 for year ended December 31, 2007 an increase of \$897,000, related to the increase in staffing and operating costs and \$66,000 in stock-based compensation. General and administrative expense consists primarily of salaries and other related costs, including share-based compensation expense for persons serving as our executive, finance, accounting and administration personnel. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, and professional fees for legal and accounting services. We expect that our general and administrative expense will increase as we add additional personnel and continue to comply with the reporting and other obligations applicable to public companies.

Interest Income increased \$15,000 in the 2007 period due to higher invested cash balances.

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Interest expenses increased during the 2007 period due to the accrual of interest on members' loan balances.

### **Liquidity**

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since inception. Additionally, in connection with our involvement as a plaintiff in the True Position litigation, we incurred costs of approximately \$45,000 during our 2007 fiscal year, which reduced cash flow and will continue so long as we stay involved in the litigation. We do not expect to have any current source of revenues. To date, we have funded our operations primarily with proceeds from the private placement of stock and credit facilities available to us. However, our management believes that our cash balance as of December 31, 2007 of approximately \$0.6 million, together with our \$4.0 million line of credit is sufficient to fund our current cash flow requirements through at least the next twelve months. Our management has currently budgeted expenditures of approximately \$4.0 million for our 2008 fiscal year, which will fund the final development and initial marketing of three of our product candidates, as well as continuing research and development on our gastroplasty (GERD and obesity) and Barrett's devices.

### **Plan of Operations 2008**

Through the end of our 2008 fiscal year, we plan the following, although there is no assurance all of it will be completed:

- FDA Registration of standard and airway bite blocks.
- Continued product development of gastroplasty device for obesity and GERD.
- Manufacturing of gastroplasty devices for clinical trials and engineering (performance, validation) testing.
- Feasibility trial of gastroplasty device and commencement of multicenter US and international trials.
- Continued product development of Barrett's Excision Device.
- Final product development of smart dilator and application for FDA approval.
- Initial marketing and commercialization of standard and airway bite blocks and smart dilator.
- Institutional Review Board (IRB) clinical evaluation trials for standard and airway bite blocks and smart dilator.
- Early development efforts on hernia device and NOTES devices, of which we have existing intellectual property and licenses.

### **Future Funding Requirements**

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being a public company, including the costs of directors' and officers' insurance, investor relations programs and increased professional fees.

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We believe that our existing cash and cash equivalents and the \$4.0 million credit facility available to us will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions and the above-described Plan of Operations that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development, and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

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### **Item 7. Financial Statements**

The following financial statements of SafeStitch Medical, Inc. are included as required to be filed by Item 7 of Regulation S-B, under the Exchange Act.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**Board of Directors and Stockholders**

SafeStitch Medical, Inc

We have audited the accompanying consolidated balance sheet of SafeStitch Medical, Inc. (formerly known as Cellular Technical Services Company, Inc.) (a development stage company) (the "Company") as of December 31, 2007, and the related statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2007 and 2006 and for the period from September 15, 2005 (inception) through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our 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 the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2007 and the consolidated result of their operations and cash flows for years ended December 31, 2007 and 2006 and for the period from September 15, 2005 (inception) through December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner LLP  
New York, New York  
March 26, 2008

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

	December 31, 2007
<b>CURRENT ASSETS</b>	
Cash and cash equivalents	\$ 631
Prepaid Expenses	99
Total Current Assets	730
<b>FIXED ASSETS</b>	
Property and equipment, net	196
<b>OTHER ASSETS</b>	
Security Deposits	56
Deferred Finance Cost	1,702
Total Other Assets	1,759
LONG-TERM INVESTMENT, net of valuation adjustment of \$1,754	0
<b>TOTAL ASSETS</b>	<b>\$ 2,684</b>
<b>CURRENT LIABILITIES</b>	
Accounts payable and accrued liabilities	\$ 253
Total Current Liabilities	253
Shareholder Loans	10
Commitments and contingencies (Note I)	
<b>STOCKHOLDERS' EQUITY</b>	
Preferred Stock, \$.01 par value per share, 25,000,000 shares authorized, none issued and outstanding (effective January 8, 2008)	0
Common Stock, \$.001 par value per share, 225,000,000 shares authorized, 16,093,016 shares issued and outstanding (effective January 8, 2008)	16
Additional Paid-in Capital	6,582
Deficit accumulated during the development stage	(4,177)
Total Stockholders' Equity	2,421
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 2,684</b>

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

**SAFESTITCH MEDICAL, INC.**  
**(A Developmental Stage Company)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in 000s, except share and per share amounts)

	Year Ended December 31,		September 15, 2005 (Inception) to December 31, 2007
	2007	2006	
REVENUES			
COSTS AND EXPENSES			
Research & Development	\$ 1,636	\$ 739	\$ 2,451
General and administrative	1,135	340	1,475
Total Costs and Expenses	2,771	1,079	3,926
LOSS FROM OPERATIONS	(2,771)	(1,079)	(3,926)
OTHER INCOME (NET)			
INTEREST INCOME	34	19	53
AMORTIZATION OF FINANCE COSTS	(283)		(283)
INTEREST EXPENSE	(21)		(21)
NET LOSS	<u>\$ (3,041)</u>	<u>\$ (1,060)</u>	<u>\$ (4,177)</u>
BASIC SHARE DATA:			
NET LOSS	<u>\$ (0.19)</u>	<u>\$ (0.07)</u>	
DILUTED SHARE DATA			
NET LOSS	<u>\$ (0.19)</u>	<u>\$ (0.07)</u>	
WEIGHTED AVERAGE SHARES OUTSTANDING:	<u>16,093,000</u>	<u>16,050,000</u>	

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



**SAFESTITCH MEDICAL, INC.****(A Developmental Stage Company)****Statement of Stockholder's Equity for the period September 15, 2005 (inception) through December 31, 2007**

(in 000s)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
<b>Inception-September 15, 2005</b>							<u>—</u>
Capital Contributed -					\$ 1		\$ 1
Net Loss						\$ (76)	(76)
<b>Balance at December 31, 2005</b>					1	(76)	(75)
Capital Contributed -			11,256	\$ 11	1,493		1,504
Net Loss						(1,060)	(1,060)
<b>Balance at December 31, 2006</b>	<u>—</u>	<u>\$ —</u>	<u>11,256</u>	<u>\$ 11</u>	<u>\$ 1,494</u>	<u>\$ (1,136)</u>	<u>\$ 369</u>
Exercise of options (CTS)- September 23, 2007 at \$0.79 per share			42	0	35		35
Stock-Based Compensation- September 4, 2007					77		77
Issuance shares in recapitalization - September 4, 2007 at \$0.64 per share			4,795	5	3,078		3,083
SafeStitch expenses associated with recapitalization					(156)		(156)
Stock based compensation					65		65
Warrants issued in connection with credit facility-September 4, 2007 at \$2.46 per share					1,985		1,985
Rule 16 payment received					4		4
Net loss						(3,041)	(3,041)
<b>Balance at December 31, 2007</b>	<u>—</u>	<u>\$ —</u>	<u>16,093</u>	<u>\$ 16</u>	<u>\$ 6,582</u>	<u>\$ (4,177)</u>	<u>\$ 2,421</u>

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

**SAFESTITCH MEDICAL, INC.**  
**(A Developmental Stage Company)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in 000's)

	Year Ended		September 15, 2005 (Inception) to December 31, 2007
	2007	2006	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (3,041)	\$ (1,060)	\$ (4,177)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of Deferred Finance Costs	283		283
Stock-Based Compensation Expense	142		142
Depreciation	4		4
(Increase) in other current assets	(79)		(79)
(Increase) in other assets	(56)		(56)
Increase (Decrease) in accounts payable and accrued liabilities	(199)	153	(32)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,946)</b>	<b>(907)</b>	<b>(3,915)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Net cash provided in connection with the acquisition of SafeStitch LLC	3,192		3,192
Purchase of equipment	(200)		(200)
Payment received under Rule 16b	4		4
<b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>	<b>2,996</b>	<b>0</b>	<b>2,996</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Capital Contributions		1,430	1,431
Shareholders Loans			84
Exercise of Options	35		35
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>35</b>	<b>1,430</b>	<b>1,550</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>85</b>	<b>523</b>	<b>631</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>546</b>	<b>23</b>	<b>0</b>
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<b>\$ 631</b>	<b>\$ 546</b>	<b>\$ 631</b>
Supplemental disclosure of non cash activities:			
Shareholder loan contributed to capital	\$ 74		\$ 74

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

**SAFESTITCH MEDICAL, INC.**

**(A Developmental Stage Company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE A — BASIS OF PRESENTATION AND LIQUIDITY:**

Cellular Technical Services Company, Inc., (“Cellular”) a non-operating public company was incorporated in 1988 as NCS Ventures Corp. under the laws of the State of Delaware.

On July 25, 2007 Cellular entered into a Share Transfer, Exchange and Contribution Agreement with SafeStitch LLC (“SafeStitch”) a limited liability company formed in Virginia on September 15, 2005. On September 4, 2007, Cellular acquired all of the members’ equity of SafeStitch in exchange for 11,256,369 shares of its common stock, which represented a majority of outstanding shares after the date of acquisition. For accounting purposes, the acquisition has been treated as a recapitalization of SafeStitch, with SafeStitch as the acquirer (reverse acquisition). The historical financial statements prior to September 4, 2007 are those of SafeStitch, which began operations on September 15, 2005. The accompanying financial statements give retroactive effect to the recapitalization as if it had occurred on September 15, 2005 (inception). Effective January 8, 2008 Cellular changed its name to SafeStitch Medical, Inc. (“Medical” or “the Company”)

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

The accompanying financial statements have been prepared assuming that it will continue as a going concern. For the period from September 15, 2005 (inception) through December 31, 2007, the Company has accumulated a deficit of \$4,177,000 and has not generated positive cash flows from operations. The Company has been dependent upon equity financing and advances from stockholders to meet its obligations and sustain operations. The Company’s efforts had been principally devoted to the development of its technologies and commercializing its products. Management believes that based upon its current cash position, its budget for its business operations through December 31, 2008, an outstanding line of credit of \$4.0 million from The Frost Group LLC and the Company’s President and CEO, Jeffrey G. Spragens and monitoring its discretionary expenditures; the Company will be able to continue operations through December 31, 2008. The Company’s ability to continue as a going concern is ultimately dependent upon achieving profitable operations and generating sufficient cash flows from operations to meet future obligations.

**NOTE B — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

[1] Consolidation:

The consolidated financial statements include the accounts of the Company and its subsidiaries Isis Tele-Communications, Inc. and SafeStitch LLC. All inter-company accounts and transactions have been eliminated in consolidation.

[2] Cash and cash equivalents:

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

[3] Property and Equipment:

Property and equipment are carried at cost less accumulated depreciation. Major additions and improvements are capitalized, while maintenance and repairs that do not extend the lives of the assets are expensed.

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Gain or loss, if any, on the disposition of fixed assets is recognized currently in operations. Depreciation is calculated primarily on a straight-line basis over estimated useful lives of the assets.

### [4] Research and development:

Substantially all research and development activities are outsourced (see Note J). Research and development costs represent principally clinical trials and manufacturing development expenses, which are charged to expense as incurred.

### [5] Patent costs:

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

### [6] Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions, such as useful lives of property and equipment, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

### [7] Stock-based compensation:

Commencing January 1, 2006, Medical has adopted Statement of Financial Accounting Standards (“SFAS”) No. 123R, “Share Based Payment” (“SFAS 123R”), which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values.

### [8] Fair value of financial instruments:

The carrying amounts of cash, accounts payable, and accrued expenses approximate fair value based on their short-term maturity. Shareholder loans are carried at cost since these are related parties.

### [9] Long-Term Investment

In accordance with SFAS No. 144, “Accounting for the impairment or Disposal of Long-Lived Assets”, the Company reviews the carrying values of its long-lived assets for possible impairment whenever events of changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less costs to sell.

### [10] Income taxes:

The Company follows the liability method of accounting for income taxes, as set forth in SFAS No. 109, “Accounting for Income Taxes”. SFAS No. 109 prescribes an asset and liability approach, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of the assets and liabilities. The Company’s policy is to record a valuation allowance against deferred tax assets, when the deferred tax asset is not recoverable. The Company considers estimated future taxable income or loss and other available evidence when assessing the need for its deferred tax valuation allowance.

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### [11] Comprehensive income (loss):

SFAS No. 130, "Reporting Comprehensive Income (Loss)", requires companies to classify items of other comprehensive income (loss) in a financial statement. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive net loss is equal to its net loss for all periods presented.

### NOTE C — PROPERTY AND EQUIPMENT:

Machinery and equipment consist of the following (in thousands):

	<u>December 31, 2007</u>	<u>Estimated Useful lives</u>
Machinery and equipment	160	5 years
Furniture and fixtures	40	5 years
	00	
Accumulated depreciation and amortization	(4)	
	<u>\$196</u>	

Depreciation and amortization expense for the years ended December 31, 2007 and 2006 was \$ 4 and \$ 0, respectively.

### NOTE D — LONG TERM INVESTMENT:

In November 1999, the Company invested in a one-year, \$1.0 million 10% convertible note of KSI, Inc. ("KSI"). The Company also received warrants to purchase KSI common stock in connection with this investment. All of the outstanding stock of KSI was acquired by TruePosition, Inc., a majority owned subsidiary of Liberty Media Corporation, ("Liberty Media") in August 2000. Prior to the acquisition, the convertible note was exchanged for KSI common stock. The Company exercised warrants and purchased additional KSI common stock for approximately \$754,000. The Company's investment in KSI common stock was exchanged for TruePosition common stock on the date of the acquisition. The Company accounts for the investment in TruePosition using the cost method. In December 2002 the Company received certain valuation information from TruePosition, indicating a range of values for TruePosition. Based upon its review of available information and communications with Liberty Media, the Company concluded there had been an other-than-temporary decline in estimated fair value of its investment, and reduced the recorded carrying value of this investment from its cost basis of \$1,754,000 to zero, representing its best estimate of the current fair value of the Company's investment in the net equity of TruePosition. TruePosition's operations have required significant infusions of cash by Liberty Media to date, and have not generated significant revenues. The Company's investment in TruePosition common stock has been diluted by these advances, which were converted to preferred stock in late 2002. It is possible that in the future the Company may receive proceeds from sale of this investment, but no such amount can be estimated at this time.

### NOTE E — STOCK BASED PAYMENTS:

Medical's 1996 Stock Option Plan authorizes the grant of both incentive ("ISO") and non-qualified stock options up to a maximum of 335,000 shares of Medical's Common Stock to employees (including officers and directors who are employees) of and consultants to Medical. The exercise price, term and vesting provision of each option grant is fixed by the Compensation Committee with the provision that the exercise price of an ISO may not be less than the fair market value of Medical's Common Stock on the date of grant, and the term of an ISO may not exceed ten years. Medical has not granted any options under this plan during the years ended December 31, 2007 and 2006. The plan expired and no new options may be granted under the plan.

As of the date of the share exchange, all options issued to former officers and directors, with exercise prices in excess of the current share price were cancelled in exchange for the issuance of 2,000 shares per person, or, in total, 6,000 shares of common stock of the Company. The Company recognized compensation expense of \$77,000 for the fair value of the shares vested.

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On November 13, 2007, the Board of Directors and a majority of the stockholders of the Company approved the SafeStitch Medical Inc., 2007 Incentive Compensation Plan (the "2007 Plan"). Under the 2007 Plan, which is administered by a compensation committee, the Company is allowed to grant options, stock appreciation rights, restricted or deferred stock grants employees, officers, directors, consultants and vendors to purchase up to 2,000,000 shares of the Company's common stock, fully reserved for future issuance. The exercise price of options or stock appreciation rights may not be less than fair market value of Company's share at the date of grant and within any 12 months period, no person can receive options or stock appreciation rights for more than one million shares. Additionally, no stock options or stock appreciation rights granted under the plan may have a term exceeding ten years.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets. We elected to adopt the alternative method of calculating the historical pool of windfall tax benefits as permitted by FASB Staff Position (FSP) No. SFAS 123R-3, "Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards." This is a simplified method to determine the pool of windfall tax benefits that is used in determining the tax effects of stock compensation in the results of operations and cash flow reporting for awards that were outstanding as of the adoption of SFAS 123R.

The following summarizes the activity of the Medical's stock options for the year ended December 31, 2007:

	Shares (in 000s)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2007	173	\$ 6.20	4.75	
Granted	89	2.60	9.95	
Exercised	(42)	0.79		
Canceled or expired	(131)	7.96		
Outstanding at December 31, 2007	89	\$ 2.60	9.96	\$ 177,000
Exercisable at December 31, 2007	22	\$ 2.60	9.96	\$ 59,000
Vested and expected to vest at December 31, 2007	59	\$ 2.60	9.96	\$ 118,000

The Company granted 88,667 options, outside of plans, during the year ended December 31, 2007, all of which had an exercise price of \$2.60. The Company determined the estimated aggregate fair value of these options on the grant date to be \$195,954 based on the Black-Scholes valuation model using the following assumptions: expected volatility of 82%, dividend yield of 0%, risk free interest rate of 4.88% and expected life of 10 years. Stock option compensation expense was \$66,000 for the year and is included in general and administrative expense.

Of the 88,667 options granted outside of plans during our 2007 fiscal year, 25% of such options were vested as of December 31, 2007. A summary of the status of the Company's nonvested options and changes during the year ended December 31, 2007 is presented below.

	Stock Options (in 000s)	Weighted Average Grant Date Fair Value
Non-Vested at January 1, 2007	0	\$ —
Options Granted	89	\$2.21
Options Vested	22	\$2.21
Non-Vested at December 31, 2007	67	\$2.21

At December 31, 2007, there was \$130,000 of total unrecognized compensation cost related to non-vested employee and director share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 2.66 years.

The weighted-average fair values at date of grant for options granted during the year ended December 31, 2007 were \$2.21.

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The intrinsic value of options exercised during the year ended December 31, 2007 was \$77,000.

### **NOTE F — CREDIT FACILITY:**

In connection with the acquisition of SafeStitch, Medical entered into a Note and Security Agreement with both The Frost Group, LLC, a Florida limited liability company whose members include Frost Gamma Investments Trust, a trust indirectly controlled by Dr. Phillip Frost, the largest beneficial holder of the issued and outstanding shares of common stock of Medical, as well as Dr. Jane H. Hsiao and Steven D. Rubin, two of the Company's directors, and Jeffrey G. Spragens, Medical Chief Executive Officer and President and a director for \$4 million in total available borrowings, \$3.9 million from The Frost Group, LLC and \$100,000 from Mr. Spragens. The credit facility has been granted for 28 months and bears interest on outstanding borrowings under the line of credit at a 10% annual rate.

