SafeStitch Medical, Inc.
Form 10-K
March 27, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

S Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2008

OR

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

Commission File Number 0-19437

SAFESTITCH MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	11-2962080
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

Securities registered pursuant to Section 12(b) of the Exchange Act: None

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

Common Stock, $0.001 par value per share
(Title of Class)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. ¨

Indicate by check mark 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not 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-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of June 30, 2008 was: $13.4 million

As of March 15, 2009 there were 17,962,718 shares of Common Stock, $0.001 par value outstanding.

SAFESTITCH MEDICAL, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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, among other things, 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-K. We do not undertake any obligation to update forward-looking statements, except as required by applicable law. We intend that all forward-looking statements be subject to the safe harbor provisions of the 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.

- The current worldwide economic crisis and concurrent market instability may materially and adversely affect the demand for our products and, if and when approved, our product candidates, as well as our ability to obtain credit or secure funds through sales of our stock, which may materially and adversely affect our business, financial condition and ability to fund our operations.

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

- Most of our technologies are in an early stage of development and are unproven.

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

- The results of previous clinical experience with devices similar to the devices that we have licensed and are developing 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 are highly dependent on the success of our product candidates, and we cannot give any assurance that each of them will receive regulatory clearance or that any of them will be successfully commercialized.

- 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.

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

- 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 obtain regulatory clearances or approvals to market our product candidates, the market may not be receptive to our products or third-party payors, including government payors, such as Medicare, Medicaid or TriCare, may not provide coverage for our products or for procedures using our products which could undermine our financial viability.

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

- As we are evolving 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.

- We rely heavily on licenses from third parties.

- Most 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.

- 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.

- 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 products and 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.

- 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.

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

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

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

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

- The market price of our common stock may fluctuate significantly.

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

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

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

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

* * * * *

PART I

Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K 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 our 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 OTCBB 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 LLC 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. These 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

The Share Exchange was accounted for as a recapitalization of LLC, and LLC has been treated as the continuing reporting entity. Since CTS did not have an operating business at the time of the Share Exchange, the transaction has not been accounted for as a business combination. Instead, the transaction has been 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, approximating fair value with no goodwill or other intangibles recorded.

Company Overview

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

We have utilized our expertise in intraperitoneal surgery to test certain of our devices in in vivo and ex vivo animal trials and ex vivo human trials, and with certain products, in limited in vivo human trials. Certain of our products did

not or may not require clinical trials, including our SMART DilatorTM, standard and airway bite blocks and hernia stapler. Where required, we intend to rapidly, efficiently and safely move into clinical trials for certain other devices, including those utilized in surgery for the treatment of obesity, GERD and for the treatment and diagnosis of Barrett's Esophagus. Clinical trials for gastroplasty product candidates should begin in 2010.

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

- Increased effectiveness;
- Safer procedures;
- Fewer complications; and
- Reduced costs.

We believe that we can accomplish these goals by developing devices that, among other things, allow the endoscopic performance of certain types of surgery that are currently performed through an abdominal incision, including laparoscopically. Devices such as these are expected to reduce the need for inpatient hospital stay and decrease the likelihood of complications and their associated costs.

We plan to use our endoscopic, laparoscopic and general surgery experience, our internal product design expertise and our relationships with third-party product developers to further develop a pipeline of surgical devices to be utilized in treating intraperitoneal abnormalities such as 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 ("Creighton") 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 Opportunities

We believe the market for our products and 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 intraperitoneal abnormalities; and
- An increased awareness of the benefits of minimally invasive surgery.

Our lead product candidates are designed for use in operations necessitated in large part by obesity. The incidence of obesity (defined as 100 pounds over ideal body weight) is increasing, despite increased public awareness of the health risks associated with obesity and the growth of the diet and fitness industries. According to recent surveys and medical journal reports, approximately two thirds of individuals living in the United States are overweight and as many as 70 million Americans, roughly 25% of the U.S. population, are currently considered obese. Some estimates project that 100 million Americans, or approximately 35% of the anticipated U.S. population, will be obese by the year 2017. The incidence of obesity is increasing not only in the U.S., but is becoming a problem in industrialized countries worldwide, including China and India.

Current treatment options for obesity include exercise and dieting, prescription drugs, bariatric surgical alternatives and, in the near future, gastric stimulators. Exercise and dieting are often not successful, and, if successful, the results are often not permanent. In addition, although there are a number of drug alternatives currently in the market for treating obesity, they often result in moderate weight loss (typically no more than 10% of body weight).

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 bariatric surgery methods include gastric bypass, gastric banding and gastroplasty. The leading and most successful type of bariatric surgery is gastric bypass, which combines 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, thereby decreasing the body's ability to absorb nutrients from food. Other types of bariatric surgery include gastric banding, in which a small inflatable/dilatable band (which allows adjustment to the size of the opening between the pouch and the stomach) 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 are expensive, require significant incisions and have a moderate to high level of complications.

Our lead product candidates can also be used to treat GERD and GERD related complications such as Barrett's Esophagus. Up to 40% of the adult population in the United States suffers GERD symptoms monthly. Left untreated for a prolonged period of time, GERD 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. Worldwide, there are approximately 200,000 – 250,000 GERD or acid reflux surgical or transoral procedures performed annually. None of the currently available outpatient endoscopic procedures have proven effective in reversing inflammation of the esophagus or the amount of acid reflux. Another common GERD complication is scar tissue in the esophagus that inhibits the movement of swallowed food and drink. This and other types of esophageal restrictions are treated by inserting a dilator tube or inflatable balloon at the stricture and dilating the esophagus. Approximately 2 million esophageal dilations are performed annually worldwide, and 20 million endoscopies are performed annually worldwide. All endoscopies require a bite block to protect both the endoscope and the patient's teeth.

Additionally, we are developing our Amid Hernia Stapler for use in both inguinal and ventral open hernia repairs. Hernias impact approximately 1% of the World's population, and roughly 800,000 inguinal hernias are repaired annually in the United States. Greater than 80% of the surgeries for this most common form of hernia are performed using the Lichtenstein Hernia Repair, whereby a surgeon repairs and reinforces the abdominal wall by affixing mesh through an open incision.

Products

SMART DilatorTM

Dilators are used when an endoscopy demonstrates the narrowing of the esophagus. Narrowing may be treated by administering GERD medication or by using a dilator to expand the esophagus. Studies have estimated that approximately 10,000 instances of perforation of the esophagus occur annually as a result of esophageal 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, during dilation, the physician should place no greater than two pounds of pressure on the dilator. Our SMART DilatorTM has a handle that changes from green to yellow and then to red, providing the physician a visual indicator of how close he or she is to the recommended two pound limit. Additionally, the SMART DilatorTM handle locks in place when the force applied to the dilator exceeds 2.5 pounds of pressure. While there are numerous dilators on the market, none include a feedback mechanism similar to that contained in the SMART DilatorTM.

We received FDA clearance to market the SMART DilatorTM as a Class II device in February 2009, and we expect to begin commercial sales of the SMART DilatorTM by the second half of 2009.

Bite Blocks

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.

Standard Bite Block. 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 on the market. Because this is a Class I device, significant testing has not been necessary; however, in 2008, Creighton University Medical Center performed a bite block study. See "-FDA Regulation of the Design, Manufacture and Distribution of Medical Devices". This product candidate was tested for comfort during endoscopic procedures in in vivo human patients. We believe this is a Class I 510(k)-exempt device that requires no preclearance from the FDA prior to marketing, which we expect to commence by the second half of 2009.

Airway Bite Block. The Airway Bite Block contains a built-in airway that assists breathing in patients with larger tongues or smaller throats, usually because of obesity, during an endoscopic procedure. The Airway Bite Block was also tested following Institutional Review Board (IRB) approval at Creighton University Medical Center in 2008. The Airway Bite Block will come in two sizes. We believe this is a Class I 510(k)-exempt device that requires no preclearance from the FDA prior to marketing, which we expect to commence by the second half of 2009.

Product Candidates

We have prioritized our product development efforts on those candidates aimed at opportunities within gastroenterology, in which attractive markets combine with an emerging understanding of intraluminal surgery. In that regard, our initial key product candidates focus on obesity and obesity-related conditions, as well as other intraperitoneal abnormalities, which often may be treated by bariatric surgery.

Intraluminal Gastroplasty Device for Obesity and GERD ("Gastroplasty Device")

Our Gastroplasty Device consists of a set of instruments designed to perform incision-less, endoscopic surgery by introduction through the mouth and esophagus. Bariatric and GERD surgeries are 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.