The Company granted a security interest in all presently existing and hereafter acquired or arising collateral in order to secure prompt, full and complete payment of the amounts due under the Credit Facility. The collateral includes all assets of the Company inclusive of intellectual property (patents, patent rights, trademarks, service marks, etc.).

As a part of the credit facility arrangements, Medical granted warrants to purchase 805,521 shares of our common stock to The Frost Group, LLC and Mr. Spragens. The fair value of the warrants were determined to be \$1,984,691 on the grant date based on the Black-Scholes valuation model using the following assumptions: expected volatility of 82%, dividend yield of 0%, risk free interest rate of 4.88% and expected life of 10 years. The fair values of the warrants were recorded as deferred financing cost and will be amortized over the life of the credit facility. Amortization expenses of deferred financing cost were \$283,083 for the year ended December 31, 2007.

### **NOTE G — CAPITAL TRANSACTIONS:**

As described in Note A, on September 4, 2007, Medical acquired all of the member's equity of SafeStitch in exchange for the issuance of 11,256,369 shares of its common stock. For accounting purposes the transaction has been treated as a recapitalization of SafeStitch and all membership interests of SafeStitch were eliminated, ordinary shares received in exchange were recorded at par value and the difference between membership interest and the value of the ordinary shares received was recorded to additional paid-in capital to effect the transaction as of the beginning of the year. Additionally, as of the date of the transaction, net assets of Cellular, its ordinary shares and additional paid-in capital were recorded to reflect the transaction. SafeStitch incurred \$155,855 of transaction expenses, which were recorded as a reduction of additional paid-in capital.

### **NOTE H — BASIC AND DILUTED NET LOSS PER SHARE:**

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options and warrants. In computing diluted net loss per share for the year ended December 31, 2007 and 2006, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants is anti-dilutive.

Potential common shares not included in calculating diluted net loss per share are as follows (in 000s):

	<u>December 31, 2007</u>	<u>December 31, 2006</u>
Stock options	89	173
Stock warrants	806	0
Total	<u>895</u>	<u>173</u>

**NOTE I — COMMITMENTS AND CONTINGENCIES**

The Company is obligated under various operating lease agreements for office space. Generally, the lease agreements require the payment of base rents plus escalations for increases in building operating costs and real estate taxes. Rental expense under operating leases amounted to \$23,675 and \$4,145 for the years ended December 31, 2007 and December 31, 2006, respectively.

At December 31, 2007, the Company was obligated under non-cancellable operating leases to make future minimum lease payments as follows:

<u>Year Ending December 31,</u>	
2008	\$119,747
2009	99,763
2010	99,763
2011	99,763
2012	99,761
Thereafter	0
	<u>\$518,797</u>

We are presently a plaintiff in a securities fraud and appraisal action in respect of our ownership of 191,118 shares of common stock of True Position, Inc., a Delaware corporation (referred to as “True Position”). This action was filed November 13, 2007 in the United States District Court for the District of Connecticut, and we and other plaintiffs party to the suit seek damages and other relief totaling \$80 million.

In August 2007, we were informed that that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of True Position’s outstanding capital stock, was being merged into True Position. As a result of the merger, all of the issued and outstanding shares of common stock of True Position were cancelled, and True Position’s minority stockholders, including ourselves, became entitled to receive \$3.5116 in cash in exchange for each share held. We and other minority stockholders considered that the consideration payable in respect of our shares under the merger was not representative of the true value of our shares of True Position stock.

We have joined with certain other minority stockholders of True Position in bringing the aforementioned appraisal and securities fraud action, and, on August 10, 2007, we entered into a joint shareholder litigation governance and funding agreement (referred to as the funding agreement) with such stockholders. Under the funding agreement, we have agreed to fund a portion of the litigation expenses in connection with the appraisal and securities fraud action. To date, we have contributed approximately \$45,000, and we anticipate that we will be called upon to fund at least a similar, and possibly significantly greater, amount during our 2008 fiscal year. The extent to which we will be called upon to contribute additional funds is determined in part by the majority vote of those stockholders party to the funding agreement. We may elect to terminate our participation in the funding agreement upon ten days’ written notice to the administrative agent under the agreement. Upon termination, we would no longer be required to fund any amounts not already paid by us under the funding agreement, but we would lose all rights to participate under the funding agreement, including access to any additional work-product created after the date of termination. Additionally, if we elect to terminate our participation under the funding agreement, our portion of any proceeds from a favorable disposition of the litigation may be reduced. The outcome of this litigation is not now known, nor can it be reasonably predicted at this time.

**NOTE J — NEW ACCOUNTING PRONOUNCEMENTS**

In September 2006, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 157, Fair Value Measurements, or SFAS 157, which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 with early adoption permitted; in November 2007, the FASB agreed to defer the effective date



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of SFAS 157 for one year for all nonfinancial assets and nonfinancial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis. Generally, the provisions of this statement should be applied prospectively as of the beginning of the fiscal year in which this statement is initially applied. We have determined that the adoption of SFAS 157 will not have a material effect on our consolidated financial statements.

In February 2007, FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities- including an amendment of FASB Statement 115”, (“SFAS 159”). This statement provides companies with an option to report selected financial assets and liabilities at fair value. This statement is effective for fiscal years beginning after November 15, 2007 with early adoption permitted. We have determined that the adoption of SFAS 159 will not have a material affect on our consolidated financial position, results of operations, cash flows or financial statement disclosures.

In December 2007, the FASB issued FAS No. 160, “*Noncontrolling Interests in Consolidated Financial Statements-an amendment of ARB No. 51*”. FAS No. 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. FAS No. 160 is effective for the Company in its fiscal year beginning January 1, 2009. The Company is currently evaluating the impact of FAS No. 160 on its consolidated financial position and results of operations.

In December 2007, the FASB issued FAS No. 141 R “*Business Combinations*”. FAS No. 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree. FAS No. 141R also provides guidance for recognizing and measuring the goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. FAS No. 141R is effective for the Company in its fiscal year beginning January 1, 2009. While the Company has not yet evaluated this statement for the impact, if any, that FAS No. 141R will have on its consolidated financial position and results of operations, the Company will be required to expense costs related to any acquisitions after September 30, 2009.

### **NOTE K — AGREEMENT WITH CREIGHTON UNIVERSITY**

On May 26, 2006, SafeStitch entered into an exclusive license and development agreement with Creighton University granting us a worldwide exclusive (even as to the university), with rights to sublicense, license to all our product candidates and associated know-how, including the exclusive right to manufacture, use and sell the product candidates.

During such time as we sell any product licensed under this agreement, we are obligated to pay Creighton University, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from such sales, less certain amounts, including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The agreement does not provide for minimum royalties.

We have agreed to invest in the aggregate, at least \$2.5 million over 36 months, beginning May 26, 2006, towards development of any licensed product, not including the first \$150,000 of costs related to the prosecution of patents, which we have done and SafeStitch has to pay to Creighton University 20 percent of its research and development expenditures as reimbursement for use of Creighton University’s facilities.

Our failure to do so would have resulted in all rights in the licensed patents and know-how reverting back to the university. Through December 31, 2007, we had invested \$2,709,183 in the licensed products, inclusive of our costs to date relating to prosecution of patents. Pursuant to the agreement, we are entitled to exercise our own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion or other commercial exploitation of any licensed products, provided that if we have not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the agreement or the date such technology is disclosed to and accepted by us, then the licensed patent and associated know-how shall revert back to the university, with no rights retained by us, and the university will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless we purchase one year extensions.

**NOTE L — INCOME TAXES**

The Company accounts for income taxes using the asset and liability method described in SFAS No. 109, “Accounting For Income Taxes,” the objective of which is to establish deferred tax assets and liabilities for the temporary differences between the financial reporting and the tax bases of the Medical’s assets and liabilities at enacted tax rates expected to be in effect when such amounts are realized or settled. A valuation allowance related to deferred tax assets is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. As a result of the share exchange transaction on September 4, 2007 with SafeStitch, LLC our net operating losses for Medical may be limited under Section 382 of the Internal Revenue Code due to a more than 50% change in ownership over a three year period.

At December 31, 2007, we have approximately \$561,000 of net operating loss carryforwards to offset future federal taxable income and approximately \$85,000 of research and development tax credit carryforwards available to offset future federal income tax, subject to limitations for alternative minimum tax.

The net operating loss and research and development credit carryforwards expire in 2027 and 2027, respectively.

The deferred federal tax asset, which amounted to \$561,000 at December 31, 2007, has been offset by a valuation allowance against the entire benefit due to management’s uncertainty regarding the future profitability of our Company. The valuation allowance has been increased by \$561,000 in 2007.

The difference between income taxes at the statutory federal income tax rate and income taxes reported in the statements of operations are attributable to the following:

	<u>December 31, 2007</u>
Income tax benefit at the federal statutory rate	34.00%
State and local income taxes, net of effect on federal taxes	3.63
Increase in valuation allowance	<u>(37.63)</u>
Provision for income tax	<u>0%</u>

The deferred tax asset at December 31, 2007 consists of the following:

	<u>2007</u>
Net operating loss carryforward	\$ 423,000
Research and development credit carryforward	85,000
Stock-based compensation	<u>53,000</u>
	561,000
Less: Valuation allowance	<u>(561,000)</u>
Net deferred tax asset	<u>\$ 0</u>

For comparative purposes, the following table shows the proforma effect as if SafeStitch was a C-Corp from inception.

The deferred tax asset at December 31, 2007 and 2006 consists of the following:

	2007 Proforma	2006 Proforma
Net operating loss carryforward	\$ 4,177,000	\$ 1,136,000
Research and development credit carryforward	320,000	107,000
	<u>4,497,000</u>	<u>1,243,000</u>
Less: Valuation allowance	<u>(4,497,000)</u>	<u>(1,243,000)</u>
Net deferred tax asset	<u>\$ 0</u>	<u>\$ 0</u>

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At December 31, 2006, CTS had available for federal income tax purposes, net operating loss carryforwards of approximately \$54.1 million which expire through 2026, and research and development tax credits of approximately \$1.2 million that will expire through 2024. The Company has provided a valuation allowance of 100% of the net deferred tax asset related to the operating loss carryforwards and tax credits. Upon consummation of the share exchange with SafeStitch LLC, these net deferred tax assets along with net operating losses up to September 4, 2007 were forfeited in accordance with Section 382 of the Internal Revenue Code.

At December 31, 2006, CTS has AMT credits of \$53,000 to be utilized in future tax periods to the extent that the regular tax exceeds the AMT liability. Under Section 383 of the Internal Revenue Code, these AMT credits are forfeited due to change in control.

The Company adopted Financial Standards Board Interpretation No. 48 Accounting for Uncertainty in Income Taxes ("FIN 48") an interpretation of FASB Statement 109 ("SFAS 109") on January 1, 2007. The adoption of FIN48 did not have a material impact on our results or operations and financial position. At the adoption date of January 1, 2007, we did not have any unrecognized tax benefits.

Medical recognizes interest and penalties related to uncertain tax positions in general and administrative expense. As of December 31, 2007, the Company has not recorded any provisions for accrued interest and penalties related to uncertain tax positions.

Tax years 2003-2006 remain open to examination by the major taxing jurisdictions to which we are subject.

### **NOTE M — CONCENTRATION OF RISK**

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash. The Company maintains its cash at financial institutions it considers to be of high credit quality. Cash balances with any one institution may exceed federally insured amounts.

For the years ended December 31, 2007 and 2006, one vendor represented approximately 43% of Company's expenses.

### **NOTE N — SUBSEQUENT EVENTS**

On January 8, 2008, we changed our name from Cellular Technical Services Company, Inc. to SafeStitch Medical, Inc. On the same date, we increased the aggregate number of shares of all classes of capital stock that we may issue from 35,000,000 to 250,000,000, which is composed of 225,000,000 shares of common stock, par value \$0.001 per share, and 25,000,000 shares of preferred stock, par value \$0.01 per share

On March 10, 2008, we drew down \$1.0 million from our \$4.0 credit facility.

On March 18, 2008, we issued an aggregate of 95,500 options to purchase our common stock under the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, each at a strike price of \$3.10 per share. These options were issued as follows: each of our independent and non-employee directors, Kevin Wayne, Kenneth Heithoff, Dr. Jane Hsiao, Steven Rubin and Richard Pfenniger, received 10,000 options, except that Dr. Hsiao, Mr. Rubin and Mr. Pfenniger received an additional 5,000, 1,000 and 1,000 options, respectively, for their respective service as chairman of our Board of Directors, Compensation Committee and Audit Committee; and the remaining 33,500 options were issued to new and existing employees and consultants, including 5,000 to Jeffrey G. Spragens, our President and Chief Executive Officer, and 10,000 to Dr. Stewart B. Davis, our Chief Operating Officer and Secretary.

On March 24, 2008, we issued to new employees an aggregate of 53,000 options to purchase our common stock under the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, each at a strike price of \$3.00 per share.

Our principal corporate office is located at 4400 Biscayne Blvd, Suite 670, Miami, Florida. We rent this space from Frost Real Estate Holdings, LLC, which is a company controlled by Dr. Phillip Frost, our largest beneficial stockholder. We lease approximately 2,900 square feet under the lease agreement, which is for a five-year term that began on January 1, 2008, and requires annual rent of approximately \$91,000, which amount increases by approximately 4.5% per year.

**SAFESTITCH LLC**  
**(a development stage company)**

**FINANCIAL STATEMENTS**

**DECEMBER 31, 2006 and 2005**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Members  
SafeStitch LLC

We have audited the accompanying statements of financial position of SafeStitch LLC (a development stage company) (the “Company”) as of December 31, 2006 and 2005, and the related statements of operations, changes in members’ equity (deficit) and cash flows for the year ended December 31, 2006, and for the periods from September 15, 2005 (inception) through December 31, 2005 and December 31, 2006. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of SafeStitch LLC as of December 31, 2006 and 2005, and the results of their operations and their cash flows for the year ended December 31, 2006, and for the periods from September 15, 2005 (inception) through December 31, 2005 and December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner LLP  
New York, New York  
March 26, 2008

**SAFESTITCH LLC**  
(a development stage company)

**Statements of Financial Position**

	<u>December 31,</u>	
	<u>2006</u>	<u>2005</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 546,097	\$ 23,183
Total current assets	<u>\$ 546,097</u>	<u>\$ 23,183</u>
<b>LIABILITIES AND MEMBERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Loan from member	\$ 10,000	\$ 84,000
Accounts payable	<u>166,709</u>	<u>14,171</u>
Total current liabilities	<u>176,709</u>	<u>98,171</u>
<b>MEMBERS' EQUITY (DEFICIT)</b>		
Members' contributions	1,505,002	1,002
Deficit accumulated during development stage	<u>(1,135,614)</u>	<u>(75,990)</u>
Total members' equity (deficit)	<u>369,388</u>	<u>(74,988)</u>
	<u>\$ 546,097</u>	<u>\$ 23,183</u>

See notes to financial statements.

**SAFESTITCH LLC**  
(a development stage company)

**Statements of Operations**

	Year Ended December 31, 2006	September 15, 2005 (inception) Through December 31, 2005	September 15, 2005 (inception) Through December 31, 2006
Operating expenses:			
Research and development costs	\$ 738,593	\$ 76,068	\$ 814,661
General and administrative	<u>340,596</u>	<u>41</u>	<u>340,637</u>
Total operating expenses	<b>1,079,189</b>	76,109	1,155,298
Other income:			
Interest income	<u>19,565</u>	<u>119</u>	<u>19,684</u>
<b>Net loss</b>	<b><u>\$ (1,059,624)</u></b>	<b><u>\$ (75,990)</u></b>	<b><u>\$ (1,135,614)</u></b>

See notes to financial statements.

**SAFESTITCH LLC**  
(a development stage company)

**Statements of Changes in Members' Equity (Deficit)**

	<u>Members' Contributions</u>	<u>Deficit Accumulated During Development Stage</u>	<u>Total</u>
Contributions November 2005	\$ 1,002		\$ 1,002
Net loss for the period ended December 31, 2005		\$ (75,990)	(75,990)
Balance December 31, 2005	1,002	(75,990)	(74,988)
Contributions February - July 2006	1,430,000		1,430,000
Loan from a member reclassified to members' equity	74,000		74,000
Net loss for the period ended December 31, 2006		(1,059,624)	(1,059,624)
<b>Balance December 31, 2006</b>	<b><u>\$ 1,505,002</u></b>	<b><u>\$ (1,135,614)</u></b>	<b><u>\$ 369,388</u></b>

See notes to financial statements.



**SAFESTITCH LLC**  
(a development stage company)

**Statements of Cash Flows**

	Year Ended December 31, 2006	September 15, 2005 (inception) Through December 31, 2005	September 15, 2005 (inception) Through December 31, 2006
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,059,624)	\$ (75,990)	\$ (1,135,614)
Adjustments to reconcile net loss to net cash used in operating activities:			
Changes in:			
Accounts payable	<u>152,538</u>	<u>14,171</u>	<u>166,709</u>
Net cash used in operating activities	<u>(907,086)</u>	<u>(61,819)</u>	<u>(968,905)</u>
<b>Cash flows from financing activities:</b>			
Loan from member		84,000	84,000
Contributions from members	<u>1,430,000</u>	<u>1,002</u>	<u>1,431,002</u>
Net cash provided by financing activities	<u>1,430,000</u>	<u>85,002</u>	<u>1,515,002</u>
<b>Net increase in cash</b>	<b>522,914</b>	<b>23,183</b>	<b>546,097</b>
Cash - beginning	<u>23,183</u>		
<b>Cash - end</b>	<b>\$ <u>546,097</u></b>	<b>\$ <u>23,183</u></b>	<b>\$ <u>546,097</u></b>

During 2006, the managing member's loan of \$74,000 was reclassified as a members' contribution.

Interest and taxes paid during the year ended December 31, 2006 and period ended December 31, 2005 were nil.

See notes to financial statements.