The Gastroplasty Device is the most tested of our devices, and our testing to date has established its effectiveness. In animal tests and ex vivo human testing, the Gastroplasty Device has been successful in obesity surgeries for 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 2010. In GERD patients, the esophageal junction does not close completely and acid or bile from the stomach enters the esophagus. Both the hydrochloric acid and bile from the stomach can damage the esophagus. We have successfully tested a prototype in two patients with Creighton University Medical Center IRB permission, and we presently expect to continue in vivo human testing of this device in 2010. We believe that this device will result in significantly fewer complications and lower expense for both obesity and GERD procedures, both because the procedure will be less invasive and because recuperation time will be reduced. We believe this device to be a Class II 510k device that will require IDE (investigational device exemption) clinical data for FDA approval.

The Amid Hernia Stapler

We are developing the Amid Hernia Stapler in cooperation with Dr. Parviz Amid, originator of the Lichtenstein Hernia Repair. This stapler will utilize non-absorbable titanium staples for the repair of inguinal or groin hernias. The staples are used to fix mesh in place, which helps prevent the recurrence of a hernia. We believe our

stapler will make hernia repairs easier and will reduce postoperative pain as compared to traditional hand suturing techniques and currently available staplers. We expect to submit a 510(k) premarket approval application for the Amid Hernia Stapler to the FDA in the second half of 2009.

Barrett's Excision and Ablation Device for Treatment and Diagnosis ("Barrett's Device")

The Barrett's Device is the only device of which we are aware that is designed to assist in both the diagnosis of and treatment of Barrett's Esophagus. Barrett's Esophagus, which may be caused by GERD, is a condition in which the lining of the esophagus 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 would 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 2010. We believe this device to be a Class II 510(k) device that will require IDE clinical data to support a premarket notification for FDA clearance.

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 of its 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. We believe this device to be a Class II 510(k) device that will require IDE clinical data to support a premarket notification for FDA clearance. We have not yet begun significant development of the T Fastener Gun.

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. Surgery utilizing the NOTES approach requires stabilization of long flexible instruments and the organs to be operated upon. We have received a license from Creighton 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. We have not yet begun development of devices utilizing this technology.

Intellectual Property

We have exclusively licensed technology, know-how and patent applications from Creighton for most 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 intellectual property that we have not yet defined as product candidates. In total, we have eight patent applications pending in the United States, including seven that are exclusively licensed from Creighton. Six of the patent applications are also pending internationally, including five that are exclusively licensed from Creighton.

Pursuant to our exclusive license and development agreement with Creighton, 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 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 foregoing, 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 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 as a party, and the right to settle such suit with the university's consent, which shall not be unreasonably withheld. Creighton 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 has 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.

We believe that technological innovation is driving breakthroughs in the surgical markets that we intend to service. We have adopted a comprehensive intellectual property strategy that blends 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 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, 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. 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.

Pursuant to the exclusive license and development agreement we are obligated to pay Creighton, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from the sale of any product licensed under the agreement, 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 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 2008 and 2007, we recorded an expense of $177,000 and $322,000, 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, 2008, we had invested $5.1 million 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 or more one-year extensions. In addition to the expenses in connection with our agreement with Creighton, we have incurred research and development expenses of $2.5 million and $1.6 million for the years ended December 31, 2008 and 2007, 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 Gastroplasty Device; USGI Medical 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 (Helioscopie) or gastric sleeves to reduce food intake.

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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 its foreign counterparts.

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 – through a Section 510(k) premarket notification application ("510(k) submission"), or through a Section 515 premarket approval ("PMA") application. The 510(k) submission 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. Under the 510(k) submission process, the FDA will issue an 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 PMA process described below.

The more comprehensive PMA 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 PMA 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 Section 515 PMA approval, as compared to a Section 510(k) 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 a company'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 Gastroplasty 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 Gastroplasty 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 Gastroplasty 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 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 process 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 a 510(k) submission 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.

As a company that intends to manufacture medical devices, we are required to register with the FDA before we begin to manufacture devices 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 is 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.

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 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. Coverage presupposes that the device has been cleared or approved by the FDA and, further, that the coverage will be no broader than the FDA 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/MedicareApprovedFacilitie/BSF/list.asp and the surgical procedure is of a type expressly approved by CMS.

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 patient's 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%. If a device is used as part of an in-patient procedure, the hospital where the procedure is performed is reimbursed under the Inpatient Prospective Payment System ("IPPS"). In general, IPPS provides a single payment to the hospital based on the diagnosis at discharge and devices are not separately reimbursed under IPPS.

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.

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 supplier’s liquidity and financial condition. An 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. Recent changes in the law wrought by the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (Feb. 17, 2009), may increase the likelihood that we would be treated as a business associate thereby subjecting us to direct government regulation, increasing our compliance costs and our exposure to civil monetary penalties and other government sanctions.

Manufacturing

We have no commercial manufacturing facilities and we 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 make prototypes of certain of our product candidates for testing, including for limited use in animal or human clinical testing, in our Miami, Florida prototype laboratory. We have also entered into agreements with 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.

Sales & Marketing

We do not have dedicated sales or marketing personnel, and our Chief Operating Officer is presently leading our current marketing efforts. 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 initially distribute our products, including our SMART DilatorTM and bite blocks, through companies with established sales and marketing operations in the medical device industry. Although we are in discussions with such companies, there can be no assurance that we will be able to enter into distribution agreements on terms acceptable to us or at all.

Employees

As of December 31, 2008, we had fourteen full-time employees, seven of whom hold advanced degrees. In January 2009, we reduced our research and development staff by five full-time employees to reduce costs as we completed development of three products and refocused our development efforts on our most promising remaining product candidates (See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations). We plan to add to our headcount in key functional areas as required to commence commercialization activities and further the development of our product candidates. None of our employees are represented by a collective bargaining agreement.

Executive Officers of the Registrant

Jeffrey G. Spragens. Mr. Spragens, 67, has served as our President and Chief Executive Officer and as a member of our Board of Directors since the Share Exchange in September 2007, and he has served as Business Manager of SafeStitch LLC, of which he was a founding member, since August 2005. 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, 29, has served as our Chief Operating Officer and Secretary since the Share Exchange in September 2007 and had joined SafeStitch LLC as Chief Operating Officer in June 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 focusing 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, 68, has served as our Medical Director and a member of our Board of Directors since the Share Exchange in September 2007. Dr. Filipi was a founding member of SafeStitch LLC in August 2005 and has served as its Medical Director since 2006. 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.

Adam S. Jackson. Mr. Jackson, 46, joined the Company as Vice President, Finance in March 2008 and was appointed Chief Financial Officer in April 2008. Mr. Jackson also serves as Chief Financial Officer of Non-Invasive Monitoring Systems, Inc., a publicly-traded medical device company, and as Vice President, Finance of Aero Pharmaceuticals, Inc, a privately-held pharmaceutical distributor. Prior to joining the Company, Mr. Jackson served as Senior Vice President, Finance for Levitt Corporation ("Levitt"), a publicly-traded real estate development company, from 2006 to 2008, where he was responsible for the Levitt's financial planning and analysis activities. From 2003 to 2006, Mr. Jackson served as Levitt's Senior Vice President, Controller, during which period he supervised Levitt's accounting and financial reporting activities. From 2001 to 2003, Mr. Jackson served as Chief Financial Officer of Romika-USA, Inc., a privately held consumer goods manufacturing and distribution concern. From 2000 to 2001, Mr. Jackson served as Chief Operating Officer of V-Commex.com Corp., a privately-held internet company developing an international business-to-business web portal. From 1998 to 2000, Mr. Jackson served as Director of Financial Planning and Analysis at Eclipsys Corporation, a publicly-traded healthcare information technology provider.

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.

"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-K. 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 until at least the second half of 2009. Only three of our product candidates may currently be marketed in the United States without further FDA clearance or approval. 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, 2008 and 2007 were $5.2 million and $3.0 million, respectively and we had an accumulated deficit of $9.4 million as of December 31, 2008. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we 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.

The current worldwide economic crisis and concurrent market instability may materially and adversely affect the demand for our products and, if and when approved, our product candidates, as well as our ability to obtain credit or secure funds through sales of our stock, which may materially and adversely affect our business, financial condition and ability to fund our operations.

The current worldwide economic crisis may reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our products and, if and when approved, our product candidates. Such a delay could have a material adverse impact on our business, expected cash flows, results of operations and financial condition.

Additionally, we have funded our operations to date primarily through private sales of our common stock and through borrowings under credit facilities available to us from stockholders and other individuals, including our existing $4.0 million line of credit. The current economic turmoil and instability in the world's equity and credit markets may materially adversely affect our ability to sell additional shares of our stock and/or borrow cash under existing or new credit facilities. There can be no assurance that we will be able to raise additional working capital on acceptable terms or at all, which may materially adversely affect our ability to continue our operations.

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

We intend to advance multiple additional 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.

Most of 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, hernia formation, Barrett's Esophagus, esophageal obstructions and upper gastrointestinal bleeding. 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.

Many of our product candidates are still in early stages of development and are prone to the risks of failure inherent in medical device product development. We will likely be required to undertake significant clinical trials to demonstrate to the FDA that our licensed devices are safe and effective for their intended uses or that they 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.

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 or clear the labeling claims necessary or desirable for the successful commercialization of our product candidates.

We are highly dependent on the success of our product candidates, and we cannot give any assurance that each of them will receive regulatory clearance or that any of them will be successfully commercialized.

We are highly dependent on the success of our product candidates, especially the Gastroplasty Device and the Amid Hernia Stapler. 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.

If our competitors develop and market products that are more effective, safer or less expensive than our 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 and commercializing 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 device 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., 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;
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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 us, the FDA, other regulatory authorities or the IRB for any given site. 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 and clearance processes are expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals or clearances, as the case may be, for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, clearance, 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. To date, we have only received marketing clearance for our SMART DilatorTM. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews and clears a premarket notification in three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance, that even if a device is reviewed under the 510(k) premarket notification 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;

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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 510(k) 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 510(k) 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 QSR, 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 Medical Device Reports with the FDA, 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 product candidates fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.

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

that may be cleared or approved.

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

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

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

We have scientific and clinical advisors who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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

As we are evolving 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 QSR, 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 dedicated 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 minimal marketing, sales or distribution capabilities. If our product candidates are approved, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future product candidates. If we are not successful in commercializing our existing and future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

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

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

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

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

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

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

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

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.

Most of the patent applications in our patent portfolio are not owned by us, but are licensed from Creighton. Presently, we rely primarily on licensed technology for 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 most 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.

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 to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

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

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

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

products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

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

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

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

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

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

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

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

We intend to market certain of our existing and future product candidates in non-U.S. markets. In order to market our existing and future product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may

differ from that required to obtain FDA approval. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

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

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

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

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

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

The market price of our common stock may fluctuate significantly.

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

- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the medical device industry;

- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

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

Some or all of the "restricted" shares of our common stock issued 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 under the Securities Act, and these sales may have a depressive effect on the market for our common stock.

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 OTCBB. 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 63% of the issued and 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 63% 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.

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, over 75% 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 national securities exchanges. 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 board of directors members, 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. Properties.

Our principal corporate office is located at 4400 Biscayne Blvd., 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 initially leased 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, increasing by approximately 4.5% per year. Pursuant to a lease amendment effective February 2009, we relocated our corporate office to approximately 3,200 square feet of alternate space within the same building at an initial annual cost of approximately $68,000, increasing 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 also leased a warehouse in Miami, Florida which is used as our prototype lab. The initial one-year lease term began on January 1, 2008 and has been extended for a period of six months to June 30, 2009.

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Item 3. Legal Proceedings.

We are presently a plaintiff in securities fraud and appraisal actions in respect of our ownership of 191,118 shares of common stock of TruePosition, Inc., a Delaware corporation (referred to as "TruePosition"). The securities fraud action was filed November 13, 2007 in the United States District Court for the District of Connecticut, whereby we and other plaintiffs party to the suit seek damages and other relief totaling $80 million. The related appraisal action was filed in the Chancery Court of the State of Delaware on August 31, 2007.

In August 2007, we were informed that that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of TruePosition's outstanding capital stock, was being merged into TruePosition. As a result of the merger, all of the issued and outstanding shares of common stock of TruePosition were cancelled, and TruePosition'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 TruePosition stock.

We have joined with certain other minority stockholders of TruePosition in bringing the aforementioned appraisal and securities fraud actions, 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. Through December 31, 2008, we have contributed approximately $81,000 in cash and have recorded additional liabilities of approximately $38,000 as of that date. We anticipate that we will be called upon to contribute additional amounts during our 2009 fiscal year, the extent of which will be 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.

In February 2009, the United States District Court for the District of Connecticut granted the defendants' motion to dismiss the securities fraud action. In March 2009, we, together with the other plaintiffs filed an appeal of the District Court's dismissal with the United States 2nd Circuit Court of Appeals. The outcomes of the appeal and the appraisal action are not now known, nor can they be reasonably predicted at this time.

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

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is quoted on the OTCBB under the symbol "SFES". The table below sets forth, for the respective periods indicated, the high and low bid prices for our common stock in the over-the-counter market as reported on the OTCBB. The bid prices represent inter-dealer transactions, without adjustments for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions. Prior to February 11, 2008, our trading symbol on the OTCBB was "CTSC".

	Bid Prices	
	High	Low
2008		
First Quarter	$ 4.60	$ 2.60
Second Quarter	2.90	2.25
Third Quarter	2.60	1.12
Fourth Quarter	1.65	0.51
2007		
First Quarter	$ 1.80	$ 1.26
Second Quarter	2.05	1.55
Third Quarter	3.20	1.60
Fourth Quarter	4.43	2.95

As of March 15, 2009, there were approximately 200 record holders of our common stock, and we estimate that there are in excess of 1,300 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, 2008 and 2007, 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.

On December 30, 2008, we issued 8,197 shares of our common stock to RSLS Investments, LLC, an entity controlled by Mr. Spragens as repayment in full of a $10,000 non-interest bearing loan originally made in 2005 by RLSL Investments, LLC to SafeStitch LLC. The exchange ratio was based upon the average closing price of our common stock on the OTCBB for the five trading days immediately preceding the transaction. The issuance of shares in this transaction was exempt from registration under the Securities Act pursuant to Section 4(2) thereof.

EQUITY COMPENSATION PLAN INFORMATION

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 our sole equity compensation plan. 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, 2008, 168,000 options to purchase shares of common stock have been granted under the 2007 Plan. A more detailed summary of the 2007 Plan is contained in Note 5 to our consolidated financial statements set forth under Item 8 to this Annual Report on Form 10-K. 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.

The following table provides information about our equity compensation plans as of December 31, 2008:

	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)	168,000	$	2.90	1,832,000
Equity compensation plans not approved by security holders	88,667(2)	$	2.60(2)	–
Total	256,667(3)	$	2.80	1,832,000

(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 February 11, 2009, we issued an aggregate of 358,500 options to purchase our common stock under the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, each at a strike price of $0.80 per share. These options were issued as follows: Dr. Jane Hsiao, chairman of our Board of Directors received 60,000 options; each of our other independent and non-employee directors, Kevin Wayne, Kenneth Heithoff, Steven Rubin and Richard Pfenniger, received 5,000 options, except that Mr. Rubin and Mr. Pfenniger each received an additional 1,000 options for their respective service as chairman of Compensation Committee and Audit Committee; and the remaining 276,500 options were issued to existing employees and consultants, including 60,000 to Jeffrey G. Spragens, our President and Chief Executive Officer, 85,000 to Dr. Stewart B. Davis, our Chief Operating Officer and Secretary, 40,000 to Adam S. Jackson, our Chief Financial Officer and 10,000 to Dr. Charles J. Filipi, our Chief Medical Officer.

Item 6. Selected Financial Data.

As a smaller reporting company as defined in Rule 12b-2 of the Exchange Act, we are not required to include information otherwise required by this item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Annual Report on Form 10-K 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-K. We do not undertake any obligation to update forward-looking statements, except as required by applicable law. We intend that all forward-looking statements be subject to the safe harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Overview

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

We have utilized our expertise in intraperitoneal surgery to test certain of our devices in in vivo and ex vivo animal trials and ex vivo human trials, and with certain products, in limited in vivo human trials. Certain of our products did not or may not require clinical trials, including our SMART DilatorTM, standard and airway bite blocks and hernia stapler. Where required, we intend to rapidly, efficiently and safely move into clinical trials for certain other devices, including those utilized in surgery for the treatment of obesity, GERD and for the treatment and diagnosis of Barrett's Esophagus. Clinical trials for certain of these product candidates are anticipated to begin in 2010.