**SAFESTITCH LLC**  
(a development stage company)

**Notes to Financial Statements**  
**December 31, 2006 and 2005**

**NOTE A — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

SafeStitch LLC (the “Company”) was formed as a limited liability company pursuant to Articles of Organization in the Office of Virginia State Corporation Commission on September 15, 2005 and commenced operations on December 21, 2005. The Company is a development stage company that was formed to finance, develop, market and license or sell medical devices that manipulate tissues for obesity, gastro esophageal reflux disease (“GERD”), Barrett’s Esophagus, esophageal obstructions, upper gastrointestinal bleeding, hernia formation and other intraperitoneal abnormalities through endoscopic and minimally invasive surgery pursuant to the license and development agreement with Creighton University (Note C).

Based on management plans, these financial statements have been prepared under the “going concern” assumption which presumes that the Company will continue its existence.

The Company does not expect to have any current source of revenues. However, management believes that as the result of the share exchange with CTSC (Note H), the Company will have sufficient resources to fund its current cash flow requirements through December 31, 2007.

**[1] Use of estimates:**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

**[2] Income taxes:**

No provision or benefit for income taxes has been included in these financial statements since taxable income or loss passes through to, and is reportable by, the members individually.

**[3] Cash and cash equivalents:**

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

**[4] Research and development costs:**

Research and development costs are expensed as incurred.

**NOTE B — CONSULTANTS**

The Company entered into agreements with various consultants to provide consulting services effective September 1, 2006. The consultants will receive compensation on an hourly rate for services performed for the Company. The consultants shall also be reimbursed all reasonable expenses incurred on behalf of the Company. The agreements had various term dates which expired in 2007 and, in October 2007, were renewed for one year periods. Termination of the agreements prior to the expiration can only be executed by the events stated in the agreements. As of December 31, 2006 and 2005, consultant fees totaled \$523,186 and \$0 and are included in research and development costs.

**SAFESTITCH LLC**  
(a development stage company)

**Notes to Financial Statements**  
**December 31, 2006 and 2005**

**NOTE C — LICENSE AND DEVELOPMENT AGREEMENT**

On May 26, 2006, the Company entered into an exclusive license and development agreement with Creighton University granting a worldwide exclusive license, with rights to sublicense, to all our product candidates and associated know-how, including the exclusive right to manufacture, use and sell the product candidates. In accordance with the agreement, Creighton University is entitled to 1.5 percent of the licensed products' net sales. In accordance with the license and development agreement with Creighton University, the Company is to invest, in aggregate, at least \$2,500,000 within 36 months of the execution of this agreement towards the development of the licensed product, including reimbursement of Creighton University's overhead expenses, related to the Company's use of its facilities and calculated as 20% of the Company's direct development expenditures. If the Company fails to meet its development obligations, all rights in the licensed patent rights and associated know-how shall revert back to Creighton University.

**NOTE D — DUE TO MEMBER**

As of December 31, 2005, the managing member advanced \$84,000 to the Company in addition to its initial capital contribution. During 2006, \$74,000 of this advance was reclassified as a capital contribution. The outstanding balance as of December 31, 2006 is \$10,000, which will be reclassified as a capital contribution in 2008.

**NOTE E — LEASE**

The Company entered into a lease agreement on May 31, 2006. The lease agreement has a two-year term which expires on May 31, 2008. The rental payments are \$346 per month and are due on the first day of each month. As of December 31, 2006, the Company paid \$3,959 in rental payments which is included in general and administrative expenses on the statement of operations.

Future minimum lease payments on the operating lease for the remainder of the lease term is:

December 31, 2007	\$4,158
2008	\$1,733

**NOTE F — CONCENTRATION OF CREDIT RISK**

The Company maintains its cash balances in one bank. The balances are insured by the Federal Deposit Insurance Corporation up to \$100,000. As of December 31, 2006, the uninsured portion of the cash balances held at the banks was \$446,097.

**SAFESTITCH LLC**  
(a development stage company)

**Notes to Financial Statements**  
**December 31, 2006 and 2005**

**NOTE G — NEW ACCOUNTING PRONOUNCEMENTS**

In September 2006, FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Earlier application is encouraged provided that the reporting entity has not yet issued financial statements for that fiscal year including financial statements for an interim period within that fiscal year. We have determined that the adoption of SFAS 157 will not have a material affect on our consolidated financial position, results of operations, cash flows or financial statement disclosures.

In February 2007, FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities- including an amendment of FASB Statement 115” (“SFAS 159”). This statement provides companies with an option to report selected financial assets and liabilities at fair value. This statement is effective for fiscal years beginning after November 15, 2007 with early adoption permitted. We have determined that the adoption of SFAS 159 will not have a material affect on our consolidated financial position, results of operations, cash flows or financial statement disclosures.

In December 2007, the FASB issued SFAS No. 141(R), “Business Combinations”. This statement replaces SFAS No. 141, Business Combinations. This statement retains the fundamental requirements in Statement 141 that the acquisition method of accounting (which Statement 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. This statement also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) will apply prospectively to business combinations for which the acquisition date is on or after Company’s fiscal year beginning January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, “Non-controlling Interests in Consolidated Financial Statements”. This statement amends ARB 51 to establish accounting and reporting standards for the non-controlling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The Company has not yet determined the impact, if any, that SFAS No. 160 will have on its consolidated financial statements. SFAS No. 160 is effective for the Company’s fiscal year beginning January 1, 2009.

**NOTE H — SUBSEQUENT EVENTS**

On September 4, 2007, Cellular Technical Services Company, Inc. (“CTSC”), a public company, acquired the Company pursuant to a Share Transfer, Exchange and Contribution Agreement, dated as of July 25, 2007 (referred to as the “Share Exchange Agreement”). The Share Exchange Agreement provided for the exchange of all issued and outstanding membership interests of the Company for 11,256,369 shares of CTSC’s common stock (the “Share Exchange”).

**NOTE H — SUBSEQUENT EVENTS (CONTINUED)**

The Share Exchange will be accounted for as a recapitalization of the Company pursuant to the Share Exchange Agreement. For accounting purposes, the Company is treated as the continuing reporting entity. Because the members of the Company end up with control of CTSC, the transaction would normally be considered a purchase by the Company. However, since CTSC is not a business, the transaction is not a business combination. Instead the transaction is accounted for as a recapitalization of the Company and the issuance of stock by the Company (represented by the outstanding shares of CTSC) for the assets and liabilities of the CTSC.

In connection with the consummation of the Share Exchange, CTSC entered into a Note and Security Agreement with a company controlled by the largest beneficial holder of CTSC and certain of the Company's directors, and the Chief Executive Officer, President and a director, for a credit line of up to \$4 million. The loan will bear 10% interest on the outstanding balance. In connection with entering into this line of credit, the CTSC granted warrants to purchase a total of 805,521 shares of the CTSC's common stock to the holders of the Note with an exercise price of \$.25, computed as stockholders' equity of CTSC after taking into consideration all accrued and contingent liabilities at the closing of the Share Exchange plus \$1,250,000 divided by the number of fully-diluted shares of CTSC after the Share Exchange, and having a ten-year term.

**Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 8A(T). Controls and Procedures**

The Company's management, with the participation of its Chief Executive Officer and 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 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 a material weakness in our internal control over financial reporting. Our remediation efforts are discussed further below under Management's Report on Internal Control over Financial Reporting.

There were no changes in the Company's internal control over financial reporting during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

***Management's Report on Internal Control over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

For the period ended December 31, 2007, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, management (with the participation of our principal executive officer and principal financial officer) conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that, as of December 31, 2007, our internal control over financial reporting were not effective due to the material weakness disclosed below under "Changes in Internal Controls Over Financial Reporting and Management's Remediation Initiatives".

***Changes in Internal Controls Over Financial Reporting and Management's Remediation Initiatives***

As defined by Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended, a "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

We identified the following material weakness in our internal control over financial reporting as we did not have adequate controls in place to establish and maintain an effective control environment. The following deficiency in the control environment constituted a material weakness:

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We did not 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. This weakness was evidenced during the preparation of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007 by the need for significant revisions to our consolidated financial statements and related disclosures in the notes thereto.

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 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.

Although this material weakness over preparation of the financial statements and related disclosures existed at year end, it has been corrected, and the consolidated financial statements in this Annual Report on Form 10-KSB fairly present, in all material respects, our financial condition as of December 31, 2007 and 2006 and our results of operations and cash flows for the years ended December 31, 2007 and 2006, in conformity with GAAP.

While we have taken appropriate steps to remediate the material weakness described above, additional measures may be required. The effectiveness of our internal controls following our remediation efforts will not be known until we test those controls in connection with management's tests of internal control over financial reporting that will be performed after the close of our first fiscal quarter of 2008, ending March 30, 2008.

This annual report does not include an attestation report of our registered public accounting firm, Eisner LLP, regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

### **Item 8B. Other Information**

On March 26, 2008, our Board of Directors adopted the Amended and Restated Bylaws of SafeStitch Medical, Inc., a copy which is attached as Exhibit 3.2 to this Annual Report on Form 10-KSB and incorporated by reference herein.

## PART III

**Item 9. Directors, Executive Officers, Promoters and Control Persons and Corporate Governance; Compliance with Section 16(a) of the Exchange Act**

The following table sets forth information concerning our executive officers and directors, including their ages:

<u>Name</u>	<u>Age</u>	<u>Title</u>
Jane H. Hsiao, Ph.D., MBA	60	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
Kenneth Block	60	Chief Financial Officer
Dr. Kenneth Heithoff	64	Director
Richard Pfenniger, Jr.	52	Director
Steven D. Rubin	47	Director
Kevin Wayne	44	Director

**Jane H. Hsiao, Ph.D., MBA.** Dr. Hsiao has served as a director of the Company since April 2005 and became Chairman of the Board in September 2007. Dr. Hsiao also serves as the Vice Chairman and Chief Technology Officer of Opko Health, Inc. since May 2007. Dr. Hsiao is a member of The Frost Group, LLC, a private investment firm. Dr. Hsiao served as the Vice Chairman-Technical Affairs of IVAX from 1995 to January 2006, when Teva acquired IVAX. Dr. Hsiao served as IVAX's Chief Technical Officer since 1996, and as Chairman, Chief Executive Officer and President of IVAX Animal Health, IVAX's veterinary products subsidiary, since 1998. From 1992 until 1995, Dr. Hsiao served as IVAX's Chief Regulatory Officer and Assistant to the Chairman. Dr. Hsiao is also a director of Modigene, Inc., a development stage biopharmaceutical company.

**Jeffrey G. Spragens.** Since August 2005, Mr. Spragens has been Business Manager and a member of SafeStitch. He has been a director, Chief Executive Officer and President of the Company since September 2007. From January 2002 to December 2006 he was a member of Board of Directors of ETOC, Inc., a privately owned hotel and lodging company based in Minneapolis, Minnesota. Since April 2002 he has been a Founding Board of Directors Member and Treasurer of the Foundation for Peace, Washington, D.C. From 1990 to 1995, he was Managing Partner, Gateway Associates, Inc., a company that secured full subdivision and planning approval for properties under its control. Prior to that and from 1987 to 1993, he was one of three founding board of directors members of North American Vaccine which was an AMEX company sold to Baxter International in 1999. Mr. Spragens also has previous experience as a developer and attorney.

**Stewart B. Davis M.D.** Dr. Davis has been Chief Operating Officer of SafeStitch since June 2007. He has also been Chief Operating Officer and Secretary of the Company since September 2007. Prior to that and from July 2003, Dr. Davis was Assistant Medical Director for Innovia LLC, a privately-held bio medical device company in Miami, Florida and its affiliates, including InnFocus LLC, InnoGraft LLC and InnCardia LLC. Innovia and its affiliates design implantable medical devices, many based on a novel polymer, and focus on ophthalmology implants, vascular grafts and percutaneous heart valves. From 2006 he has also been managing partner and medical director of Parasol International, LLC, a privately-owned global healthcare advisory firm. Dr. Davis has approximately ten peer-reviewed articles and three NIH grants and has published a book. Dr. Davis graduated from the University of Miami School of Medicine in 2003.

**Charles J. Filipi M.D.** Dr. Filipi has been Medical Director of SafeStitch since 2006 and became a director of the Company in September 2007. He is also Professor of Surgery in the Department of Surgery at Creighton University School of Medicine in Omaha, Nebraska and has served in this position since 1999. During the last five years, Dr. Filipi served as president of the American Hernia Society, editor of the Journal Hernia and has published approximately thirty peer-reviewed articles and ten book chapters. He has been the inventor of over twenty provisional or utility patents. His primary areas of interest are intraluminal surgery for the correction of gastroesophageal reflux disease, obesity, Barrett's Esophagus, gastrointestinal bleeding and natural orifice transluminal intraperitoneal surgery.



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**Kenneth Block.** Mr. Block joined the Company in 2005 as Secretary and Chief Financial Officer. He is currently Chief Financial Officer. From 1991 through 2005, Mr. Block had been the controller of Shadybrook Charter Corp. and Sunrise Charter Management Corp., each of which was a real estate management company. As of January 1, 2006, he became the controller of Manhattan Leasing Enterprises, Ltd., a lessor of exotic automobiles. Mr. Block graduated from Bernard Baruch College with a Bachelors of Business Administration degree. He is a certified public accountant in the State of New York.

**Dr. Kenneth Heithoff, M.D.** Dr. Heithoff has been a director of the Company since September 2007. Dr. Heithoff is a director of the Center for Diagnostic Imaging (“CDI”) headquartered in Minneapolis, Minnesota, which he founded in December 1981. CDI now includes 40 clinics throughout six states, representing one of the largest teleradiology networks in the United States. Prior to that and from July 1, 1973 to June 1, 1975, Dr. Heithoff served as a Clinical Associate for the U.S. Public Health Service National Institutes of Health. Dr. Heithoff has authored and co-authored more than 40 articles and book chapters, and lectures internationally on topics related to spine imaging. He serves, and has served, on the editorial boards of several journals, including Spine and Radiology. His professional affiliations include the American College of Radiology, the North American Spine Society, the International Society for the Study of the Lumbar Spine, and the International Society of Magnetic Resonance in Medicine.

**Richard Pfenniger, Jr.** Richard C. Pfenniger, Jr., has been a director of the Company since April 2005. Mr. Pfenniger has been Chief Executive Officer and President of Continucare Corporation (healthcare) since October 2003, and the Chairman of Continucare’s Board of Directors since 2002. He served as CEO and Vice Chairman of Whitman Education Group, Inc. (proprietary education) from 1997 until 2003. Mr. Pfenniger is a director of GP Strategies, Inc. (corporate training) and Opko Health, Inc..

**Steven D. Rubin.** Mr. Rubin has served as a director of the Company since September 2007. Mr. Rubin has been the Executive Vice President and a director of Opko Health, Inc. since February 2007. Mr. Rubin is a member of The Frost Group, LLC, a private investment firm. Mr. Rubin served as the Senior Vice President, General Counsel and Secretary of IVAX from August 2001 until September 2006. Prior to joining IVAX, Mr. Rubin was Senior Vice President, General Counsel and Secretary with privately held Telergy, Inc., a provider of business telecommunications and diverse optical network solutions, from early 2000 to August 2001. In addition, he was with the Miami law firm of Stearns Weaver Miller Weissler Alhadeff & Sitterson from 1986 to 2000 in the Corporate and Securities Department. Mr. Rubin had been a stockholder of that firm since 1991 and a director since 1998. Mr. Rubin currently serves on the Board of Directors of Dreams, Inc., a vertically integrated licensed sports products company, Modigene, a development state biopharmaceutical company, Ideation Acquisition Corp., a special purposes acquisition company formed for the purpose of acquiring businesses in digital medial, and Longfoot Communications Corp., a shell company seeking a merger or other business combination candidate.

**Dr. Kevin Wayne.** Dr. Wayne is an Associate Professor of Business Administration at Rivier College in Nashua, New Hampshire and has been with the College since 2003. Dr. Wayne has been a director of the Company since September 2007. Prior to this and from 1999 until 2002, he was co-founder and Vice President of Onux Medical, Inc., a medical device company acquired by C.R. Bard in 2004. At Onux, Dr. Wayne was responsible for marketing and business development. He was also an Adjunct Professor of Marketing at Daniel Webster College from 2002-2003 and a Faculty Associate at Worcester Polytechnic Institute in 2002. Additionally, he has served in product development and marketing functions at Smith & Nephew Endoscopy, Visualization Technology (now part of GE), and Bard’s Endoscopy Division. His medical and surgical device experience includes work in general surgery, GI endoscopy, arthroscopy/sports medicine and computer-assisted spine and neurosurgery applications. He is a member of the Medical Device Group of Boston, the Association of University Technology Managers and the Academy of Management.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Under section 16(a) of the Exchange Act, the Company's directors, executive officers and persons who own more than ten percent (10%) of our common stock are required to file with the SEC initial reports of ownership and reports of changes in ownership of the common stock and other equity securities of the Company. To the Company's knowledge, based solely on a review of copies of such reports furnished to the Company during and/or with respect to fiscal 2007, the Company believes that there were three late filings. The Form 4 filed with the SEC in respect of options granted to Dr. Stewart B. Davis, our Chief Operating Officer and Secretary, was filed on September 14, 2007, which was one day past the filing deadline of September 13, 2007. Additionally, Form 3s for our directors, Kevin Wayne and Dr. Kenneth Heithoff, were not timely filed. Neither Mr. Wayne nor Dr. Heithoff owned, beneficially or otherwise, any of our securities during our fiscal year ended December 31, 2007. Except for the foregoing, the Company is not aware of any other late or delinquent filings required under Section 16(a) of the Exchange Act in respect of the Company's common stock or other equity securities.

### **Code of Ethics**

See Exhibit 14.1

### **Board Nominees by Security Holders**

There have been no changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors.

### **Audit Committee**

The Company has a separately-designated standing audit committee, established in accordance with section 3(a)(58)(A) of the Exchange Act.

The Audit Committee is composed of the following non-employee directors:

Richard Pfenniger, Jr., Chairman

Dr. Kenneth Heithoff

Steven D. Rubin

Kevin Wayne

The Company's Board of Directors has determined that Richard Pfenniger, Jr. is an independent audit committee financial expert as defined in Item 407 (d)(5)(ii) of the Exchange Act.

**Item 10. Executive Compensation**

Summary Compensation Table

The following table sets forth information concerning compensation, paid or accrued, for the Named Executive Officers (as such term is defined in Item 402 of Regulation S-B) for services in all capacities to the Company during fiscal years 2007 and 2006.

**SUMMARY COMPENSATION TABLE**

	Year	Salary	Bonus	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Jeffrey G. Spragens, Chief Executive Officer and President	2007	\$ 0	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$ 0
	2006	\$ 0	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$ 0
Dr. Stewart B. Davis, Chief Operating Officer and Secretary	2007	\$ 70,000	\$0	\$ 0	\$195,732	0	\$ 0	\$ 0	\$265,732
	2006	\$ 0	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$ 0
Dr. Charles Filipi, Medical Director and Director	2007	\$150,000	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$150,000
	2006	\$150,000	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$150,000
Stephen Katz, former CEO and Chairman of the Board	2007	\$ 0	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$ 0
	2006	\$ 0	\$0	\$ 0	\$ 0	0	\$ 0	\$ 0	\$ 0

Jeffrey G. Spragens, our Chief Executive Officer, currently serves without compensation.

**Aggregated Option Exercises in 2007 and Year-End Option Values**

The following table sets forth information with respect to the Outstanding Equity Awards as of December 31, 2007 for the Named Executive Officers.

Name	Option Awards				Stock Awards					
	Option Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$/Share)	Option Expiration Date	Number of Shares or Units of Stock That Have not Vested (#)	Market Value of Shares or Units of Stock That Have not Vested (\$)	Incentive Plan Awards: Number Of Unearned Shares, Units, or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units, or Other Rights That Have Not Vested (#)
Dr. Stewart B. Davis	09/11/2007	22,167	66,500	0	\$ 2.60	09/04/2017	0	0	0	0
Jeffrey G. Spragens		0	0	0	0	—	0	0	0	0
Dr. Charles Filipi		0	0	0	0	—	0	0	0	0
Stephen Katz		0	0	0	0	—	0	0	0	0

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**Director Compensation**

No cash, stock awards, option awards, non-equity incentive plan compensation, non-qualified deferred compensation earnings or any other compensation was paid to any Director during 2007.

In connection with the Share Exchange, Stephen Katz, our former Chief Executive Officer and director, agreed to the cancellation of certain outstanding stock options held by him in exchange for the grant of 2,000 shares of our common stock, resulting in the cancellation of 88,400 stock options held by him upon the issuance of such shares. Such disposition was approved by our board of directors in advance and in accordance with Rules 16b-3(e) and 16b-3(d)(1) promulgated under the Exchange Act, for the purpose of exempting the dispositions under Rule 16b-3 of the Exchange Act.

**Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

**Security Ownership of Certain Beneficial Owners**

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares</u>	<u>Percentage of Outstanding Common Shares</u>
Phillip Frost 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	4,835,948(1)	28.7%
Frost Gamma Investments Trust(2) 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	4,835,948(1)	28.7%

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Name and Address of Beneficial Owner	Number of Shares	Percentage of Outstanding Common Shares
The Frost Group, LLC 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	785,383(2)	4.8%

(5) Frost Gamma Investments Trust holds 4,051,565 shares of the Company's common stock. Dr. Phillip Frost is the trustee and Frost Gamma, Limited Partnership is the sole and exclusive beneficiary of Frost Gamma Investments Trust. Dr. Frost is one of two limited partners of Frost Gamma, Limited Partnership. The general partner of Frost Gamma Limited Partnership is Frost Gamma Inc. and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is also the sole shareholder of Frost-Nevada Corporation. The number of shares included above also includes warrants to purchase 785,383 shares of the Company's common stock owned directly by The Frost Group, LLC. Frost Gamma Investments Trust is a principal member of The Frost Group, LLC. Dr. Frost and the Frost Gamma Investments Trust disclaims beneficial ownership of these warrants to purchase common stock, except to the extent of any pecuniary interest therein.

(6) Includes warrants to purchase 785,383 shares of our common stock.

**Security Ownership of Directors and Named Executive Officers**

Name and Address of Beneficial Owner	Number of Outstanding Shares Beneficially Owned(1)	Percentage of Outstanding Shares of Common Stock
Jane H. Hsiao, Ph.D., MBA, Chairman of the Board of Directors 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	3,589,348(2)	21.3%
Jeffrey G. Spragens, Chief Executive Officer, President and Director 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	2,834,230(3)	17.6%
Dr. Charles Filipi, Medical Director and Director 12370 Rose Lane Omaha, Nebraska 68154	2,814,092	17.5%
Dr. Stewart B. Davis, Chief Operating Officer 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	22,167(4)	*
Kenneth Block, Chief Financial Officer 20 East Sunrise Highway Valley Stream, New York 11581	7,500	*

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<u>Name and Address of Beneficial Owner</u>	<u>Number of Outstanding Shares Beneficially Owned(1)</u>	<u>Percentage of Outstanding Shares of Common Stock</u>
Dr. Kenneth Heithoff, Director 5775 Wayzata Boulevard Suite 190 Minneapolis, Minnesota 55416	0	*
Richard Pfenninger, Jr., Director 7200 Corporate Center Drive Suite 600 Miami, Florida 33426	115,000	*
Steven D. Rubin, Director 4400 Biscayne Boulevard Suite 1500 Miami, Florida 33137	1,025,511(5)	6.1%
Kevin Wayne, Director 24 Pine Tree Lane Lowell, Massachusetts 01854	0	*
All Executive Officers and Directors as a group (10 persons)	13,673,030	80.8%

\* less than 1%.

- (1) All shares beneficially owned represent solely shares of common stock unless otherwise indicated.
- (2) Includes warrants to purchase 785,383 shares of the Company's common stock held by The Frost Group, LLC. Dr. Hsiao is a member of The Frost Group, LLC. Dr. Hsiao disclaims beneficial ownership of the securities held by The Frost Group, LLC, except to the extent of her pecuniary interest therein.
- (3) Includes 562,818 shares owned by each of the Joy Fowler Spragens Family Trust, and RSLs Investments LLC. The Trust is an irrevocable trust established by Joy Fowler Spragens, the spouse of Mr. Spragens, for the benefit of her descendants and relatives who are unrelated to Mr. Spragens. Although Mr. Spragens is the manager of RSLs Investments LLC, the LLC is 100% owned by his adult children. Accordingly, Mr. Spragens disclaims any beneficial ownership of the shares held by the Joy Fowler Spragens Family Trust and RSLs Investment LLC. Includes warrants to purchase 20,138 shares of the Company's common stock held by Mr. Spragens.
- (4) Includes options to purchase 22,167 shares of the Company's common stock. Dr. Davis holds options to purchase an additional 66,500 shares of the Company's common stock, 1/3 of which becomes exercisable on September 11th of each of 2008, 2009 and 2010.
- (5) Includes warrants to purchase 785,383 shares of the Company's common stock held by The Frost Group, LLC. Mr. Rubin is a member of The Frost Group, LLC. Mr. Rubin disclaims beneficial ownership of the securities held by The Frost Group, LLC, except to the extent of his pecuniary interest therein.

### **Item 12. Certain Relationships and Related Transactions, and Director Independence.**

Jane H. Hsiao and Steven D. Rubin, two of our directors, and a trust controlled by Dr. Phillip Frost, are members of The Frost Group, LLC, an entity, which, together with Jeffrey G. Spragens, has warrants to purchase approximately 5% of our outstanding voting securities. Furthermore, the trust that is a member of the Frost Group beneficially owns 28.7% of our outstanding common stock.

We are parties to a credit agreement with The Frost Group, LLC and Jeffrey G. Spragens under which we have access to a line of credit with available borrowings of \$4 million. We are obligated to pay interest at a 10% annual rate on the borrowings on the line of credit. In connection with entering into the line of credit, we have granted warrants to purchase a total of 805,521 shares of common stock to The Frost Group, LLC and Jeffrey G.

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Spragens. SafeStitch had short-term borrowings from its members aggregating \$876,000. The Company repaid these borrowings upon consummation of the Share Exchange.

Our principal corporate office is located at 4400 Biscayne Blvd, Suite 670, Miami, Florida. We rent this space from Frost Real Estate Holdings, LLC, which is a company controlled by Dr. Phillip Frost, our largest beneficial stockholder. We lease approximately 2,900 square feet under the lease agreement, which is for a five-year term that began on January 1, 2008, and requires annual rent of approximately \$91,000, which amount increases by approximately 4.5% per year.

Until a formal policy is established, the independent members of the our board of directors will review and approve all future transactions that would be required to be reported under Item 404(a) of Regulation S-K

The Board has affirmatively determined that none of its of Directors has any material relationship with the Company (either directly or as a partner, shareholder or officer of an organization that has a relationship with the Company) and all are independent, and that all members of the Audit Committee are independent

### **Item 13. Exhibits**

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#### **Exhibits:**

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3.1	Restated Certificate of Incorporation of the Registrant, as amended, filed as Annex A to our Definitive Information Statement on Schedule 14C filed with the SEC on December 7, 2007 and incorporated by reference herein.
3.2*	Amended and Restated Bylaws of SafeStitch Medical, Inc.
4.1*	Specimen Certificate for Common Stock of Registrant
4.2	Form of Common Stock Warrant, filed as Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein.
10.1+	1996 Stock Option Plan filed with our Quarterly Report on Form 10-Q filed with the SEC on August 8, 1995 and incorporated by reference herein.
10.2+	Amendment to 1996 Stock Option Plan dated December 14, 1998, filed as Exhibit 7.8 to our Annual Report on Form 10-K filed with the SEC on March 30, 1999 and incorporated by reference herein.
10.3	Form of Lockup Agreement, filed as Exhibit 2.4 to our Current Report on Form 8-K filed with the SEC on July 31, 2007 and incorporated by reference herein.
10.4	Note and Security Agreement, dated as of September 4, 2007, by and among the Company, SafeStitch LLC, the Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein.
10.5*	Exclusive License and Development Agreement, dated as of May 26, 2006, by and between Creighton University and SafeStitch LLC.
10.6+	Letter Agreement for Terms of Employment between SafeStitch LLC and Stewart B. Davis, M.D., dated May 16, 2007, filed as Exhibit 10.4 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein.
10.7+	SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, filed as Annex B to our Definitive Information Statement on Schedule 14C, filed with the SEC on December 7, 2007 and incorporated by reference herein.
14.1	Code of Ethics Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002 filed as exhibit 14 to our Annual Report on Form 10-K filed with the SEC on March 30, 2005 and incorporated by reference herein.

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**Exhibits:**

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21.1*	Subsidiaries of the Registrant
23.1*	Consent of Eisner LLP independent registered public accounting firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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\* Filed herewith

+ Compensation Plan or Arrangement or Management Contract

**Item 14. Principal Accountant Fees and Services**

The firm Eisner LLP (“Eisner”) served as the Company’s independent accountants for the year ended December 31, 2007.

**Audit Fees:** Audit fees billed to the Company by Eisner for its audit of the Company’s consolidated annual financial statements for the year ended December 31, 2007 and 2006 and for its review of the financial statements included in the Company’s Quarterly Reports on Form 10-QSB filed with the SEC for the year ended December 31, 2007 and 2006 totaled \$ 146,000 and \$45,000, respectively.

**Audit-Related Fees:** The Company did not engage Eisner to provide any audit related fees to the Company during the years ended December 31, 2007 and 2006.

**Tax Fees:** No tax fees were billed to the Company for the years ended December 31, 2007 and 2006 by Eisner.

**All Other Fees:** The Company did not engage Eisner to provide any other non-audit services to the Company during 2007 or 2006.

**Audit Committee Approval:** The Audit Committee pre-approved all fees for 2007 and 2006.

**Pre-Approval Policies and Procedures**

Our audit committee currently has a policy in place that requires its review and pre-approval of all audit and permissible non-audit services provided by our independent auditors. These services requiring pre-approval by the audit committee may include audit services, audit related services, tax services and other services.



**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 26, 2008

**SAFESTITCH MEDICAL, INC.**

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

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jeffrey G. Spragens</u> Jeffrey G. Spragens	Chief Executive Officer and President (Principal Executive Officer)	March 26, 2008
<u>/s/ Jane H. Hsiao, Ph.D.</u> Jane H. Hsiao, Ph.D.	Chairman of the Board of Directors	March 26, 2008
<u>/s/ Dr. Charles Filipi</u> Dr. Charles Filipi	Medical Director and Director	March 26, 2008
<u>/s/ Dr. Kenneth Heithoff</u> Dr. Kenneth Heithoff	Director	March 26, 2008
<u>/s/ Steven D. Rubin</u> Steven D. Rubin	Director	March 26, 2008
<u>/s/ Richard Pfenniger, Jr.</u> Richard Pfenniger, Jr.	Director	March 26, 2008
<u>/s/ Kevin Wayne</u> Kevin Wayne	Director	March 26, 2008
<u>/s/ Kenneth Block</u> Kenneth Block	Chief Financial Officer (Principal Financial Officer)	March 26, 2008

**AMENDED AND RESTATED**

**BYLAWS**

**OF**

**SAFESTITCH MEDICAL, INC.  
(a Delaware corporation)**

The following are the Bylaws ("Bylaws") of **SAFESTITCH MEDICAL, INC.**, a Delaware corporation (the "Corporation"), effective as of March 26, 2008.

**ARTICLE I  
OFFICES**

Section 1.01. **PRINCIPAL EXECUTIVE OFFICE.** The principal executive office of the Corporation shall be located at 4400 Biscayne Boulevard, Suite 670, Miami, Florida 33137. The Board of Directors of the Corporation (the "Board of Directors") may change the location of said principal executive office.

Section 1.02. **OTHER OFFICES.** The Corporation may also have an office or offices at such other place or places, either within or without the State of Delaware, as the Board of Directors may from time to time determine or as the business of the Corporation may require.

**ARTICLE II  
MEETINGS OF STOCKHOLDERS**

Section 2.01. **ANNUAL MEETINGS.** The annual meeting of stockholders of the Corporation shall be held at a date and at such time as the Board of Directors shall determine. At each annual meeting of stockholders, directors shall be elected in accordance with the provisions of Section 3.03 hereof and any other proper business may be transacted.

Section 2.02. **SPECIAL MEETINGS.** Special meetings of stockholders for any purpose or purposes may be called at any time by a majority of the Board of Directors, by the Chairman of the Board or by the President. Special meetings may not be called by any other person or persons. Each special meeting shall be held at such date and time as is requested by the person or persons calling the meeting, subject to limits fixed by applicable law.

Section 2.03. **PLACE OF MEETINGS.** Each annual or special meeting of stockholders shall be held at such location as may be determined by the Board of Directors or, if no such determination is made, at such place as may be determined by the Chairman of the Board. If no location is so determined, any annual or special meeting shall be held at the principal executive office of the Corporation.

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Section 2.04. **NOTICE OF STOCKHOLDER MEETINGS.** Written notice of each annual or special meeting of stockholders (the “Meeting Notice”) shall be delivered either personally or by mail to stockholders entitled to vote at such meeting no fewer than ten (10) nor more than sixty (60) days before the date of the meeting. The Meeting Notice shall include the time, date and location of the meeting to which such Meeting Notice relates. The purpose or purposes for which the meeting is called may, in the case of an annual meeting, and shall, in the case of a special meeting, be set forth in the Meeting Notice. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it shall appear on the stock books of the Corporation, unless he shall have filed with the Secretary of the Corporation a written request that notices intended for him be mailed to some other address, in which case such notice shall be mailed to the address designated in such request.

Section 2.05. **NOTICE REQUIREMENTS FOR DIRECTOR NOMINATIONS AND STOCKHOLDER PROPOSALS.**

(a) Only persons who are nominated in accordance with the procedures set forth in these Bylaws shall be eligible to serve as directors. Nominations of persons for election to the Board of Directors of the Corporation may be made at a meeting of stockholders (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice provided for in this Section 2.05, who is entitled to vote for the election of directors at the meeting and who complies with the notice procedures set forth in this Section 2.05.

(b) Nominations by stockholders shall be made pursuant to timely notice in writing to the Secretary of the Corporation. To be timely, a stockholder’s notice shall be delivered to or mailed and received at the Corporation’s principal executive office: (i) in the case of an annual meeting, no fewer than 90 days nor more than 120 days prior to the first anniversary of the date of the Meeting Notice for the preceding year’s annual meeting; provided, however, that in the event that the date of the annual meeting is changed by more than 30 days from such anniversary date, notice by the stockholder to be timely must be so received not later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made; and (ii) in the case of a special meeting at which directors are to be elected, not later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made.

(c) Such stockholder’s notice shall set forth: (i) as to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for elections of directors, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (including such person’s written consent to being named in the proxy statement as a nominee and to serving as a director if elected); (ii) as to the stockholder giving the notice, (A) the name and address, as they appear on the Corporation’s books, of such stockholder and (B) the class and number of shares of the Corporation which are owned beneficially and of record by such stockholder of record and by the beneficial owner, if any, on whose behalf the nomination is made; and (iii) as to the beneficial owner, if any, on whose behalf the nomination is made, (A) the name and address of such person and (B) the class and number of shares of the Corporation which are beneficially owned by such person. At the request of the Board of Directors, any person nominated by the Board of Directors for election as a director shall furnish to the Secretary of the Corporation that information required to be set forth in a stockholder’s notice of nomination which pertains to the nominee.

(d) At an annual meeting of the stockholders, only such business shall be conducted as shall have been brought before the meeting (i) pursuant to the Corporation's Meeting Notice, (ii) by or at the direction of the Board of Directors or (iii) by any stockholder of the Corporation who is a stockholder of record at the time of giving of the notice provided for in this Section 2.05, who is entitled to vote at such meeting and who complies with the notice procedures set forth in Section 2.05(e).

(e) For business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of paragraph (d) of this Section 2.05, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation. To be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive office of the Corporation no fewer than 90 days nor more than 120 days prior to the first anniversary of the date of the Meeting Notice for the preceding year's annual meeting; provided, however, that in the event that the date of the meeting is changed by more than 30 days from such anniversary date, to be timely, notice by the stockholder must be received no later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made. A stockholder's notice to the Secretary shall set forth as to each matter the stockholder proposes to bring before the meeting: (i) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting; (ii) the name and address, as they appear on the Corporation's books, of the stockholder proposing such business, and the name and address of the beneficial owner, if any, on whose behalf the proposal is made; (iii) the class and number of shares of the Corporation which are owned beneficially and of record by such stockholder of record and by the beneficial owner, if any, on whose behalf the proposal is made; and (iv) any material interest of such stockholder of record and the beneficial owner, if any, on whose behalf the proposal is made in such business.