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

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

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

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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 and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to investments, including the carrying value of our long term 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 2 in the Notes to the Consolidated Financial Statements set forth in Item 8 of this Annual Report on Form 10-K. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Our losses totaled $9.4 million from September 15, 2005 (inception) through December 31, 2008. Such losses included $5.2 million and $3.0 million for the years ended December 31, 2008 and 2007, respectively. At December 31, 2008, we had an accumulated deficit of $9.4 million. Since we do not currently generate revenue from any of our product candidates, including those already approved for commercial marketing by the FDA, we expect to continue to generate losses in connection with the initial commercial launch of such FDA-approved products and the continual development of our other products and technologies. Our research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe our operating losses are likely to be substantial over the next several years.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Research and Development costs and expenses were $2.7 million for the year ended December 31, 2008, an increase of approximately $715,000 compared with the same period in 2007, resulting from the operation of our Miami prototype lab and the addition of engineering staff to perform R&D activities internally. We expect research and development costs and expenses to decline in 2009 as we realize the benefit of the staff reductions we implemented in January 2009. R&D expense is anticipated to increase in 2010 and beyond as we enter into more advanced stages of development for our Gastroplasty Device and other surgical product candidates, including the commencement of clinical trials.

General and Administrative costs and expenses were $1.7 million for year ended December 31, 2008 an increase of approximately $848,000 from the year ended December 31, 2007, primarily related to an increase in accounting and administrative staffing and related operating costs and a $174,000 increase in stock-based compensation expense. General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense. Other general and administrative costs and expenses include facility-related costs not otherwise included in research and development costs and expenses, and professional fees for legal and accounting services. We expect that our general and administrative costs and expenses will increase during 2009 from the addition of personnel as we commence commercialization activities for our SMART DilatorTM and bite block products and the Amid Hernia Stapler, which we expect will be cleared for marketing before the end of 2009. Additionally, we expect increased costs to comply with the reporting and other obligations applicable to public companies.

Interest Income decreased $10,000 for the year ended December 31, 2008 as compared to 2007, primarily due to lower invested cash balances resulting from the use of cash in our operating activities. Interest expense increased for the year ended December 31, 2008 as compared to 2007 due to the drawdown of funds under the Credit Facility prior to our sale of an aggregate of 1,861,505 shares of our common stock in a private placement in May 2008, which generated gross proceeds to us, before expenses, of approximately $4.0 million. We expect interest expense to increase as we utilize the Credit Facility to fund operations for the foreseeable future.

Liquidity and Capital Resources

As a result of our significant research and development expenditures and the lack, until February 2009, of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since inception. Additionally, in connection with our involvement as a plaintiff in the TruePosition litigation, we spent approximately $36,000 during our 2008 fiscal year, which reduced our available cash and will continue to do so for so long as we stay involved in the litigation. We do not expect to have any source of revenues before the second half of 2009, and we expect to incur losses from operations for the foreseeable future. Beginning in 2010, we expect to incur increasing research and development costs and expenses, including expenses related to hiring new personnel and conducting clinical trials. We expect that general and administrative costs and expenses will also increase as we expand our finance and administrative staff, add infrastructure and incur additional costs related to being a public company, including the costs of directors' and officers' insurance, investor relations programs and increased professional fees.

To date, we have funded our operations primarily with proceeds from the private placement of stock and credit facilities available to us. Our ability to sell additional shares of our stock and/or borrow cash under existing or new credit facilities could be materially adversely affected by the recent economic turmoil in the world's equity and credit markets. There can therefore be no assurance that we will be able to raise funds on acceptable terms or at all, which may materially adversely affect our ability to continue our operations. Additionally, the current economic turmoil could also reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our product candidates. Such delay could have a material adverse impact on our expected cash flows, liquidity, results of operations and financial position. In order to address this uncertainty, our management has taken steps to reduce our near-term cash requirements by focusing our product development efforts primarily on the significant product candidates, including the Gastroplasty Device and Amid Hernia Stapler, which are expected to have the most promising market potential and the shortest remaining development time.

As a result of these actions, our management has currently budgeted expenditures of approximately $2.4 million for our 2009 fiscal year to fund the final development of our hernia stapler and the initial marketing of the hernia stapler and the three other product candidates already developed, as well as to continue research and development of our Gastroplasty Device. Our management believes that our cash balance as of December 31, 2008 of approximately $561,000, together with our $4.0 million line of credit, the maturity date of which has been extended from December 2009 to June 2010, is sufficient to fund our current cash flow requirements through at least the next twelve months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the precise amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials.

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

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company as defined in Rule 12b-2 of the Exchange Act, we are not required to include the information otherwise required by this item.

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

SafeStitch Medical, Inc.

We have audited the accompanying consolidated balance sheets of SafeStitch Medical, Inc. (a development stage company) (the “Company”) as of December 31, 2008 and 2007, and the related statements of operations, stockholders’ equity, and cash flows for the years ended December 31, 2008 and 2007 and for the period from September 15, 2005 (inception) through December 31, 2008. 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 audits 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, 2008 and 2007 and the consolidated result of their operations and cash flows for years ended December 31, 2008 and 2007 and for the period from September 15, 2005 (inception) through December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner LLP
New York, New York
March 27, 2009

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONSOLIDATED BALANCE SHEETS
(in 000s, except share and per share data)

	December 31, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 561	$ 631
Other receivable – related-party	13	–
Prepaid expenses	151	99
Total Current Assets	725	730
FIXED ASSETS		
Property and equipment, net	168	196
OTHER ASSETS		
Security deposits	2	56
Deferred financing costs, net	851	1,702
Total Other Assets	853	1,758
LONG-TERM INVESTMENT, net of valuation adjustment of $1,754	–	–
TOTAL ASSETS (Note 6)	$ 1,746	$ 2,684
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 273	$ 253
Total Current Liabilities	273	253
Stockholder loans	–	10
Commitments and contingencies (Note 9)	–	–
STOCKHOLDERS' EQUITY		
Preferred stock, $.01 par value per share, 25,000,000 shares authorized, no shares issued and outstanding	–	–
Common stock, $.001 par value per share, 225,000,000 shares authorized, 17,962,718 and 16,093,016 shares issued and outstanding, respectively	18	16
Additional paid-in capital	10,817	6,582
Deficit accumulated during the development stage	(9,362)	(4,177)
Total Stockholders' Equity	1,473	2,421
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,746	$ 2,684

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)

	Years Ended December 31,		September 15, 2005 (Inception) to December 31,
	2008	2007	2008
REVENUES	$ -	$ -	$ -
COSTS AND EXPENSES			
Research and development	2,682	1,967	5,587
General and administrative	1,652	804	2,673
Total Costs and Expenses	4,334	2,771	8,260
LOSS FROM OPERATIONS	(4,334)	(2,771)	(8,260)
INTEREST INCOME	24	34	77
AMORTIZATION OF DEFERRED FINANCING COSTS	(851)	(283)	(1,134)
INTEREST EXPENSE	(24)	(21)	(45)
LOSS BEFORE INCOME TAX	(5,185)	(3,041)	(9,362)
PROVISION FOR INCOME TAX	–	–	–
NET LOSS	(5,185)	(3,041)	(9,362)
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	17,215	12,767	
NET LOSS PER BASIC AND DILUTED SHARE	$ (0.30)	$ (0.24)	

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

SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in 000's, except share amounts)

	Preferred Stock		Common Stock		Additional Paid-in	Deficit Accumulated During the Development	
	Shares	Amount	Shares	Amount	Capital	Stage	Total
Inception – September 15, 2005	–	$ –	–	$ –	$ –	$ –	$ –
Capital contributed	–	–	–	–	1	–	1
Net loss	–	–	–	–	–	(76)	(76)
Balance at December 31, 2005	–	$ –	–	$ –	$ 1	$ (76)	$ (75)
Capital contributed	–	–	11,256	11	1,493	–	1,504
Net loss	–	–	–	–	–	(1,060)	(1,060)
Balance at December 31, 2006	–	$ –	11,256	$ 11	$ 1,494	$ (1,136)	$ 369
Exercise of options (CTS) – September 23, 2007 at $0.79 per share	–	–	42	–	35	–	35
Stock-based compensation-September 4, 2007	–	–	–	–	77	–	77
Issuance of common shares in recapitalization - September 4, 2007 at $0.64 per share	–	–	4,795	5	3,078	–	3,083
SafeStitch expenses associated with recapitalization	–	–	–	–	(156)	–	(156)
Stock-based compensation	–	–	–	–	65	–	65
Warrants issued in connection with credit facility-September 4, 2007 at $2.46 per share	–	–	–	–	1,985	–	1,985
Rule 16 payment received	–	–	–	–	4	–	4
Net loss	–	–	–	–	–	(3,041)	(3,041)
Balance at December 31, 2007	–	$ –	16,093	$ 16	$ 6,582	$ (4,177)	$ 2,421
Issuance of common shares in private offering – May 2008 at $2.15 per share, net of offering costs	–	–	1,862	2	3,986	–	3,988
Issuance of common shares as repayment of stockholder note-December 30, 2008 at			8	–	10	–	10