(f) Notwithstanding anything in these Bylaws to the contrary, no business shall be conducted at an annual meeting except in accordance with the procedures set forth in this Section 2.05. Additionally, no person shall be eligible to serve as a director of the Corporation unless nominated in accordance with the procedures set forth in this Section 2.05. The chairman of the meeting shall, if the facts warrant, determine and declare to the meeting that (i) the business was not properly brought before the meeting and in accordance with the procedures prescribed by this Section 2.05 or (ii) a nomination was not made in accordance with the procedures prescribed by these Bylaws. If the chairman of the meeting should so determine, he or she shall so declare to the meeting, and any such business not properly brought before the meeting shall not be transacted or the defective nomination shall be disregarded. Notwithstanding the foregoing provisions of this Section 2.05, a stockholder shall also comply with all applicable requirements of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder with respect to the matters set forth in this Section 2.05.

Section 2.06. **CONDUCT OF MEETINGS.** All actual and special meetings of stockholders shall be conducted in accordance with such rules and procedures as the Board of Directors may determine subject to the requirements of applicable law and, as to matters not governed by such rules and procedures, as the chairman of such meeting shall determine. The Chairman of the Board shall be the chairman of any annual or special meeting of stockholders. The Secretary, or in the absence of the Secretary, a person designated by the Chairman of the Board, shall act as secretary of the meeting.

Section 2.07. **QUORUM.** At any meeting of stockholders of the Corporation, the presence, in person or by proxy, of the holders of record of a majority of the shares then issued and outstanding and entitled to vote at the meeting shall constitute a quorum for the transaction of business; provided, however, that this Section 2.07 shall not affect any different requirement which may exist under statute, pursuant to the rights of any authorized class or series of stock, or under the Certificate of Incorporation of the Corporation, as amended or restated from time to time (the "Certificate of Incorporation"), for the vote necessary for the adoption of any measure governed thereby. The stockholders present at a duly called and held meeting at which a quorum is present may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, if any action taken (other than adjournment) is approved by at least a majority of the shares required to constitute a quorum.

In the absence of a quorum, the stockholders present in person or by proxy, by majority vote and without further notice, may adjourn the meeting from time to time until a quorum is attained, but in the absence of a quorum, no other business may be transacted at that meeting, except as provided in this section. At any reconvened meeting following such adjournment at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally noticed.

Section 2.08. **VOTES REQUIRED.** The affirmative vote of a majority of the shares present in person or represented by proxy at a duly called meeting of stockholders of the Corporation, at which a quorum is present and entitled to vote on the subject matter, shall be sufficient to take or authorize action upon any matter which may properly come before the meeting, except that the election of directors shall be by plurality vote, unless the vote of a greater or different number thereof is required by statute, by the rights of any authorized class of stock or by the Certificate of Incorporation.

Unless the Certificate of Incorporation or a resolution of the Board of Directors adopted in connection with the issuance of shares of any class or series of stock provides for a greater or lesser number of votes per share, or limits or denies voting rights, each outstanding share of stock, regardless of class or series, shall be entitled to one (1) vote on each matter submitted to a vote at a meeting of stockholders.

Section 2.09. **PROXIES.** Every person entitled to vote for directors or on any other matter shall have the right to do so either in person or by one or more agents authorized by a written proxy signed by the person and filed with the Secretary of the Corporation. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission, or otherwise) by the stockholder or the stockholder's attorney in fact. A validly executed proxy which does not state that it is irrevocable shall continue in full force and effect unless: (i) revoked by the person executing it, before the vote pursuant to that proxy, by a writing delivered to the Corporation stating that the proxy is revoked, or by a subsequent proxy executed by, or as to any meeting by attendance at such meeting and voting in person by, the person executing the proxy; or (ii) written notice of the death or incapacity of the maker of that proxy is received by the Corporation before the vote pursuant to that proxy is counted; provided, however, that no proxy shall be valid after the expiration of three (3) years from the date of the proxy, unless otherwise provided in the proxy.

A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient under applicable law to support an irrevocable power. A proxy may be made irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally.

Section 2.10. **STOCKHOLDER ACTION BY WRITTEN CONSENT.** To the fullest extent permitted by law, whenever any action is required or permitted to be taken at a meeting of stockholders, by law, by the Certificate of Incorporation or by these Bylaws, such action may be taken without a meeting, without prior notice and without a vote of stockholders, if a consent in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Section 2.11. **RECORD DATE FOR STOCKHOLDER NOTICE AND VOTING.** For purposes of determining the stockholders entitled to notice of any meeting or to vote or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty (60) days nor fewer than ten (10) days before the date of any such meeting nor more than sixty (60) days before any such other action, and in this event only stockholders at the close of business on the record date are entitled to notice or to vote, as the case may be, notwithstanding any transfer of any shares on the books of the Corporation after the record date, except as otherwise provided in the Delaware General Corporation Law.

If the Board of Directors does not so fix a record date:

(a) The record date for determining the stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the business day immediately preceding the day on which notice is given, or, if notice is waived, at the close of business on the business day immediately preceding the day on which the meeting is held.

(b) The record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

(c) A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

Section 2.12. **LIST OF STOCKHOLDERS.** The Secretary of the Corporation shall prepare and make (or cause to be prepared and made), at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order and showing the address of, and the number of shares registered in the name of, each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the duration thereof, and may be inspected by any stockholder present at such meeting.

Section 2.13. **VOTING.** The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.12. The stockholders' vote may be by voice vote or by ballot. Any stockholder may vote any number of his or her shares entitled to vote in favor of the proposal and refrain from voting the remaining shares or vote them against the proposal, but, if the stockholder fails to specify the number of shares which the stockholder is voting affirmatively, it will be conclusively presumed that the stockholder's approving vote is with respect to all shares that the stockholder is entitled to vote.

Section 2.14. **WAIVER OF NOTICE OR CONSENT BY ABSENT STOCKHOLDERS.** The transactions of any meeting of stockholders, either annual or special, however called and noticed, and wherever held, shall be as valid as though effected at a meeting duly held after regular call and notice, if a quorum be present either in person or by proxy, and if, either before or after the meeting, each person entitled to vote, who was not present in person or by proxy, signs a written waiver of notice or a consent to a holding of the meeting, or an approval of the minutes. The waiver of notice, consent or approval need not specify either the business to be transacted or the purpose of any annual or special meeting of stockholders. All such waivers, consents or approvals shall be filed with the corporate records or made a part of the minutes of the meeting. Attendance by a person at a meeting shall also constitute a waiver of notice of that meeting, except when the person attends the meeting for the express purpose of objecting and objects, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened, and except that attendance at a meeting is not a waiver of any right to object to the consideration of matters required by law to be included in the notice of the meeting but not so included if that objection is expressly made at the meeting.

Section 2.15. **INSPECTORS OF ELECTION.** In advance of any meeting of stockholders, the Board of Directors shall appoint Inspectors of Election to act at such meeting or at any adjournment or adjournments thereof. If such Inspectors are not so appointed or fail or refuse to act, the chairman of any such meeting may (and, upon the demand of any stockholder or stockholder's proxy, shall) make such an appointment.

The number of Inspectors of Election shall be one (1) or three (3). If there are three (3) Inspectors of Election, the decision, act or certificate of a majority shall be effective and shall represent the decision, act or certificate of all. No such Inspector need be a stockholder of the Corporation.

Subject to any provisions of the Certificate of Incorporation, the Inspectors of Election shall determine the number of shares outstanding, the voting power of each, the shares represented at the meeting, the existence of a quorum and the authenticity, validity and effect of proxies; they shall receive votes, ballots or consents, hear and determine all challenges and questions in any way arising in connection with the right to vote, count and tabulate all votes or consents, determine when the polls shall close and determine the result; and finally, they shall do such acts as may be proper to conduct the election or vote with fairness to all stockholders. On request, the Inspectors of Election shall make a report in writing to the secretary of the meeting concerning any challenge, question or other matter as may have been determined by them and shall execute and deliver to such secretary a certificate of any fact found by them.

### **ARTICLE III DIRECTORS**

Section 3.01. **POWERS.** The business and affairs of the Corporation shall be managed by and be under the direction of the Board of Directors. The Board of Directors shall exercise all the powers of the Corporation, except those that are conferred upon or reserved to the stockholders by statute, the Certificate of Incorporation or these Bylaws.

Section 3.02. **NUMBER.** The number of directors shall be fixed from time to time by resolution of the Board of Directors but shall not be less than three (3) nor more than fifteen (15).

Section 3.03. **ELECTION AND TERM OF OFFICE.** The directors shall be elected at the annual meeting of the stockholders, except as provided in Section 3.06 of this Article III, and each director shall hold office for the term for which he is elected and until his successor is elected and qualified. Directors need not be residents of the State of Delaware, stockholders of the Corporation or citizens of the United States. Unless provided otherwise by applicable law, any director may be removed at any time, with or without cause, at a special meeting of the stockholders called for that purpose.

Section 3.04. **ELECTION OF CHAIRMAN OF THE BOARD.** At the organizational meeting immediately following the annual meeting of stockholders, the directors shall elect a Chairman of the Board from among the directors who shall hold office until the corresponding meeting of the Board of Directors in the next year and until his successor shall have been elected or until his earlier resignation, removal or death. Any vacancy in such office may be filled for the unexpired portion of the term in the same manner by the Board of Directors at any regular or special meeting.

Section 3.05. **REMOVAL.** Any director may be removed from office only as provided in the Certificate of Incorporation.

Section 3.06. **VACANCIES AND ADDITIONAL DIRECTORSHIPS.** Except as the Delaware General Corporation Law may otherwise require, and subject to the rights of the holders of any series of Preferred Stock with respect to the filling of vacancies or new directorships in the Board of Directors, newly created directorships resulting from death, resignation, disqualification, removal or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor shall have been elected and qualified. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.



Section 3.07. **REGULAR AND SPECIAL MEETINGS.** Regular meetings of the Board of Directors shall be held: (i) immediately following the annual meeting of the stockholders; (ii) without call at such time as shall from time to time be fixed by the Board of Directors; and (iii) as called by the Chairman of the Board in accordance with applicable law.

Special meetings of the Board of Directors shall be held upon call by or at the direction of the Chairman of the Board, the President or any two (2) directors, except that when the Board of Directors consists of one (1) director, then the one director may call a special meeting. Except as otherwise required by law, notice of each special meeting shall be mailed to each director, addressed to him at his residence or usual place of business at least three (3) days before the day on which the meeting is to be held, or shall be sent to him at such place by telex, telegram, cable, facsimile transmission or telephoned or delivered to him personally, not later than the day before the day on which the meeting is to be held. Such notice shall state the time and place of such meeting, but need not state the purpose or purposes thereof, unless otherwise required by law, the Certificate of Incorporation or these Bylaws.

Notice of any meeting need not be given to any director who attends such meeting in person (except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened) or who waives notice thereof in a signed writing before or after such meeting.

Section 3.08. **QUORUM.** At all meetings of the Board of Directors, a majority of the fixed number of directors shall constitute a quorum for the transaction of business, except that when the Board of Directors consists of one (1) director, then the one director shall constitute a quorum. In the absence of a quorum, the directors present, by majority vote and without notice other than by announcement, may adjourn the meeting from time to time until a quorum shall be present. At any reconvened meeting following such an adjournment at which a quorum shall be present, any business may be transacted which might have been transacted at the meeting as originally noticed.

Section 3.09. **VOTES REQUIRED.** Except as otherwise provided by applicable law or by the Certificate of Incorporation, the vote of a majority of the directors present at a meeting duly held at which a quorum is present shall be sufficient to pass any measure.

Section 3.10. **PLACE AND CONDUCT OF MEETINGS.** Each regular meeting and special meeting of the Board of Directors shall be held at a location determined as follows: the Board of Directors may designate any place, within or without the State of Delaware, for the holding of any meeting. If no such designation is made: (a) any meeting called by a majority of the directors shall be held at such location, within the county of the Corporation's principal executive office, as the directors calling the meeting shall designate; and (b) any other meeting shall be held at such location, within the county of the Corporation's principal executive office,

as the Chairman of the Board may designate or, in the absence of such designation, at the Corporation's principal executive office. Subject to the requirements of applicable law, all regular and special meetings of the Board of Directors shall be conducted in accordance with such rules and procedures as the Board of Directors may approve and, as to matters not governed by such rules and procedures, as the chairman of such meeting shall determine. The chairman of any regular or special meeting shall be the Chairman of the Board, or, in his absence, a person designated by the Board of Directors. The Secretary, or, in the absence of the Secretary, a person designated by the chairman of the meeting shall act as secretary of the meeting. Any meeting, regular or special, may be held by conference telephone or similar communication equipment, so long as all directors participating in the meeting can hear one another, and all such directors shall be deemed to be present in person at the meeting.

Section 3.11. **FEES AND COMPENSATION.** Directors shall be paid such compensation as may be fixed from time to time by resolution of the Board of Directors: (a) for their usual and contemplated services as directors; (b) for their services as members of committees appointed by the Board of Directors, including attendance at committee meetings as well as services which may be required when committee members must consult with management staff; and (c) for extraordinary services as directors or as members of committees appointed by the Board of Directors, over and above those services for which compensation is fixed pursuant to items (a) and (b) in this Section 3.11. Compensation may be in the form of an annual retainer fee or a fee for attendance at meetings, or both, or in such other form or on such basis as the resolutions of the Board of Directors shall fix. Directors shall be reimbursed for all reasonable expenses incurred by them in attending meetings of the Board of Directors and committees appointed by the Board of Directors and in performing compensable extraordinary services. Nothing contained herein shall be construed to preclude any director from serving the Corporation in any other capacity, such as an officer, agent, employee, consultant or otherwise, and receiving compensation therefor.

Section 3.12. **COMMITTEES OF THE BOARD OF DIRECTORS.** To the full extent permitted by applicable law, the Board of Directors may from time to time establish committees, including, but not limited to, standing or special committees and an executive committee with authority and responsibility for bookkeeping, with authority to act as signatories on Corporation bank or similar accounts and with authority to choose attorneys for the Corporation and direct litigation strategy, which shall have such duties and powers as are authorized by these Bylaws or by the Board of Directors. Committee members, and the chairman of each committee, shall be appointed by the Board of Directors. The Chairman of the Board, in conjunction with the several committee chairmen, shall make recommendations to the Board of Directors for its final action concerning members to be appointed to the several committees of the Board of Directors. Any member of any committee may be removed at any time with or without cause by the Board of Directors. Vacancies which occur on any committee shall be filled by a resolution of the Board of the Directors. If any vacancy shall occur in any committee by reason of death, resignation, disqualification, removal or otherwise, the remaining members of such committee, so long as a quorum is present, may continue to act until such vacancy is filled by the Board of Directors. The Board of Directors may, by resolution, at any time deemed desirable, discontinue any standing or special committee. Members of standing committees, and their chairmen, shall be elected yearly at the regular meeting of the Board of Directors which is held immediately following the annual meeting of stockholders. The provisions of Sections 3.07, 3.08, 3.09 and 3.10 of these Bylaws shall apply, *MUTATIS MUTANDIS*, to any such Committee of the Board of Directors.

Section 3.13. **WAIVER OF NOTICE.** The transactions of any meeting of the Board of Directors, however called and noticed or wherever held, shall be as valid as though had at a meeting duly held after regular call and notice if a quorum is present and if, either before or after the meeting, each of the directors not present signs a written waiver of notice, a consent to holding the meeting or an approval of the minutes. The waiver of notice or consent need not specify the purpose of the meeting. All such waivers, consents, and approvals shall be filed with the corporate records or made a part of the minutes of the meeting. Notice of a meeting shall also be deemed given to any director who attends the meeting without protesting, before or at its commencement, the lack of notice to that director.

Section 3.14. **ADJOURNMENT.** A majority of the directors present, whether or not constituting a quorum, may adjourn any meeting to another time and place.

Section 3.15. **NOTICE OF ADJOURNMENT.** Notice of the time and place of holding an adjourned meeting need not be given to absent directors if the time and place are fixed at the meeting adjourned.

Section 3.16. **ACTION WITHOUT MEETING.** Any action required or permitted to be taken by the Board of Directors or any committee thereof may be taken without a meeting, if all members of the Board of Directors shall individually or collectively consent in writing to that action. Such action by written consent shall have the same force and effect as a unanimous vote of the Board of Directors. Such written consent or consents shall be filed with the minutes of the proceedings of the Board of Directors.

#### **ARTICLE IV OFFICERS**

Section 4.01. **DESIGNATION, ELECTION AND TERM OF OFFICE.** The Corporation shall have a Chairman of the Board, a President, a Treasurer or Chief Financial Officer, such senior vice presidents and vice presidents as the Board of Directors deems appropriate, a Secretary and such other officers as the Board of Directors may deem appropriate. These officers shall be elected annually by the Board of Directors at the organizational meeting immediately following the annual meeting of stockholders, and each such officer shall hold office until the corresponding meeting of the Board of Directors in the next year and until his successor shall have been elected and qualified or until his earlier resignation, death or removal. Any vacancy in any of the above offices may be filled for the unexpired portion of the term by the Board of Directors at any regular or special meeting. Any number of offices may be held by the same person in accordance with Section 4.08 herein.

Section 4.02. **CHAIRMAN OF THE BOARD.** The Chairman of the Board of Directors shall preside at all meetings of the directors and shall have such other powers and duties as may from time to time be assigned to him by the Board of Directors.

Section 4.03. **PRESIDENT.** The President shall be the chief executive officer of the Corporation and shall, subject to the power of the Board of Directors, have general supervision, direction and control of the business and affairs of the Corporation. He shall preside at all meetings of the stockholders and, in the absence of the Chairman of the Board, at all meetings of the directors. He shall have the general powers and duties of management usually vested in the office of president of a corporation, and shall have such other duties as may be assigned to him from time to time by the Board of Directors.

Section 4.04. **TREASURER OR CHIEF FINANCIAL OFFICER.** The Treasurer or Chief Financial Officer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of account of the properties and business transactions of the Corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital, retained earnings and shares. The books of account shall at all reasonable times be open to inspection by the directors. The Treasurer or Chief Financial Officer shall deposit all moneys and other valuables in the name and to the credit of the Corporation with such depositories as may be designated by the Board of Directors. He shall disburse the funds of the Corporation as may be ordered by the Board of Directors, shall render to the President and directors, whenever they request it, an account of all of his transactions as the Treasurer or Chief Financial Officer and of the financial condition of the Corporation, and shall have such other powers and perform such other duties as may be prescribed by the Board of Directors or the Bylaws.