$1.22 per share							
Stock-based compensation	–	–	–	–	239	–	239
Net loss	–	–	–	–	–	(5,185)	(5,185)
Balance at December 31, 2008	– $	–	17,963 $	18 $	10,817 $	(9,362) $	1,473

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)

	Years Ended December 31,		September 15, 2005 (Inception) to December 31,
	2008	2007	2008
OPERATING ACTIVITIES			
Net loss	$ (5,185)	$ (3,041)	$ (9,362)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred financing costs	851	283	1,134
Stock-based compensation expense	239	65	304
Stock-based compensation expense related to Share Exchange	–	77	77
Depreciation and amortization	55	4	59
Changes in operating assets and liabilities:			
Increase in receivables and other current assets	(65)	(79)	(144)
Decrease (Increase) in other assets	54	(56)	(2)
Increase (Decrease) in accounts payable and accrued liabilities	20	(199)	(12)
NET CASH USED IN OPERATING ACTIVITIES	(4,031)	(2,946)	(7,946)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of equipment	(27)	(200)	(227)
Payment received under Exchange Act Rule 16b	–	4	4
NET CASH USED IN INVESTING ACTIVITIES	(27)	(196)	(223)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net cash provided in connection with the acquisition of SafeStitch LLC	–	3,192	3,192
Issuance of 1,861,505 shares of common stock, net of offering costs	3,988	–	3,988
Capital contributions	–	–	1,431
Proceeds from stockholder loans	1,000	876	1,960
Repayment of stockholder loans	(1,000)	(876)	(1,876)
Exercise of options	–	35	35
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,988	3,227	8,730
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(70)	85	561
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	631	546	–
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 561	$ 631	$ 561
Supplemental disclosures:			

Cash paid for interest	$ 24	$ –	$ 45
Non cash activities:			
Stockholder loans contributed to capital	$ 10	$ –	$ 84
Warrants issued in connection with credit facility	$ –	$ 1,985	$ 1,985

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 1 – BASIS OF PRESENTATION AND LIQUIDITY

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

Cellular Technical Services Company, Inc. ("Cellular"), a non-operating public company, was incorporated in 1988 as NCS Ventures Corp. under the laws of the State of Delaware. On July 25, 2007 Cellular entered into a Share Transfer, Exchange and Contribution Agreement (the "Share Exchange") with SafeStitch LLC, a Virginia limited liability company. On September 4, 2007, Cellular acquired all of the members' equity interests in SafeStitch LLC in exchange for 11,256,369 shares of Cellular's common stock, which represented a majority of Cellular's outstanding shares immediately following the Share Exchange. Effective January 8, 2008, Cellular changed its name to SafeStitch Medical, Inc. and increased the aggregate number of shares of capital stock that may be issued from 35,000,000 to 250,000,000, comprising 225,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 25,000,000 shares of preferred stock, par value $0.01 per share. For accounting purposes, the acquisition has been treated as a recapitalization of SafeStitch LLC, with SafeStitch LLC as the acquirer (reverse acquisition). The historical financial statements prior to September 4, 2007 are those of SafeStitch LLC, which began operations on September 15, 2005. The accompanying financial statements give retroactive effect to the recapitalization as if it had occurred on September 15, 2005 (inception). Certain reclassifications have been made to prior periods' consolidated financial statements to be consistent with the current period's presentation.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. For the period from September 15, 2005 (inception) through December 31, 2008, the Company has accumulated a deficit of $9.4 million, including a net loss of $5.2 million for the year ended December 31, 2008, and has not generated revenue or positive cash flows from operations. The Company has been dependent upon equity financing and loans from stockholders to meet its obligations and sustain operations. The Company's efforts have been principally devoted to developing its technologies and commercializing its products. Based upon its current cash position, availability under the extended term of its $4.0 million line of credit from The Frost Group, LLC (the "Frost Group") and the Company's President and CEO, Jeffrey G. Spragens, and by monitoring its discretionary expenditures, management believes that the Company will be able to fund operations without revenues or additional financing at least through March 2010. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate its research and development programs, reduce its planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that it might otherwise seek to develop or commercialize independently. Although the Company plans to secure additional funds through the issuance of equity and/or debt, no assurance can be given that additional financing will be available to the Company on acceptable terms, or at all. The Company's ability to continue as a going concern is ultimately dependent upon generating revenues from those products that do not require further marketing clearance by the U.S. Food and Drug Administration ("FDA"), obtaining FDA clearance to market its other product candidates, and achieving profitable operations and generating sufficient cash flows from operations to meet future obligations.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

Cash and cash equivalents. The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company holds cash and cash equivalent balances in banks and other financial institutions. Balances in excess of FDIC limitations may not be insured.

Property and equipment. Property and equipment are carried at cost less accumulated depreciation. Major additions and improvements are capitalized, while maintenance and repairs that do not extend the lives of assets are expensed. Gain or loss, if any, on the disposition of fixed assets is recognized currently in operations. Depreciation is calculated primarily on a straight-line basis over estimated useful lives of the assets.

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

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

Stock-based compensation. The Company follows Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share Based Payment", which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values on the date of grant. Stock-based compensation is included in general and administrative expenses for all periods presented.

Fair value of financial instruments. The Company follows SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. The carrying amounts of cash and cash equivalents, accounts payable and accrued expenses approximate fair value based on their short-term maturity. Related party receivables and stockholder loans are carried at cost.

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

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

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

NOTE 3 – PROPERTY AND EQUIPMENT

Machinery and equipment consist of the following:

	Estimated Useful lives	December 31, 2008	December 31, 2007
Machinery and equipment	5 years	$ 153,000	$ 160,000
Furniture and fixtures	3-5 years	37,000	40,000
Software*	3-5 years	37,000	–
		227,000	200,000
Accumulated depreciation and amortization		(59,000)	(4,000)
Property and equipment, net		$ 168,000	$ 196,000

* Software was included in machinery and equipment or furniture and fixtures, as appropriate, at December 31, 2007.

Depreciation of fixed assets utilized in research and development activities is included in research and development expense. All other depreciation is included in general and administrative expense. Depreciation and amortization expense was $55,000 and $4,000, respectively, for the years ended December 31, 2008 and 2007.

NOTE 4 – LONG-TERM INVESTMENT

In November 1999, Cellular invested in a one-year, $1.0 million 10% convertible note of KSI, Inc. (“KSI”) and also received warrants to purchase KSI common stock. All of the outstanding stock of KSI was acquired in August 2000 by TruePosition, Inc. (“TruePosition”), a majority owned subsidiary of Liberty Media Corporation (“Liberty Media”). Prior to the acquisition, the convertible note was exchanged for KSI common stock. Cellular exercised the KSI warrants and purchased additional KSI common stock for approximately $754,000. Cellular’s investment in KSI common stock was exchanged for TruePosition common stock on the date of the acquisition. The Company currently holds 191,118 shares of TruePosition common stock and accounts for the investment in TruePosition using the cost method. In December 2002, Cellular received certain valuation information from TruePosition, indicating a range of values for TruePosition. Based upon its review of available information and communications with Liberty Media, Cellular concluded there had been an other-than-temporary decline in the estimated fair value of its investment and reduced the recorded carrying value of this investment from its cost basis of $1,754,000 to zero, representing its best estimate of the then-current fair value of Cellular’s investment in the net equity of TruePosition. TruePosition’s operations have been funded by significant infusions of cash by Liberty Media, and the Company’s investment in TruePosition common stock has been diluted by these advances, which were converted to preferred stock in late 2002. In August 2007, the Company was informed that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of TruePosition’s outstanding capital stock, was being merged into TruePosition. Pursuant to the terms of the merger, TruePosition’s minority stockholders, including the Company, were entitled to receive $3.5116 in cash in exchange for each share held. The Company has exercised its statutory appraisal rights in respect of this merger, and is now a party to an appraisal action and a securities fraud litigation (see Notes 9 and 16). The Company may possibly receive proceeds from the merger, the litigation or other disposition of this investment, but no such amount can be estimated at this time.