Section 4.05. **SECRETARY.** The Secretary shall keep the minutes of the meetings of the stockholders, the Board of Directors and all committees. He shall be the custodian of the corporate seal and shall affix it to all documents which he is authorized by law or the Board of Directors to sign and seal. He also shall perform such other duties as may be assigned to him from time to time by the Board of Directors or the Chairman of the Board or President.

Section 4.06. **ASSISTANT OFFICERS.** The President may appoint one or more assistant secretaries and such other assistant officers as the business of the Corporation may require, each of whom shall hold office for such period, have such authority and perform such duties as may be specified from time to time by the President.

Section 4.07. **WHEN DUTIES OF AN OFFICER MAY BE DELEGATED.** In the case of absence or disability of an officer of the Corporation or for any other reason that may seem sufficient to the Board of Directors, the Board of Directors or any officer designated by it, or the President, may, for the time of the absence or disability, delegate such officer's duties and powers to any other officer of the Corporation.

Section 4.08. **OFFICERS HOLDING TWO OR MORE OFFICES.** The same person may hold any two (2) or more of the above-mentioned offices.

Section 4.09. **COMPENSATION.** The Board of Directors shall have the power to fix the compensation of all officers and employees of the Corporation.

Section 4.10. **RESIGNATIONS.** Any officer may resign at any time by giving written notice to the Board of Directors, to the President or to the Secretary of the Corporation. Any such resignation shall take effect at the time specified therein unless otherwise determined by the Board of Directors. The acceptance of a resignation by the Corporation shall not be necessary to make it effective.

Section 4.11. **REMOVAL.** Any officer of the Corporation may be removed, with or without cause, by the affirmative vote of a majority of the entire Board of Directors. Any assistant officer of the Corporation may be removed, with or without cause, by the President or by the Board of Directors.

**ARTICLE V  
INDEMNIFICATION OF DIRECTORS, OFFICERS,  
EMPLOYEES AND OTHER CORPORATE AGENTS**

Section 5.01. **ACTION, ETC., OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION.** The Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee, trustee or agent of a subsidiary of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to hereinafter as an "Agent"), against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Corporation, and with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, that he had reasonable cause to believe that his conduct was unlawful.

Section 5.02. **ACTION, ETC., BY OR IN THE RIGHT OF THE CORPORATION.** The Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that he is or was an Agent against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation by a court of competent jurisdiction, after exhaustion of all appeals therefrom, unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

Section 5.03. **DETERMINATION OF RIGHT OF INDEMNIFICATION.** Any indemnification under Sections 5.01 or 5.02 (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the Agent is proper in the circumstances because the Agent has met the applicable standard of conduct set forth in Sections 5.01 and 5.02 hereof, which determination is made (a) by the Board of Directors, by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (b) if such a quorum is not obtainable, or, even if obtainable, if a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (c) by the stockholders.

Section 5.04. **INDEMNIFICATION AGAINST EXPENSES OF SUCCESSFUL PARTY.** Notwithstanding the other provisions of this Article V, to the extent that an Agent has been successful on the merits or otherwise, including the dismissal of an action without prejudice or the settlement of an action without admission of liability, in defense of any action, suit or proceeding referred to in Sections 5.01 or 5.02 hereof, or in defense of any claim, issue or matter therein, such Agent shall be indemnified against expenses, including attorneys' fees actually and reasonably incurred by such Agent in connection therewith.

Section 5.05. **ADVANCES OF EXPENSES.** Except as limited by Section 5.06 of this Article V, expenses incurred by an Agent in defending any civil or criminal action, suit, or proceeding may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding at the discretion of the Board of Directors. If the Board of Directors authorizes advancement of expenses, then the Agent shall be entitled to receive such amount as the Board of Directors has authorized only upon the Agent entering into and delivering to the Board of Directors a written undertaking to repay such amount if it shall ultimately be determined that such Agent is not entitled to indemnification as authorized in this Article V. Notwithstanding the foregoing, no advance shall be made by the Corporation if a determination is reasonably and promptly made by the Board of Directors by a majority vote of a quorum of disinterested directors, or (if such a quorum is not obtainable or, even if obtainable, a quorum of disinterested directors so directs) by independent legal counsel in a written opinion, that, based upon the facts known to the Board of Directors or counsel at the time such determination is made, such person acted in bad faith and in a manner that such person did not believe to be in or not opposed to the best interest of the Corporation, or, with respect to any criminal proceeding, that such person believed or had reasonable cause to believe his conduct was unlawful.

Section 5.06. **RIGHT OF AGENT TO INDEMNIFICATION UPON APPLICATION; PROCEDURE UPON APPLICATION.** Any indemnification or advance under this Article V shall be made promptly, and in any event within ninety (90) days, upon the written request of the Agent, unless, in the case of advancement, the Board of Directors has in its discretion determined not to advance expenses as provided in Section 5.05. The right to indemnification or advances as granted by this Article V shall be enforceable by the Agent in any court of competent jurisdiction, if the Board of Directors or independent legal counsel denies the claim, in whole or in part, or if no disposition of such claim is made within ninety (90) days. The Agent's expenses incurred in connection with successfully establishing his right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation.

Section 5.07. **OTHER RIGHTS AND REMEDIES.** The indemnification and advancement of expenses provided by, or granted pursuant to, this Article V shall not be deemed exclusive of any other rights to which an Agent seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another

capacity while holding such office, and shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be an Agent and shall inure to the benefit of the heirs, executors and administrators of such a person. All rights to indemnification under this Article V shall be deemed to be provided by a contract between the Corporation and the Agent who serves in such capacity at any time while these Bylaws and other relevant provisions of the Delaware General Corporation Law and other applicable law, if any, are in effect. Any repeal or modification thereof shall not affect any rights or obligations then existing.

Section 5.08. **INSURANCE.** Upon resolution passed by the Board of Directors, the Corporation may purchase and maintain insurance on behalf of any person who is or was an Agent against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the Corporation would have the power to indemnify him against such liability under the provisions of this Article V.

Section 5.09. **CONSTITUENT CORPORATIONS.** For the purposes of this Article V, references to “the Corporation” shall include, in addition to the Corporation, all constituent corporations (including all constituents of constituents) absorbed in a consolidation or merger as well as the resulting or surviving corporation, which, if the separate existence of such constituent corporation had continued, would have had power and authority to indemnify its Agents, so that any Agent of such constituent corporation shall stand in the same position under the provisions of the Article V with respect to the resulting or surviving corporation as that Agent would have with respect to such constituent corporation if its separate existence had continued.

Section 5.10. **OTHER ENTERPRISES, FINES, AND SERVING AT CORPORATION’S REQUEST.** For purposes of this Article V: references to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to “serving at the request of the Corporation” shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to any employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Corporation” as referred to in this Article V.

Section 5.11. **SAVINGS CLAUSE.** If this Article V or any portion thereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Agent as to expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement with respect to any action, suit or proceeding, whether civil, criminal, administrative or investigative, and whether internal or external, including a grand jury proceeding and an action or suit brought by or in the right of the Corporation, to the full extent permitted by any applicable portion of this Article V that shall not have been invalidated, or by any other applicable law.

**ARTICLE VI  
STOCK**

Section 6.01. **SHARES OF STOCK.** The shares of the Corporation shall be represented by certificates, each of which shall represent and certify the number and class (and series, if appropriate) of shares of stock represented by such certificate in the Corporation; provided, that the Board of Directors may adopt a resolution permitting shares to be uncertificated. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical. Every holder of stock represented by certificates shall be entitled to have a certificate signed in the name of the Corporation by the Chairman of the Board or a Vice-Chairman of the Board or the President or a Vice President, together with the Treasurer or an Assistant Treasurer or the Chief Financial Officer, or the Secretary or an Assistant Secretary. Any or all of the signatures on any certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 6.02. **TRANSFER OF SHARES.** Shares of stock shall be transferable on the books of the Corporation (i) in the case of certificated shares, only by the registered holder thereof, in person or by such person's duly authorized attorney lawfully constituted in writing, upon the surrender of the certificate representing the shares to be transferred, properly endorsed, to the Corporation's transfer agent, if the Corporation has a transfer agent, or to the Corporation's registrar, if the Corporation has a registrar, or to the Secretary, if the Corporation has neither a transfer agent nor a registrar or (ii) in the case of uncertificated shares, upon receipt of proper transfer instructions from the registered holder thereof or by such person's duly authorized attorney lawfully constituted in writing, and upon payment of all necessary taxes and compliance with appropriate procedures for transferring shares of stock in uncertificated form; provided, however, that such surrender and endorsement, compliance or payment of taxes shall not be required in any case in which the Corporation shall determine to waive such requirement. The Board of Directors shall have power and authority to make such other rules and regulations concerning the issue, transfer and registration of certificates of the Corporation's stock as it may deem expedient. With respect to certificated shares of stock, every certificate exchanged, returned or surrendered to the Corporation shall be marked "Cancelled," with the date of cancellation, by the Secretary or Assistant Secretary of the Corporation or the transfer agent thereof. No transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing from and to whom transferred.

Section 6.03. **TRANSFER AGENTS AND REGISTRARS.** The Corporation may have one or more transfer agents and one or more registrars of its stock whose respective duties the Board of Directors or the Secretary may, from time to time, define. No certificate of stock shall be valid until countersigned by a transfer agent, if the Corporation has a transfer agent, or until registered by a registrar, if the Corporation has a registrar. The duties of transfer agent and registrar may be combined.



Section 6.04. **STOCK LEDGERS.** Original or duplicate stock ledgers, containing the names and addresses of the stockholders of the Corporation and the number of shares of each class of stock held by them, shall be kept at the principal executive office of the Corporation or at the office of its transfer agent or registrar.

Section 6.05. **LOST, STOLEN OR DESTROYED CERTIFICATES.** In respect of any previously issued stock certificate that is alleged to have been lost, destroyed or wrongfully taken, the Corporation shall issue either a new stock certificate or uncertificated shares in place of such lost, destroyed or wrongfully taken certificate; provided, that the holder of record of the certificate (a) makes proof in affidavit form that it has been lost, destroyed or wrongfully taken; (b) requests the issuance of a new certificate or uncertificated shares before the Corporation has notice that the certificate has been acquired by a purchaser for value in good faith and without notice of any adverse claims; (c) gives bond in such form as the Corporation may direct, to indemnify the Corporation, the transfer agent and registrar against any claim that may be made on account of the alleged loss, destruction or theft of a certificate; and (d) satisfies any other reasonable requirements imposed by the Board of Directors. When any certificate has been lost, apparently destroyed or wrongfully taken, if the owner of record of the certificate fails to notify this Corporation within a reasonable time after notice that the certificate has been lost, destroyed or stolen, and if the proper officers or transfer agent of the Corporation register a transfer of the certificate before receiving such notification, such prior owner of record shall be precluded from asserting against the Corporation, any officer of the Corporation and the transfer agent of the Corporation, any claim for wrongful transfer of the certificate, any claim to a new certificate or any claim for rights normally accorded to stockholders of the Corporation.

## **ARTICLE VII MISCELLANEOUS**

Section 7.01. **RELATIONSHIP BETWEEN BYLAWS, CERTIFICATE OF INCORPORATION, AND DELAWARE GENERAL CORPORATION LAW.** To the extent that the Certificate of Incorporation or the Delaware General Corporation Law grant to any person any rights which are restricted under these Bylaws, and the Certificate of Incorporation or the Delaware General Corporation Law preclude the Bylaws from imposing such restriction, then the extent of such rights shall be as provided in the Certificate of Incorporation or the Delaware General Corporation Law, as the case may be, and these Bylaws shall be so interpreted.

Section 7.02. **AMENDMENT.** These Bylaws may be amended, altered or repealed by resolution adopted by the Board of Directors.



AMERICAN BANK NOTE COMPANY  
 711 ARMSTRONG LANE  
 COLUMBIA, TENNESSEE 38401  
 (831) 388-3003  
 SALES: J. WEATHERLY 615-261-0610  
 7 / LIVE JOBS / S / Safestitch 29253 FC

PRODUCTION COORDINATOR: DENISE HOPKINS 821-650-1714  
 PROOF OF: JANUARY 28, 2008  
 SAFESTITCH MEDICAL, INC.  
 TSB 29253 FC  
 OPERATOR: AP  
 Rev. 1

COLORS SELECTED FOR PRINTING: Logo prints PMS 365 at 90% and PMS 361. Intaglio prints in SC-20 Dark Brown.

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PLEASE INITIAL THE APPROPRIATE SELECTION FOR THIS PROOF:  OK AS IS  OK WITH CHANGES  MAKE CHANGES AND SEND ANOTHER PROOF

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN CON—as tenants in common

TEN ENT—as tenants by the entireties

JT TEN—as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT—                    —Custodian—                      
(Cust) (Minor)  
under Uniform Gifts to Minors Act—                      
(State)

Additional abbreviations may also be used though not in the above list.

*For Value Received, \_\_\_\_\_ hereby sell, assign and transfer unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

[Empty box for Social Security or other identifying number]

(PLEASE TYPEWRITE NAME AND ADDRESS)

*\_\_\_\_\_ Shares  
of the Stock represented by the within certificate and do hereby  
irrevocably constitute and appoint*

*\_\_\_\_\_ attorney,  
to transfer the same on the books of the within named Corporation,  
with full power of substitution in the premises.*

*Dated \_\_\_\_\_*

*Notes: The Signatures on this document must correspond with the name as written upon the facing the Certificate unless otherwise noted with an abbreviation or endorsement in any change instrument.*

Signature(s) Guaranteed:

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS, AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 1745-15.

AMERICAN BANK NOTE COMPANY  
711 ARMSTRONG LANE  
COLUMBIA, TENNESSEE 38401  
(931) 388-3000  
SALES: J. WEATHERLY 615-261-0610  
7 / LIVE JOBS / S / SafeStitch 29253 BK

PRODUCTION COORDINATOR: DENISE HOPKINS 931-460-1714  
PROOF OF: JANUARY 25, 2008  
SAFESTITCH MEDICAL, INC.  
TSB 29253 BK (LITHO)  
OPERATOR: AP  
NEW



**EXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT**

THIS EXCLUSIVE LICENSE AND DEVELOPMENT AGREEMENT (this "Agreement") is made as of the 26<sup>th</sup> day of May 2006, by and between Creighton University (the "University") and SafeStitch LLC, a Virginia limited liability company (the "Company"). References to an Article, Section, or paragraph mean an Article, Section or paragraph of this Agreement, unless otherwise specified.

WHEREAS, the University is the owner of United States Provisional Patent Application No. 60/698,748 filed July 13, 2005, and titled SUTURING SYSTEM FOR TRANSORAL GASTROPLASTY and United States Provisional Patent Application No. 60/742,826 filed December 6, 2005, and titled SYSTEMS AND TECHNIQUES FOR TRANSORAL GASTROPLASTY, as well as International Patent Application No. PCT/US04/028516 entitled SUTURING DEVICES AND METHODS, filed September 2, 2004 (claiming benefit of U.S. Provisional Patent Application Serial No. 60/499,539, filed September 2, 2003; U.S. Provisional Patent Application Serial No. 60/507,837, filed October 1, 2003; and U.S. Provisional Patent Application Serial No. 60/576,510, filed June 3, 2004), including any current and future Improvements (defined below) under the above-listed patents, and the University wishes to license such technologies to the Company under the terms of this Agreement; and

WHEREAS, the University has developed and will continue to develop Additional Technologies (defined below), and the University wishes to grant the Company an option to license such Additional Technologies during the first thirty-six (36) months of this Agreement; and

WHEREAS, the University agrees to grant the Company an Exclusive License (defined below) to use, develop and sell such technologies described above; and

NOW, THEREFORE, for and in consideration of the mutual representations and covenants hereinafter set forth, the parties hereby agree as follows:

Section 1. Definitions. The following terms, when used with initial capital letters, shall have the meanings set forth below:

1.1 "Additional Technologies" or "Additional Technologies and associated Know-How" shall mean any current technologies in development or future technologies commenced within the first thirty-six (36) months after the effective date of this Agreement by the University (with Dr. Charles Filipi as an inventor) related to any devices, material, and methods used in the practice of bariatric medicine and treatment of gastroesophageal reflux disease ("GERD"), transoral surgical techniques, and further relating to all alimentary and gastrointestinal components associated therewith, including but not limited to the esophagus, stomach, intestines and digestive tract, as well as such conditions as gastric bleeding, hernias, and other medical conditions that may benefit from such technologies.

1.2 "Affiliate" shall mean any entity that directly or indirectly controls, is controlled by, or is under common control with the Company, and for such purpose "control" shall mean the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the entity, whether through the ownership of voting securities, by contract or otherwise.

1.3 “Development” or “Developed” shall mean actions constituting commercially reasonable development activities with a goal such that, if successful and commercially viable, the inventions of the Licensed Patents will be utilized to provide Licensed Products for sale in the retail market.

1.4 “Improvements” shall mean any inventions, discoveries, trade secrets, improvements, and technical, clinical and other information, whether or not patented or patentable, together with all experience, data, formulas, procedures and results, and including all chemical, pharmacological, toxicological, clinical, and assay information relating to any Licensed Patent Rights.

1.5 “Know-How” shall mean all know-how, trade secrets, inventions, data processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether or not patentable, which are confidential and useful or necessary in making or using the devices set forth in the Licensed Patents, including, without limitation, all chemical, biochemical, toxicological and scientific research information necessary or useful in making, using, or obtaining approval for any device or method disclosed in the Licensed Patents.

1.6 “Licensed Patent Rights” and “Licensed Patents” shall mean (1) United States Provisional Patent Application No. 60/698,748 filed July 13, 2005, and titled SUTURING SYSTEM FOR TRANSORAL GASTROPLASTY and United States Provisional Patent Application No. 60/742,826 filed December 6, 2005, and titled SYSTEMS AND TECHNIQUES FOR TRANSORAL GASTROPLASTY; (2) International Patent Application No. PCT/US04/028516 entitled SUTURING DEVICES AND METHODS, filed September 2, 2004 (claiming benefit of U.S. Provisional Patent Application Serial No. 60/499,539, filed September 2, 2003; U.S. Provisional Patent Application Serial No. 60/507,837, filed October 1, 2003; and U.S. Provisional Patent Application Serial No. 60/576,510, filed June 3, 2004); (3) any and all Patent Rights under the patents or patent applications for any Additional Technologies and associated Know-How licensed by the Company pursuant to the Option granted in Section 5.3; and (4) future Improvements resulting from items described in (1), (2), and (3).