NOTE 5 – STOCK-BASED COMPENSATION

Cellular’s 1996 Stock Option Plan (the “1996 Plan”) authorized the grant of both incentive (“ISO”) and non-qualified stock options, up to a maximum of 335,000 shares of Common Stock, to employees of and consultants to the Company. The exercise price, term and vesting provision of each option grant was fixed by the compensation committee of the Board of Directors (the “Compensation Committee”) with the provision that the exercise price of an ISO may not be less than the fair market value of the Common Stock on the date of grant, and the term of an ISO may

not exceed ten years. The Company has not granted any options under the 1996 Plan since December 31, 2005. The 1996 Plan has been terminated and no new options may be granted under the 1996 Plan.

As of the date of the Share Exchange, all options issued to former officers and directors under the 1996 Plan with exercise prices in excess of the then-current share price of the Common Stock were cancelled in exchange for the issuance of 2,000 shares of Common Stock per person, for an aggregate issuance of 6,000 shares of Common Stock. The Company recognized compensation expense of $77,000 on the date of the Share Exchange relating to the intrinsic value of the options outstanding on that date.

The Company granted 88,667 options outside of plans in September 2007 at an exercise price of $2.60 per share. The Company determined the estimated aggregate fair value of these options on the grant date to be $196,000, or approximately $2.21 per option. The stock-based compensation recorded for these options in the years ended December 31, 2008 and 2007 was $47,000 and $65,000, respectively, and is included in general and administrative expense.

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

The Company granted 168,000 options under the 2007 Plan during the year ended December 31, 2008. No options were granted under the 2007 Plan during the year ended December 31, 2007. The exercise prices of these options ranged from $1.16 to $3.10 per share. The Company determined the estimated aggregate fair value of these options on the grant dates to be $318,000, and stock option compensation expense related to these grants was $192,000 for the year ended December 31, 2008. Total stock-based compensation recorded for the years ended December 31, 2008 and 2007 was $239,000 and $65,000, respectively, and is included in general and administrative expense. The fair values of options granted are estimated on the date of their grant using the Black-Scholes option pricing model based on the assumptions included in the table below. The fair value of the Company's stock option awards is expensed over the vesting life of the underlying stock options using the graded vesting method, with each tranche of vesting options valued separately. Expected volatility is based on the historical volatility of the Company's stock. Due to the short period of time that the Company has been publicly traded since the Share Exchange, the historical volatilities of similar publicly traded entities are reviewed to validate the Company's expected volatility assumption. The risk-free interest rate for periods within the contractual life of the stock option award is based on the yield of U.S. Treasury bonds on the grant date with a maturity equal to the expected term of the stock option. The expected life of stock option awards is based upon the "simplified" method for "plain vanilla" options described in the United States Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107, as amended by SEC Staff Accounting Bulletin No. 110. Forfeiture rates are based on management's estimates. The fair value of each option granted during the years ended December 31, 2008 and 2007 was estimated using the following assumptions.

	Year ended December 31, 2008	Year ended December 31, 2007
Expected volatility	63.05% - 94.46%	82.00%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.76% – 3.35%	4.88%
Expected life	3.5 – 5.5 years	10.0 years
Forfeiture rate	0% - 2.50%	0%

The following summarizes the Company's stock option activity for the year ended December 31, 2008:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	88,667	$ 2.60		
Granted	168,000	$ 2.90		
Exercised	–	–		
Canceled or expired	–	–		
Outstanding at December 31, 2008	256,667	$ 2.80	7.12	$ 540
Exercisable at December 31, 2008	109,834	$ 2.90	7.22	$ –
Vested and expected to vest at December 31, 2008	250,906	$ 2.80	7.14	$ 527

Of the 168,000 options granted during the year ended December 31, 2008, 39% of such options were vested as of December 31, 2008. A summary of the status of the Company's non-vested options and changes during the year ended December 31, 2008 is presented below.

	Stock Options	Weighted Average Grant Date Fair Value
Non-Vested at December 31, 2007	66,500	$ 2.21
Options Granted	168,000	1.89
Options Vested	(87,667)	1.96
Non-Vested at December 31, 2008	146,833	$ 2.00

At December 31, 2008, there was $197,000 of total unrecognized compensation cost related to non-vested employee and director share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.90 years.

No options were exercised during the year ended December 31, 2008.

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 (See Note 11 - Income Taxes).

NOTE 6 – DEBT

Credit Facility. In connection with the acquisition of SafeStitch LLC, the Company entered into a Note and Security Agreement (the "Credit Facility") with both The Frost Group, LLC (the "Frost Group") and Jeffrey G. Spragens, the Company's Chief Executive Officer and President and a director. The Frost Group is a Florida limited liability company whose members include Frost Gamma Investments Trust, a trust controlled by Dr. Phillip Frost, the largest beneficial holder of the issued and outstanding shares of the Company's common stock, Dr. Jane H. Hsiao, the Company's Chairman of the Board and Steven D. Rubin, a director. The Credit Facility provides for $4.0 million in

total available borrowings, consisting of $3.9 million from the Frost Group and $100,000 from Mr. Spragens. The Company has granted a security interest in all present and subsequently acquired collateral in order to secure prompt, full and complete payment of the amounts due under the Credit Facility. The collateral includes all assets of the Company, inclusive of intellectual property (patents, patent rights, trademarks, service marks, etc.). Outstanding borrowings under the Credit Facility accrue interest at a 10% annual rate. The Credit Facility had an initial term of 28 months, expiring in December 2009, and was amended in March 2009 to extend the Maturity Date to June 2010 (see Note 16).

In connection with the Credit Facility, the Company granted warrants to purchase an aggregate of 805,521 shares of its Common Stock to the Frost Group and Mr. Spragens at an assumed exercise price of $0.25 per share. The fair value of the warrants was determined to be approximately $2.0 million on the grant date based on the Black-Scholes valuation model using the following assumptions: expected volatility of 82%, dividend yield of 0%, risk-free interest rate of 4.88% and expected life of 10 years. The fair value of the warrants was recorded as deferred financing costs and will be amortized over the life of the Credit Facility. The Company recorded amortization expense of $851,000 and $283,000 related to these deferred financing costs during the years ended December 31, 2008 and 2007, respectively.

The Company borrowed $1.0 million under the Credit Facility during the three months ended March 31, 2008 and repaid the entire outstanding balance in June 2008 using the proceeds of the private placement described in Note 7. The Company recognized interest expense related to the outstanding borrowings under the Credit Facility for the years ended December 31, 2008 and 2007 of $24,000 and $0, respectively. As of December 31, 2008, there was no balance outstanding under the Credit Facility.

Stockholder Loans. As of the date of the Share Exchange, SafeStitch LLC had $10,000 in outstanding loans payable to a member controlled by Mr. Spragens. This loan was repaid in December 2008 with 8,197 shares of the Company's common stock pursuant to resolutions approved by both the Audit Committee and a majority of the Board of Directors. The exchange ratio was based upon the average closing price of the Company's common stock for the five trading days immediately preceding the transaction. Mr. Spragens did not participate in the Board vote. As of December 31, 2008, there were no stockholder loans outstanding.

NOTE 7 – CAPITAL TRANSACTIONS

Share Exchange. As described in Note 1, on September 4, 2007, the Company acquired all of the members' equity interests in SafeStitch LLC in exchange for the issuance of 11,256,369 shares of Cellular's common stock. For accounting purposes, the transaction has been treated as a recapitalization of SafeStitch LLC whereby all membership interests in SafeStitch LLC were eliminated, the ordinary shares received in exchange for those interests were recorded at par value and the difference between value of the membership interests and the value of the ordinary shares received was recorded as additional paid-in capital to give effect to the transaction as of the beginning of 2007. Additionally, as of the date of the transaction, the net assets of Cellular, its ordinary shares and additional paid-in capital were recorded to reflect the transaction. SafeStitch LLC incurred $156,000 of transaction costs, which were recorded as a reduction of additional paid-in capital.

Private Placement. During the period beginning May 22, 2008 and ended May 28, 2008, the Company entered into stock purchase subscription agreements (the "Subscription Agreements") with certain private investors (the "Investors"), pursuant to which the Company agreed to issue an aggregate of 1,861,505 shares (the "Shares") of its Common Stock at a purchase price of $2.15 per share. The Company's Board of Directors established the $2.15 purchase price based on an approximately 10% discount to the average closing price of the Common Stock on the OTCBB during the five trading days beginning April 23, 2008 and ended April 29, 2008. The Company closed on the issuance of the Shares during the period beginning May 22, 2008 and ended May 28, 2008. The Company received aggregate consideration for the Shares of $4,002,000 and has incurred $14,000 of costs related to the offering, which were recorded as a reduction of paid-in-capital. Among the Investors acquiring a portion of the Shares were Dr. Hsiao, Jeffrey G. Spragens and some of his relatives, Dr. Kenneth Heithoff, a director, Kevin Wayne, a director, and Frost Gamma Investments Trust. The Company issued the Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act"), and Rule 506 of Regulation D promulgated thereunder. Each Investor represented to the Company that such person was an "accredited investor" as defined in Rule 501(a) under the Act and that the Shares were being acquired for investment purposes. The Shares have not been registered under the Act and are "restricted securities" as that term is defined by Rule 144 under the Act. The Company

has not undertaken to register the Shares and no registration rights have been granted to the Investors in respect of the Shares.

NOTE 8 – BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding 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 years ended December 31, 2008 and 2007, 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:

	December 31, 2008	December 31, 2007
Stock options	256,667	88,667
Stock warrants	805,521	805,521
Total	1,062,188	894,188

NOTE 9 – COMMITMENTS AND CONTINGENCIES

The Company is obligated under various operating lease agreements for office space. Generally, the lease agreements require the payment of base rent plus escalations for increases in building operating costs and real estate taxes. Rental expense under operating leases amounted to $139,000 and $24,000 for the years ended December 31, 2008 and 2007, respectively. Giving effect to the lease amendment described in Note 16, at December 31, 2008, the Company was obligated under non-cancellable operating leases to make future minimum lease payments (excluding sales taxes) as follows:

Year Ending December 31,	
2009	$ 80,000
2010	71,000
2011	74,000
2012	77,000
Thereafter	—
	$ 302,000

The Company is presently a plaintiff in securities fraud and appraisal actions in respect of its ownership of 191,118 shares of common stock of TruePosition. The securities fraud action was filed November 13, 2007 in the United States District Court for the District of Connecticut, whereby SafeStitch and other plaintiffs seek damages and other relief totaling $80 million. The related appraisal action was filed in the Chancery Court of the State of Delaware on August 31, 2007. In August 2007, the Company was informed that Liberty TP Acquisition, Inc., which held an aggregate of no less than 90% of TruePosition's outstanding capital stock, was being merged into TruePosition. Pursuant to the terms of the merger, TruePosition's minority stockholders, including the Company, became entitled to receive $3.5116 in cash in exchange for each share held, which the Company and certain other minority stockholders considered insufficient compensation. The Company and other minority stockholders brought forth the aforementioned securities fraud and appraisal action and, on August 10, 2007, the Company entered into a joint stockholder litigation governance and funding agreement (the "Funding Agreement") with such other stockholders. Under the Funding Agreement, the Company has agreed to fund a portion of the litigation expenses in connection with the appraisal and securities fraud action. Through December 31, 2008, the Company has contributed approximately $81,000 in cash and has recorded additional liabilities of approximately $38,000. Management anticipates that the Company will be called upon to fund additional amounts during the next twelve months. The

Company may elect to terminate its participation in the Funding Agreement, whereby the Company would no longer be required to contribute funds; however, the Company would lose all rights under the Funding Agreement, including access to any additional work-product created after the date of termination. Additionally, the Company's portion of any proceeds from a favorable disposition of the litigation may be reduced if the Company terminates its participation. The outcomes of these actions are not now known, nor can they be reasonably predicted at this time.

NOTE 10 – AGREEMENT WITH CREIGHTON UNIVERSITY

On May 26, 2006, SafeStitch entered into an exclusive license and development agreement (the "License Agreement") with Creighton University ("Creighton"), granting the Company a worldwide exclusive (even as to the university) license, with rights to sublicense, to all the Company's product candidates and associated know-how based on Creighton technology, including the exclusive right to manufacture, use and sell the product candidates.

Pursuant to the License Agreement, the Company is obligated to pay Creighton, on a quarterly basis, a royalty of 1.5% of the revenue collected worldwide from the sale of any product licensed under the License Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. The License Agreement does not provide for minimum royalties. Also pursuant to the License Agreement, the Company has agreed to invest, in the aggregate, at least $2.5 million over 36 months, beginning May 26, 2006, towards development of any licensed product. This $2.5 million investment obligation excludes the first $150,000 of costs related to the prosecution of patents, which the Company invested outside of the License Agreement. The Company is further obligated to pay to Creighton an amount equal to 20% of certain of the Company's research and development expenditures as reimbursement for the use of Creighton's facilities. Failure to comply with the payment obligations above will result in all rights in the licensed patents and know-how reverting back to Creighton. As of December 31, 2007, the Company had satisfied the $2.5 million investment obligation described above. During the years ended December 31, 2008 and 2007, the Company paid Creighton $177,000 and $322,000, respectively, in satisfaction of the 20% facility reimbursement obligation.

Pursuant to the License Agreement, SafeStitch is entitled to exercise its own business judgment and sole and absolute discretion over the marketing, sale, distribution, promotion and other commercial exploitation of any licensed products, provided that, if the Company has not commercially exploited or commenced development of a licensed patent and its associated know-how by the seventh anniversary of the later of the date of the License Agreement or the date such technology is disclosed to and accepted by SafeStitch, then the licensed patent and associated know-how shall revert back to the university, with no rights retained by the Company, and the university will have the right to seek a third party with whom to commercialize such patent and associated know-how, unless the Company purchases one or more one-year extensions.

NOTE 11 – INCOME TAXES

The Company accounts for income taxes using the asset and liability method described in SFAS No. 109, "Accounting For Income Taxes," the objective of which is to establish deferred tax assets and liabilities for the temporary differences between the financial reporting and the tax bases of the 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.

At December 31, 2008, we have approximately $4.7 million of net operating loss carryforwards to offset future taxable income and $1.8 million of certain operating expenses which have been deferred as start up costs under Sec. 195 for federal income tax purposes, subject to limitations for alternative minimum tax. Start-up costs will continue to be capitalized until the month in which active business begins, at which time the costs may be amortized over 15 years. In addition, at December 31, 2008 we have approximately $92,000 of research and development tax credit carryforwards. The net operating loss and research and development credit carryforwards expire through 2028.

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:

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	December 31, 2008	December 31, 2007
Income tax benefit at the federal statutory rate	34.00%	34.00%
State income taxes, net of effect on federal taxes	3.44%	3.63%
Research and development credit	1.58%	–
Other	2.71%	–
Increase in valuation allowance	(41.73)%	(37.63)%
Provision for income tax	0%	0%

The deferred tax asset at December 31, 2008 and 2007 consists of the following:

	2008	2007
Net operating loss carryforward	$ 1,750,000	202,000
Deferred start up costs	669,000	221,000
Research and development credit carryforward	92,000	–
Stock-based compensation	144,000	53,000
Other	(15,000)	–
	2,640,000	476,000
Less: Valuation allowance	(2,640,000)	(476,000)
Net deferred tax asset	$ –	$ –

The change in the valuation allowance from December 31, 2007 to December 31, 2008 amounted to approximately $2.2 million. At December 31, 2006, Cellular 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 had 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 for 2007 were forfeited in accordance with Section 382 of the Internal Revenue Code.

At December 31, 2006, Cellular had 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 were forfeited due to change in control.

The Company adopted Financial Standards Board Interpretation No. 48 “Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109” (“FIN 48”) on January 1, 2007. The adoption of FIN 48 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.

The Company recognizes interest and penalties related to uncertain tax positions in general and administrative expense. As of December 31, 2008, the Company has no unrecognized tax benefit, including interest and penalties.

Tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which we are subject.

NOTE 12 – CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Company entered into a five year lease for office space in Miami, Florida with a company controlled by Dr. Phillip Frost, the Company's largest beneficial stockholder. The rental payments under the Miami office lease, which commenced January 1, 2008, are approximately $8,000 per month for the first year and escalate 4.5% annually over the life of the lease. The Company recorded $110,000 and $13,000 of rent expense related to the Miami lease for the years ended December 31, 2008 and 2007, respectively.