1.7 “Licensed Product” shall mean any device, instrument or other product, (i) which, but for the license granted under this Agreement, would infringe at least one Valid Claim in any country or (ii) the making or use of which, but for the license granted under this Agreement, would infringe at least one Valid Claim in any country. For the purposes of clarifying the meaning of “Licensed Product” by way of an illustrative example, it is to be understood that a product that would infringe a Valid Claim in the United States (but for the license granted under this Agreement) is a “Licensed Product” for all countries (e.g., England, China, etc.), irrespective of whether or not a Valid Claim exists in England, China, etc., and irrespective of whether or not the product would infringe a Valid Claim in England, China, etc.

1.8 “Patent Rights” shall mean all rights under patents and patent applications, disclosures of invention and any and all patents that issue therefrom (including utility, model and design patents and certificates of invention), together with any and all substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, reexaminations, renewals and foreign counterparts of the foregoing.

1.9 “Regulatory Filing” shall mean the formal submission of information, including clinical data if required, to the Food and Drug Agency (FDA) or other similar regulatory agencies in other countries in order to apply for approval to market any Licensed Product within the United States or other countries.

1.10 “Valid Claim” shall mean a bona fide, unexpired issued claim in a Licensed Patents which has not been held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, which has not been admitted to be invalid by the licensor or its successors or assigns though reissue or disclaimer.

## Section 2. Grant of Exclusive License.

2.1 Exclusive License. Subject to the terms and conditions of this Agreement, the University grants the Company an exclusive (even as to the University), worldwide license under the Licensed Patent Rights and associated Know-How, including the exclusive right to make, have made, use, sell, offer for sale, import or otherwise dispose of and enjoy any and all Licensed Products, subject to the University retaining a non-exclusive, non-assignable and non-sublicensable right limited solely to non-commercial practice under the Licensed Patents and associated Know-How solely for educational, research, and clinical study purposes. The University shall, at the Company’s request, execute a confirmatory license having the terms set forth herein with respect to any patent application or patent included in the Licensed Patents.

2.2 Transfer to Affiliates. The Company shall have the right to extend the rights granted herein to any of its Affiliates, upon the terms and conditions of this Agreement, provided the Company agrees in writing to be responsible for the performance by such Affiliates of all of the Company’s obligations hereunder, including the payment of earned royalties set forth below on Net Sales of any Licensed Product by the Affiliates to whom the licenses have been extended.

2.3 Sublicense Rights. The Company shall have the right under any and all of the licenses granted by the University herein to grant sublicenses to third parties at earned royalties not less than those the Company is required to pay as set forth in Section 3 of this Agreement.

(a) With respect to sublicenses that the Company grants under this Section 2.3, the Company shall pay the University that proportion of earned royalties received from its licensees necessary to provide the University with an amount of revenue from the Licensed Product sold by such sublicensees equal to the amount the University would have received from the Company if the Company had sold such Licensed Product. Additionally, with respect to sublicenses that the Company grants under this Section 2.3 within the first thirty-six months of the effective date of this Agreement, the Company shall pay to the University a percentage of all up-front sublicense revenues or fees actually paid to the Company pursuant to the grant of such sublicense, other than royalties, lines of credit, research and development funding, and other expense payments or reimbursements, in accordance with the following schedule:

Date of Sublicense Grant (from date of this Agreement)	Percent of Revenues to University
First six months	50%
Second six months	45%
Third six months	35%
Fourth six months	30%
Third year	20%

The University shall not be entitled to any percentage of up-front sublicense revenues or fees derived from sublicensing agreements entered into by the Company after the third year from the date of this Agreement.

(b) The granting of such sublicenses shall be in the discretion of the Company, and the Company shall have the sole power to determine whether or not to grant sublicenses, the identity of sublicensees, and the royalty rates and terms and conditions of such sublicenses, provided that:

(i) The University shall be provided with a complete, unredacted, fully executed copy of each executed sublicense agreement (including all exhibits, appendices, and other attachments) within thirty (30) days following its execution;

(ii) Each sublicense agreement shall contain terms requiring that the sublicense maintain complete and accurate records and permitting the University to audit such records, and said terms shall be at least as favorable to the University as those set forth in Section 3.4(vi) of this Agreement; and

(iii) Each sublicense agreement shall acknowledge that the University is a third-party beneficiary to the sublicense agreement.

2.4 **Enforcement Rights.** The University expressly grants the Company the first right to enforce any Licensed Patent, with the Company bearing all costs of such enforcement. In the event that the Company is found to have insufficient standing to be entitled to such enforcement rights, then the University agrees to enforce the Licensed Patent at the Company's reasonable request and at the Company's expense, with the Company having the right to be participate in such enforcement with counsel of the Company's choice and expense.

### Section 3. Royalty Payments.

3.1 **Royalty Defined.** In further consideration for the Exclusive License and development services granted under this Agreement, the Company shall pay the University on a quarterly basis an earned royalty of one and one-half percent (1.5%) on Net Sales (defined below) of any Licensed Product sold worldwide.



3.2. Net Sales. (i) For purposes of this Agreement, the term “Net Sales” shall mean the revenue that the Company or its Affiliates actually collect from the sale of any Licensed Product to an unaffiliated third party, less the following amounts: (a) payments made or credits allowed to customers for promotional purposes, allowances, rebates, discounts, profit share payments and other usual and customary discounts, including, without limitation, volume and prompt payment discounts, to customers, (b) the amount of chargebacks, and amounts repaid or credited by reason of rejections, damages or returns of goods, or because of retroactive price adjustments, (c) specific amounts not collectible after reasonable collection efforts, (d) invoiced taxes, duties, tariffs, surcharges and other governmental charges paid, absorbed or allowed in connection with the sale, import or export of the Licensed Product, (e) freight, postage, insurance charges and other transportation costs incurred in connection with transporting the Licensed Product, and (f) discounts or rebates or other payments required by law to be made under Medicaid, Medicare or other governmental special medical assistance programs, all as determined in accordance with generally accepted accounting principles in the U.S. consistently applied.

(ii) In the event that a Licensed Product is sold in a finished combination package with one or more other products, devices, equipment or components (a “Combination Product”), Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction  $A/(A+B)$  where A is the selling price of the Licensed Product if sold separately in finished form and B is the selling price of any other products, devices, equipment or components in the Combination Product if sold separately in finished form provided that the selling price of any Combination Product shall not be less than A+B. In the event that a product containing such Licensed Product or one or more of such products, devices, equipment or components in the Combination Product are not sold separately, then the parties shall negotiate in good faith a formula for calculating Net Sales for such Combination Product that reflects the respective contributions of the product containing the Licensed Product and such other products, devices, equipment or components to the overall value of such Combination Product. The Company covenants that it will not intentionally manipulate the fraction  $A/(A+B)$  to avoid or reduce royalty payments or obligations that would otherwise be due for sales of the Licensed Product in combination form or otherwise.

(iii) Net Sales shall not include the distribution of the Licensed Product free of charge for use in clinical trials or research or for charitable uses. The “Net Sales” for a Licensed Product that is otherwise transferred to a third party for promotional purposes without charge or at a discount shall be the average invoiced price to customers who purchased the Licensed Product during the applicable calendar quarter.

3.3 Earned Royalty Reduction for Third Party License. The Company or its Affiliates, in its sole discretion, may take a license under, or assignment of, patents or know-how of an unaffiliated third party that arguably cover in whole or in part any aspect of a Licensed Product under the terms requiring the Company to pay such third party an earned royalty for the sale of such Licensed Product. If the Company takes such a third party license or assignment, the Company shall be entitled to negotiate and enter into agreements with such third parties and fifty percent (50%) of any amounts payable by the Company, its Affiliates or sublicensees with respect to the Licensed Product under such agreements shall be credited against amounts payable to the University under this Section 2; provided, however, that the earned royalty amount due to the University shall not be reduced below 50% of royalties otherwise due (not less than 0.75% of Net Sales) for such Licensed Product.

3.4 Accounting for Payments. (i) Amounts owing to the University under this Section 3 shall be paid on a quarterly basis commencing with the calendar quarter in which the first commercial sale of any Licensed Product is made, with such amounts due and payable to the University on or before the forty-fifth (45<sup>th</sup>) day following the end of the calendar quarter ending on March 31, June 30, September 30 or December 31 in which such amounts were earned. Any amounts which remain unpaid after the date they are due to the University shall accrue interest from the due date at the rate of 1.5% per month. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. The Company shall also be responsible for repayment to the University of any attorney, collection agency, or other out-of-pocket University expenses required to collect overdue payments due from this Section, or any other applicable section of this Agreement.

(ii) Except as otherwise directed, all amounts owing to the University under this Agreement shall be paid in U.S. dollars to the University at the following address:

Lee I. Fenicle, Director  
Office of Technology Transfer  
Creighton University  
601 North 30<sup>th</sup> Street  
Suite 1609  
Omaha, NE 68131

(iii) All royalties owing with respect to Net Sales stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation — Value of Foreign Currencies on the last day of the relevant calendar quarter.

(iv) A statement showing how any amounts payable to the University under this Section have been calculated, including a description of any offsets or credits deducted therefrom, shall be submitted to the University on the date of each such payment. Such accounting statements shall also contain the total number of Licensed Products transferred by the Company, by each Affiliate, and by each sublicense, with country-by-country breakdowns, during the relevant calendar quarter; the revenue due to the Company for each of the aforementioned transfers; and the number of Licensed Products distributed during the relevant calendar quarter by the Company, by each Affiliate, and by each sublicense free of charge or at a discount per Section 3.2(iii). Such accounting statements shall contain a written representation signed by an executive officer of the Company that states that the statements are true, accurate, and fairly represent all amounts payable to the University pursuant to this Agreement.

(v) The University is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on the University by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to the University pursuant to this Agreement. The Company may withhold the appropriate tax from any payment to be made to the University under this Agreement provided that such withholding is required by applicable law and the Company submits the amounts withheld to the applicable tax authorities. In such event the Company will furnish the University with proof of payment of such tax together with official or other appropriate evidence issued by the applicable governmental authority.

(vi) During the term of this Agreement, and for a period of three years thereafter, the Company shall keep complete and accurate records in sufficient detail to permit the University to confirm the accuracy of all payments and reports due hereunder. The University shall have the right to cause an independent, certified public accountant reasonably acceptable to the Company and subject to terms of a confidentiality agreement to audit such records to confirm royalty payments for the preceding three years. Such audits may be exercised during normal business hours no more than once in any 12-month period upon at least 30 days' prior written notice to the Company. The University shall bear the full cost of such audit unless such audit discloses an underpayment by more than 5% of the amount due under this Agreement. In such case, the Company shall bear the full cost of such audit.

3.5 Survival of Royalty. The Company expressly agrees that any transfer, in whole or in part, of any rights in and/or to any Licensed Product, including but not limited to an assignment, sale of the assets of the Company, the acquisition of the Company, or merger of the Company with a third-party or parties shall not affect the Royalty or any other obligation of the Company to the University set forth in this Agreement.

3.6 Minimum Royalty Payments. The Company shall have no minimum royalty obligations to the University during the term of this Agreement.

#### Section 4. Scope of Development, Resources.

4.1 Facilities. The University shall provide and make available all necessary facilities, including animal research laboratories to accommodate Dr. Filipi's research and development of any Licensed Product. The University shall be compensated by the Company or otherwise reimbursed by the Company for use of such facilities as provided in the Research and Development Budget, which is appended hereto as Exhibit A and which is hereby incorporated into this Agreement, or as otherwise agreed upon by the parties. The Company agrees to update the Research and Development Budget not less frequently than once per year, with input from the University." The University shall not be held liable for the decisions of any third party or University authority or regulatory committee to disallow any animal research studies at the University. To the extent the University is prohibited from conducting any animal research studies on behalf of the Company, the funding requirements set forth under Section 5.1 shall be reduced by an amount equal to the amount allocated towards animal research in the Research and Development Budget and any extensions and renewals thereof.

4.2 Dr. Filipi's Research and Development. For as long as Dr. Filipi is an employee of the University, the University agrees that Dr. Filipi shall devote at least ninety percent (90%) of his working time over the next four (4) years commencing on the effective date of this Agreement and at least fifty percent (50%) of his time for two (2) years thereafter, using his best efforts, towards the research and development of any Licensed Product to a final design and prototype as a commercially viable product and assist the Company with the prosecution of any and all patent applications related thereto. Dr. Filipi shall be compensated for such work as provided for in the Research and Development Budget, or as otherwise agreed upon by the parties.

4.3 Company Ownership of Intellectual Property.

(a) Ownership of Intellectual Property Rights. The Company shall own all inventions conceived of and reduced to practice solely by its employees and agents, and all patent applications and patents claiming such inventions developed without the use of any Licensed Patent Rights or associated Know-How; and such inventions, patent applications and all resulting Patent Rights shall not be subject to this Agreement. The University shall own all inventions conceived of and reduced to practice solely by Dr. Filipi, its other employees, and/or its agents in the course of this Agreement, and all patent applications and patents claiming such inventions; and such inventions, patent applications and all resulting Licensed Patent Rights shall be subject to the exclusive license, royalty, and associated provisions of this Agreement. Company and University shall jointly own all inventions conceived of and reduced to practice jointly by (i) Dr. Filipi, the University's other employees, and/or the University's agents and (ii) the Company's employees and/or the Company's agents in the course of this Agreement; and such inventions, patent applications and all resulting Licensed Patent Rights shall be subject to the exclusive license, royalty, and associated provisions of this Agreement. Notwithstanding anything to the contrary contained in this Section 4.3, the University shall solely own all inventions conceived of or reduced to practice under the Research and Development Budget and any extensions and renewals thereof, and all patent applications and patents claiming such inventions, irrespective of whether such inventions are conceived of solely by Company employees and agents, solely by University employees and agents, or jointly by University employees and agents and Company employees and agents; and such inventions, patent applications and all resulting Licensed Patent Rights shall be subject to the exclusive license, royalty, and associated provisions of this Agreement.

(b) Ownership of Copyright and Trademark Materials. It is also contemplated that the University and its employees may create copyrightable and trademark- or servicemark-eligible work related to the Company's or any Licensed Product's marketing, promotion, and public relations ("Other Work") in connection with the performance of the development services under this Agreement. The University agrees that the copyright or mark and all other rights in and to the Other Work shall belong completely and in all respects to the Company and that the University and its employees shall retain no rights in or to such Other Work. The University further expressly agrees that the aforementioned Other Work will be considered and deemed as work made for hire for the benefit and exclusive ownership of the Company to the fullest extent permitted by law, provided, however, that if any copyrightable work shall not be legally qualified as work made for hire, the University agrees to assign, and does hereby so assign to the

Company, all rights, title and interest in and to such Other Work, including, but not limited to, the copyright or mark therein. Where the Company has authorized the University to subcontract all or a portion of any services or to engage any other organization to perform all or a portion of any services, the University further agrees to require by contract that any such subcontractor or organization assign, either to the University or to the Company as the designated client, all such Other Work created by such subcontractor or organization the University also agrees to furnish and execute such additional documents as the Company may require to establish the Company's ownership of the copyright or mark in the Other Work including, without limitation, such assignments of the copyright or mark therein throughout the world as the Company may deem appropriate. Notwithstanding the Company's ownership of any Other Work set forth above, the Company agrees that the University shall have the right to publish or present the results of scientific investigations associated with this Agreement, provided that confidential and/or propriety information of the Company not publicly known shall not be disclosed without the Company's prior written permission. The University shall provide the Company with a copy of the manuscript, paper, or poster not less than 30 days prior to any submission to any third party. If identified by the Company, the University will delete any of the Company's proprietary or confidential information contained herein. Additionally, the trademarks "SafeStitch" and "SafeStitch LLC", as well as any and all variants thereof, any domain names thereof, and goodwill associated therewith, shall be the property of the Company. The parties agree that all goodwill generated by any Licensed Product or the marks "SafeStitch" and "SafeStitch LLC", as well as any variants thereof, shall inure to the benefit of the Company.

(c) Prosecution and Maintenance of Patent Rights. The University shall, using agents or attorneys agreed to by the parties (including agreement with respect to costs associated with drafting and prosecuting patent applications), file, prosecute and maintain the Licensed Patents and all patent applications and patents disclosing and claiming inventions made in whole or in part by the University employees, agents or contractors resulting from the research and development the University engages in on behalf of the Company under the Agreement. The University shall file, prosecute and maintain one or more patent applications and patents in those countries designated by the Company. The University shall provide copies of all documents filed with or received from any domestic or foreign patent office to the Company to allow the Company adequate time to review and comment. For any patent prosecution or maintenance in any country designated by the Company, the Company shall reimburse the University within 45 days or receipt of written invoices provided to the Company by the University for all expenses, including attorney's fees and government fees associated with such filings, prosecution and maintenance costs, and for patent searches performed as part of an analysis of whether to file a patent application claiming such an invention. Reimbursement by the Company for legal services would be limited to an amount no greater than the median amount set forth in the then current AIPLA Report of the Economic Survey for comparable legal services unless otherwise agreed to in writing in advance. The amounts of this reimbursement would not be subjected to the limits or deducted from any other payments due from the Company to the University under the Agreement. The Company would reserve the right to discontinue reimbursement of such patent drafting, prosecution and/or maintenance in any country or for any patent application or patent by giving the University thirty days written notice. The Company would be responsible only for costs or fees incurred prior to such notice to the University, and the University would have the right, but not the obligation, to continue such drafting, prosecution, or maintenance at

the University's own expense. In the event that the Company chooses to discontinue reimbursement of patent drafting, prosecution, and/or maintenance in any country for any patent, then the associated Patent Rights in that country shall revert back to the University. A decision by the Company to discontinue reimbursement for patent costs in a particular country shall not affect the Company's reporting and payment obligations with respect to sales of Licensed Products by the Company, its Affiliates, and its sublicensees in the particular country.