Dr. Jane Hsiao, the Company's Chairman of the Board, is a director of Great Eastern Bank of Florida, a bank where the Company maintains a bank account in the normal course of business. As of December 31, 2008, the Company had approximately $260,000 on deposit with Great Eastern Bank of Florida.

Dr. Hsiao and Dr. Frost are each significant shareholders of Non-Invasive Monitoring Systems, Inc. ("NIMS"), a publicly-traded medical device company, and of Aero Pharmaceuticals, Inc. ("Aero"), a privately-held pharmaceutical distribution company. Commencing in March 2008, the Company's Chief Financial Officer also serves as the Chief Financial Officer and supervises the accounting staffs of NIMS and Aero under a board-approved cost sharing arrangement whereby the total salaries of the accounting staffs of the three companies are shared. The Company has recorded reductions to General and Administrative costs and expenses for the year ended December 31, 2008 of $33,000 to account for the sharing of costs under this arrangement. Accounts receivable from NIMS and Aero were approximately $10,000 and $0, respectively, as of December 31, 2008.

Dr. Hsiao, Dr. Frost and directors Steven Rubin and Richard Pfenniger are each significant stockholders, officers and/or directors of OPKO Health, Inc. ("OPKO"), a publicly-traded specialty healthcare company. Certain of the Company's employees have provided consulting services to OPKO on a cost-plus basis. The Company has recorded reductions to General and Administrative expense to account for the provision of these services totaling $49,000 and $0 for the years ended December 31, 2008 and 2007, respectively. The amounts charged may not be representative of those that would have been charged in an "arms-length" transaction. These transactions have been ratified by the Audit Committee of the Board of Directors. Accounts receivable from OPKO were approximately $4,000 as of December 31, 2008.

NOTE 13 – EMPLOYEE BENEFIT PLANS

Effective May 1, 2008, the SafeStitch 401(k) Plan (the "401k Plan") permits employees to contribute up to 100% of qualified annual compensation up to annual statutory limitations. Employee contributions may be made on a pre-tax basis to a regular 401(k) account, or on an after-tax basis to a "Roth" 401(k) account. The Company will contribute to the 401k Plan a "safe harbor" match of 100% of each participant's contributions to the 401k Plan up to a maximum of 4% of the participant's qualified annual earnings. The Company's matching contributions to the plan were approximately $32,000 for the year ended December 31, 2008.

NOTE 14 – RECENT ACCOUNTING PRONOUNCEMENTS

Effective January 1, 2008, the Company adopted SFAS 157, which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. In accordance with FASB Staff Position 157-2, "Effective Date of the FASB Statement No. 157," the Company will defer the adoption of SFAS 157 for its nonfinancial assets and nonfinancial liabilities, except those items recognized or disclosed at fair value on an annual or more recurring basis, until January 1, 2009. The partial adoption of SFAS 157 did not have a material impact on the Company's fair value measurements. SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company's financial assets subject to fair value measurements as of December 31, 2008 consisted of cash and cash equivalents, which are categorized as level 1. As of December 31, 2008, the Company does not have any financial liabilities. No gains or losses resulting from the fair value measurement of financial assets were included in the Company's earnings. The adoption of SFAS 157 has not impacted the Company's results of operations and financial position.

Effective January 1, 2008, the Company adopted 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. The Company has elected not to use the fair value option allowed by SFAS 159. Accordingly, the adoption of SFAS 159 has not impacted the Company’s results of operations and financial position.

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

In December 2007, the FASB issued SFAS No. 141 R “Business Combinations” (“SFAS 141R”). SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring the goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. SFAS 141R will be effective for the Company’s fiscal year beginning January 1, 2009. While the Company has not yet evaluated the impact, if any, that SFAS 141R will have on its consolidated financial statements, the Company will be required to expense costs related to any acquisitions consummated after December 31, 2008.

In December 2007, the FASB ratified the consensus reached on Emerging Issues Task Force Issue No. 07-1, “Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property” (“EITF 07-1”). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 will be effective for the Company’s fiscal year beginning January 1, 2009. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements.

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

In April 2008, the FASB issued EITF 07-05, “Determining whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock” ("EITF 07-05"). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of SFAS 133. EITF 07-05 will be effective for the Company’s fiscal year beginning January 1, 2009 and early application is not permitted. The Company is currently evaluating the potential impact of EITF 07-05 on its consolidated financial statements.

NOTE 15 – 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.

NOTE 16 – SUBSEQUENT EVENTS

On February 11, 2009, the Company issued an aggregate of 358,500 options to purchase the Company’s common stock under the 2007 Plan, each at an exercise price of $0.80 per share. The options were granted to directors, officers, existing employees and consultants.

In February 2009, the United States District Court for the District of Connecticut granted the defendants' motion to dismiss the securities fraud action described in Note 9. In March 2009, SafeStitch, together with the other plaintiffs filed an appeal of the District Court's dismissal with the United States 2nd Circuit Court of Appeals. The outcomes of the appeal and the appraisal action are not now known, nor can they be reasonably predicted at this time.

Pursuant to a lease amendment effective February 2009, the Company relocated its corporate office to an alternate space within the same building for annual payments of approximately $68,000. All other terms and conditions of the Company's corporate office lease remain unchanged.

In March 2009, the Company, the Frost Group and Mr. Spragens amended the Credit Facility discussed in Note 6 above to change the Credit Facility's Maturity Date from December 31, 2009 to June 30, 2010. All other terms and conditions of the Credit Facility remain unchanged.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A(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, 2008. 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 effective as of the end of the period covered by this annual report. 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.

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, 2008, 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, 2008, our internal control over financial reporting was effective.

Changes in Internal Controls 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.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) List of documents filed as part of this report:

1. Financial Statements: The information required by this item is contained in Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules: The information required by this item is included in the consolidated financial statements contained in Item 8 of this Annual Report on Form 10-K.

3. Exhibits: The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibits:

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., filed as Exhibit 3.2 to our Annual Report on Form 10-KSB, as amended, filed with the SEC on March 26, 2008 and incorporated by reference herein.

4.1 Specimen Certificate for Common Stock of Registrant, filed as Exhibit 4.1 to our Annual Report on Form 10-KSB, as amended, filed with the SEC on March 26, 2008 and incorporated by reference herein.

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 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.

10.2 Note and Security Agreement, dated as of September 4, 2008, 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.

10.3 Exclusive License and Development Agreement, dated as of May 26, 2006, by and between Creighton University and SafeStitch LLC, filed as Exhibit 10.5 to our Annual Report on Form 10-KSB, as amended, filed with the SEC on March 26, 2008 and incorporated by reference herein.

10.4+ 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.

10.5+ 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.

10.6+ Offer Letter from SafeStitch Medical, Inc. to Adam S. Jackson, dated March 11, 2008, filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on April 3, 2008 and incorporated by reference herein.

10.7 Form of Subscription Agreement, filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on May 29, 2008 and incorporated by reference herein.

10.8* Amendment to Note and Security Agreement, dated March 25, 2009, by and among the Company, SafeStitch LLC, the Frost Group, LLC and Jeffrey G. Spragens.

Exhibits:

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, 2004 and incorporated by reference herein.
21.1*	Subsidiaries of the Registrant
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

*	Filed herewith
+	Compensation Plan or Arrangement or Management Contract

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SAFESTITCH MEDICAL, INC.

Date: March 27, 2009 By: /s/ Jeffrey G. Spragens
Jeffrey G. Spragens
Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey G. Spragens Jeffrey G. Spragens	Chief Executive Officer and President (Principal Executive Officer)	March 27, 2009
/s/ Jane H. Hsiao, Ph.D. Jane H. Hsiao, Ph.D.	Chairman of the Board of Directors	March 27, 2009
/s/ Dr. Charles Filipi Dr. Charles Filipi	Medical Director and Director	March 27, 2009
/s/ Dr. Kenneth Heithoff Dr. Kenneth Heithoff	Director	March 27, 2009
/s/ Steven D. Rubin Steven D. Rubin	Director	March 27, 2009
/s/ Richard Pfenniger, Jr. Richard Pfenniger, Jr.	Director	March 27, 2009
/s/ Kevin Wayne Kevin Wayne	Director	March 27, 2009
/s/ Adam S. Jackson Adam S. Jackson	Chief Financial Officer (Principal Financial Officer)	March 27, 2009