(d) Infringement by Third Parties. If a party to this Agreement becomes aware of any infringement or potential infringement of any Licensed Patent Right, the party to this agreement shall promptly notify the other party of such infringement or potential infringement. During the term of this Agreement the Company shall have the right, but not the obligation, at its sole expense and with counsel of its own choice, to enforce the Licensed Patent Rights and associated Know-How against any infringer, including the right to file suit for patent infringement naming the University as a party, and the right to settle such suit with the University's consent, which consent shall not be unreasonably withheld. The University shall permit the use of its name in all such suits, sign all necessary papers, and do all reasonable things necessary, at the Company's expense, to facilitate the prosecution of such infringement suits. The Company shall pay to the University one and one-half percent (1.5%) of any amount collected as a result of such judgement or settlement within 30 days of the receipt thereof. The Company shall incur no other liability to the University as a consequence of such litigation, the conduct of such litigation or any unfavorable decision resulting from it, including any decision holding any of the Licensed Patent Rights invalid or unenforceable. In the event that the Company chooses not to file suit for patent infringement within 180 days after becoming aware of infringement, the University shall have the right, but not the obligation, at its sole expense and with counsel of its own choice, to enforce the Licensed Patent Rights and associated Know-How against any infringer, including the right to file suit for patent infringement naming the Company as a party, and the right to settle such suit with the Company's consent, which consent shall not be unreasonably withheld. The Company shall permit the use of its name in all such suits, sign all necessary papers, and do all reasonable things necessary, at the University's expense, to facilitate the prosecution of such infringement suits. The University shall pay to the Company one and one-half percent (1.5%) of any amount collected as a result of such judgement or settlement within 30 days of the receipt thereof. The University shall incur no other liability to the Company as a consequence of such litigation, the conduct of such litigation or any unfavorable decision resulting from it, including any decision holding any of the Licensed Patent Rights invalid or unenforceable.

#### Section 5. Commercial Funding and Development.

5.1 Funding Requirements. Company shall invest, in aggregate, at least \$2,500,000 within thirty-six (36) months of the effective date of this Agreement (i) under the Research and Development Budget and any extensions and renewals thereof, and (ii) towards development of any Licensed Product. If the Company fails to do so, all rights in the Licensed Patent Rights and associated Know-How shall revert back to the University. Further, Company agrees to pay to the University an overhead fee equal to 20% of the direct and personnel costs for services conducted at University or Company facilities in or around a 100 mile radius of Omaha, Nebraska (i) pursuant to the Research and Development Budget as set forth in Exhibit A, and

any extensions and renewals thereof and (ii) towards development of any Licensed Product. The parties may mutually agree from time to time to include direct or personnel costs for the development of a Licensed Product not conducted in the Omaha area in the calculation of the overhead fee. In this regard, the parties agree that amounts paid to Phoenix Analysis & Design Technologies (PADT) for the first two years from the date of this Agreement pursuant to the Research and Development Budget shall be included in the calculation of the overhead fee. Such overhead fee payments shall be made on a monthly basis and shall be accompanied by an accounting statement detailing expenditures made by the Company during the preceding month. Such accounting statements shall contain a written representation signed by an executive officer of the Company that states that the statements are true and accurate. The Company shall maintain records relating to such expenditures and permit audits of such records in accordance with the terms of Section 3.4(vi) of this Agreement. It is understood that the first \$150,000 of costs related to the prosecution of patents, including costs related to the defense or claims related thereto, associated with the Licensed Patent Rights and associated Know-How are not included in the \$2,500,000 amount recited in this Section 5.1.

5.2 Commercial Exploitation Term. The Company shall exercise its own business judgment and its sole and absolute discretion over the marketing, sale, distribution, promotion, or other commercial exploitation (collectively, the "Commercial Exploitation" or "Commercially Exploited") of any Licensed Product. In the event the Company has not Commercially Exploited or commenced Development of a Licensed Patent and its associated Know-How by the seventh (7<sup>th</sup>) anniversary of the later of the effective date of this Agreement or the date such technology is disclosed to and accepted by the Company, then Company shall promptly execute such papers as are necessary to cause the reversion of such Licensed Patent and associated Know-How back to the University, with no rights retained by Company, and the University will have the right to seek a third party with whom to commercialize such Patent and associated Know-How. Company may purchase one year extensions in addition to the seven years provided for Commercial Exploitation at a cost of \$100,000 per Licensed Patent per year of extension to avoid the reversion of any Patent Right that has not been Commercially Exploited or Developed. At any time, the Company may choose at its discretion not to develop one or more of the Licensed Patents. In such event, the Company will promptly notify the University in writing that the Company has decided to not commercialize such Licensed Patent, and all rights to such Licensed Patent and its associated Know-How shall revert back to the University.

5.3 New Technology Disclosure and Grant of Option. During the first thirty-six (36) months from the effective date of this Agreement, the University shall have an ongoing obligation to disclose any Additional Technologies and associated Know-How, and the Company shall have an option for thirty (30) days after such disclosure (the "Option") to accept or reject such disclosed technology for continued Development. Such disclosures shall be made no less than quarterly, and the date of written acceptance by the Company shall commence the 7-year term set forth in Section 5.2 with respect to each disclosed and accepted item. The University shall not have any right to reimbursement under this Agreement for any technology not specifically referenced in this Agreement until disclosed to and accepted by the Company subject to the terms of this Section 5.3.

5.4 Enforceability. The Company agrees to cooperate in executing any documents necessary to cause rights in the Licensed Patent Rights and associated Know-How to revert back to the University pursuant to Sections 5.1 and 5.2, and the rights of the University to such reversion shall be enforceable by specific performance. The parties agree to submit any dispute to non-binding arbitration as governed under the rules of arbitration in the Omaha, NE area before filing suit in any court of law. The prevailing party shall be entitled to reimbursement of any legal fees incurred pursuant to this Section 5.4.

## Section 6. Confidentiality and Disclosure.

### 6.1 Confidentiality.

(a) By the University. From and after the execution of this Agreement, the University shall keep secret and retain in the strictest confidence, and shall not use for the benefit of any person other than the Company, all confidential information and trade secrets disclosed to the University relating to any Licensed Product or the business and other operations of the Company, including, without limitation, the Licensed Patent Rights and associated Know-How that will be developed, designed, and/or otherwise created, whether or not any of such technology is protected or can be protected by patents, trademarks, copyrights or other intellectual property rights. The University shall use reasonable efforts to ensure that all employees, contractors and consultants employed or engaged by the University in furtherance of its business shall maintain the same confidentiality related to Company matters that are required by the University. For purposes of this Agreement, the parties understand and agree that the term "confidential information" does not include information which (i) has been published or is now in the public domain, or in the future becomes published or in the public domain through no action of the University; (ii) subsequent to disclosure hereunder, is received by the University from a third party not known by the University to be under an obligation of confidentiality to the Company; (iii) is independently developed by the University without reference to the confidential information of the Company; or (iv) is disclosed with the prior written approval of the Company. Company understands that in the course of prosecution of Patent Rights, it may be desirable and/or necessary that certain information be disclosed to one or more patent offices or otherwise, and nothing in this Agreement shall be construed as restricting the University from making such disclosures.

(b) By the Company. From and after the execution of this Agreement, the Company shall keep secret and retain in the strictest confidence, and shall not use for the benefit of any person other than the University, all confidential information and trade secrets disclosed to the Company relating to any Licensed Product or the business and other operations of the University, including, without limitation, the Licensed Patent Rights and associated Know-How that will be developed, designed, and/or otherwise created, whether or not any of such technology is protected or can be protected by patents, trademarks, copyrights or other intellectual property rights. The Company shall use reasonable efforts to ensure that all employees, contractors and consultants employed or engaged by the Company in furtherance of its business shall maintain the same confidentiality related to University matters that are required by the Company. For purposes of this Agreement, the parties understand and agree that the term "confidential information" does not include information which (i) has been published or is now in the public domain, or in the future becomes published or in the public domain through no



action of the Company; (ii) subsequent to disclosure hereunder, is received by the Company from a third party not known by the Company to be under an obligation of confidentiality to the University; (iii) is independently developed by the Company without reference to the confidential information of the University; or (iv) is disclosed with the prior written approval of the University. Notwithstanding the foregoing, the Company may exercise its sole business judgment in disclosing information related to any Licensed Product in furtherance of the Development or Commercial Exploitation of such Licensed Product and may also disclose any information legally required to be disclosed by any regulatory body related to the Commercial Exploitation or Development of any Licensed Product without the consent or prior approval of the University.

#### 6.2 Disclosure.

(a) By the University. If the University is requested or required by a court having competent jurisdiction, by oral questions, by interrogatories, or similar requests for information or documents, by subpoena, civil investigative demand or similar process, to disclose any confidential information of the Company, the University shall provide the Company with written notice of such request or requirement so that the Company may seek an appropriate protective order and/or waive compliance with the provisions of this Agreement. The University agrees to cooperate with the Company, at the Company's sole expense, in obtaining such protective order. If the Company does not obtain such protective order or provide a waiver of the obligations of this Agreement within a reasonable time after the University has provided written notice under this paragraph, the University may disclose such confidential information pursuant to such request or requirement without liability under this Agreement.

(b) By the Company. If the Company is requested or required by a court having competent jurisdiction, by oral questions, by interrogatories, or similar requests for information or documents, by subpoena, civil investigative demand or similar process, to disclose any confidential information of the University, the Company shall provide the University with written notice of such request or requirement so that the University may seek an appropriate protective order and/or waive compliance with the provisions of this Agreement. The Company agrees to cooperate with the University, at the University's sole expense, in obtaining such protective order or provide a waiver of the obligations of this Agreement within a reasonable time after the Company has provided written notice under this paragraph; the Company may disclose such confidential information pursuant to such request or requirement without liability under this Agreement.

#### Section 7. Indemnification.

7.1 By the University. The University agrees to defend and indemnify and hold the Company harmless against any and all claims, suits, proceedings, expenses, recoveries and damages, including court costs and reasonable attorneys fees and expenses, arising out of, based on, or caused by the breach by the University of any representation of warranty contained in this Agreement, except to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from or are aggravated by acts of or failure to act by the Company; provided that the Company shall provide the University with reasonably prompt written notice of any claim or action for which it seeks indemnification under this Section 7.1. The University shall have sole control of the defense and settlement of any such claim or action; and the Company shall reasonably cooperate and provide reasonable assistance in connection with the defense and settlement of any such claim or action. Nothing in this Section 7.1 shall be construed as requiring the University to defend, indemnify, or hold the Company harmless with respect to any claim, suit, proceeding, expense, recovery, or damage related to alleged infringement of any third party Patent Right by any product, device, or method developed by the University under this Agreement.

7.2 By the Company. The Company agrees to defend and indemnify and hold the University harmless against any and all claims, suits, proceedings, expenses, recoveries, and damages including court costs and reasonable attorneys fees and expenses, in connection with any of the Licensed Products sold by the Company or its Affiliates arising out of, based on, or caused by (i) the Company's use, manufacture, sale, offer for sale or disposal of the Licensed Product; (ii) the storage, sale, shipment, promotion or distribution of the Licensed Products by the Company or its Affiliates; or (iii) the breach by the Company of any representation or warranty contained in this Agreement, in each case except to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from or are aggravated by acts of or failure to act by the University; provided that (a) the University shall provide the Company with reasonably prompt written notice of any claim or action for which it seeks indemnification under this Article; (b) the Company shall have sole control of the defense and settlement of any such claim or action; and (c) the University shall reasonably cooperate and provide reasonable assistance in connection with the defense and settlement of any such claim or action.

#### Section 8. Representations and Warranties.

8.1 University Representations and Warranties. The University represents and warrants to the Company that all necessary university, corporate, and governmental authorizations, consents and approvals which are necessary or required for the entering into of this Agreement have been duly obtained; and the entering into of this Agreement by the University will not violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body to which the University is subject.

8.2. Company Representations and Warranties. The Company represents and warrants to the University that:

(a) all necessary corporate and other authorizations, consents and approvals which are necessary or required for the entering into of this Agreement have been duly obtained; the entering into of this Agreement by the Company shall not (i) violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company under its organizational documents, as amended to date, or any material note, indenture, mortgage, lease, agreement, contract, purchase order or other instrument, document or agreement in which the Company is a party or by which it or any of its properties or assets is bound or affected.

### 8.3 Disclaimer of Warranties.

(a) EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT AND THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY KIND INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

(b) NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUCCESS OF THE DEVELOPMENT OR THE COMMERCIAL EXPLOITATION OF ANY PRODUCT.

Section 9. Governing Law; Construction; Severability. This Agreement and the rights and liabilities of the parties hereunder shall be governed by and determined in accordance with the laws of the State of Illinois. All pronouns shall be deemed to be the masculine, feminine, neuter, singular or plural as the identity of the person or persons may require. References to a person or persons shall include partnerships, corporations, companies, unincorporated associations, trusts, estates and other types of entities. Every provision of this Agreement is intended to be severable. To the extent any provision of this Agreement is prohibited or otherwise ineffective under applicable law, such provision shall be considered to be ineffective to the smallest degree possible in order to make this Agreement effective under applicable law. In any judicial proceeding, if a court shall refuse to enforce the scope of any restrictions herein, including geographic and/or time restrictions, to their fullest extent, then such scope, including the geographic and/or time restrictions, shall be reduced to the extent necessary to permit enforcement of such restrictions to the fullest extent possible.

Section 10. No Partnership. Nothing contained herein shall be construed as creating a partnership (including, without limitation, a limited partnership) or joint venture between or among the parties hereto. No party shall act as or be deemed to be a partner or joint venturer of any other party.

Section 11. Captions; Headings. The captions and headings in this Agreement are for convenience only and are not to be considered in construing this Agreement.

Section 12. Counterparts. This Agreement, and any amendments hereto may be executed in counterparts all of which taken together shall constitute one agreement.

Section 13. Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter hereof. With the exception of such agreements or other documents that are expressly incorporated herein, it is the intention of the parties that this Agreement shall be the sole source of agreement of the parties and this Agreement shall govern even when inconsistent with or different from, the provisions of any applicable law or rule.

Section 14. Amendments. This Agreement may not be altered, amended, changed, supplemented, waived or modified in any respect or particular unless the same shall be in writing and unanimously agreed to by the parties hereto.

Section 15. Effect on Successors. This Agreement shall be binding upon and inure to the benefit of the parties hereto and to their respective heirs, executors, administrators, successors and assigns.

[signature page follows]

**Signature Page**

Creighton University

By: /s/ David E Burkey  
Daniel E. Burkey  
VP, Administration and Finance  
Creighton University

May 26, 2006  
Date

SafeStitch LLC

By: /s/ Jeffrey G. Spragens  
Jeffrey G. Spragens  
Business Manager  
SafeStitch LLC

May 4, 2006  
Date

**EXHIBIT A**

**RESEARCH AND DEVELOPMENT BUDGET**

	<u>Annual</u>	<u>Total</u>
<b><u>Personnel</u></b>		
Director	150,000	300,000*
Biomedical engineer — consultant	100,000	200,000*
Biomedical engineer — knotting / electrical	100,000	200,000
Biomedical engineer — needle mechanism	100,000	200,000
Biomedical engineer — automation	100,000	200,000
Animal technician	30,000	60,000
Research fellow	40,000	40,000
Administrative assistant	30,000	60,000
SUBTOTAL SALARIES		1,260,000
Taxes and Benefits — 37%		281,200
<b>TOTAL PERSONNEL</b>		<b>1,541,200</b>
<b><u>Direct Costs</u></b>		
Animals		82,400
Surgical supplies		20,000
Office supplies		10,000
Operating room equipment		10,000
Consultant costs		300,000
Prototype expense		350,000
<b>TOTAL DIRECT COSTS</b>		<b>772,400</b>
<b><u>Indirect Costs and Overhead</u></b>		
Creighton University Indirect Cost Allowance — 20%		462,700
Legal		150,000
Accounting		30,000
Insurance		50,000
Licenses and fees		10,000
Travel		20,000
Marketing		10,000
Contingency at 10%		304,630
<b>TOTAL INDIRECT COSTS</b>		<b>1,037,330</b>
<b>TOTAL BUDGET</b>		<b>3,350,930</b>

\* No benefits included

**SUBSIDIARIES**

<u>Name of Subsidiary</u>	<u>State of Incorporation</u>	<u>Name Under Which Subsidiary Is Doing Business</u>
Isis Tele-Communications, Inc.	Delaware	Isis Tele-Communications, Inc.
SafeStitch LLC	Virginia	SafeStitch LLC

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Registration Nos. 333-0849 and 333-44410) of our report dated March 26, 2008, with respect to our audits of the consolidated financial statements of SafeStitch Medical, Inc. (formerly known as Cellular Technical Services Company, Inc.) as of December 31, 2007 and for the years ended December 31, 2007 and 2006 and for the period from September 15, 2005 (inception) through December 31, 2007, included in the Annual Report in Form 10-KSB for the year ended December 31, 2007 filed with the Securities and Exchange Commission.

/s/ Eisner LLP  
New York, New York  
March 26, 2008

## CERTIFICATIONS

I, Jeffrey G. Spragens, certify that:

1. I have reviewed this Annual Report on Form 10-KSB of SafeStitch Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

By: /s/ Jeffrey g. Spragens  
Jeffrey G. Spragens  
Chief Executive Officer  
(Principal Executive Officer)  
March 26, 2008



## CERTIFICATIONS

I, Kenneth Block, certify that:

1. I have reviewed this Annual Report on Form 10-KSB of SafeStitch Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

By: /s/ Kenneth Block

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Kenneth Block  
Chief Financial Officer  
March 26, 2008

**CERTIFICATION PURSUANT  
TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-KSB of SafeStitch Medical, Inc. for the fiscal year ended December 31, 2007 (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of SafeStitch Medical, Inc.

By: /s/ Jeffrey g. Spragens

Jeffrey G. Spragens  
Chief Executive Officer  
(Principal Executive Officer)  
March 26, 2008

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes—Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of SafeStitch Medical, Inc. or the certifying officers

**CERTIFICATION PURSUANT  
TO  
SECTION 906 FO THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-KSB of SafeStitch Medical, Inc. for the fiscal year ended December 31, 2007 (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of SafeStitch Medical, Inc.

By: /s/ Kenneth Block

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Kenneth Block  
Chief Financial Officer

March 26, 2008

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes—Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of SafeStitch Medical, Inc. or the certifying officers