SafeStitch Medical, Inc.
Form 10-K
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

x **Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2011

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) 575-4600

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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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, 2011, was: $7.8 million

As of March 28, 2012 there were 48,797,755 shares of Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K is incorporated by reference to our Definitive Proxy Statement on Schedule 14A to be filed in respect of our 2012 Annual Meeting of Stockholders.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development and commercialization 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 and our other filings with the Securities and Exchange Commission (SEC). We do not undertake any obligation to update forward-looking statements, except as required by applicable law. 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.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

The continuing worldwide economic and 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.

Some 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 our devices and with devices similar to those that we are developing may not be predictive of results with our products and product candidates, 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 products and product candidates, and we cannot give any assurance that our product candidates will receive regulatory clearance or that any of our products and future products will be successfully commercialized.

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

Our product development activities could be delayed or stopped.

The regulatory clearance and approval processes are expensive, time-consuming and uncertain and may prevent us or our collaboration partners from obtaining clearances or approvals, as the case may be, 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.

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

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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 products and 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, 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 rely on third parties to manufacture and supply our products, and we will rely on third parties to manufacture and supply our product candidates, and an inability to find additional or alternate sources for our products could materially and adversely affect our financial condition and results of operations.

We currently have a limited sales, marketing and 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.

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

We rely heavily on licenses from third parties, particularly our license with Creighton University, and any loss of our rights under such license agreements could materially adversely affect our business prospects.

Most of our patent rights are licensed to us by Creighton University. If we or Creighton University do not properly maintain or enforce the patent applications underlying this license, or if we lose our rights under this license, our competitive position and results of operations will be materially adversely affected.

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

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

Some jurisdictions may require us or our licensors to grant licenses to third parties. Such compulsory licenses could be extended to include some of our products and 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.

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, any of which could materially adversely affect our liquidity, business prospects and results of operations.

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.

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

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares, and future sales of our common stock could reduce our stock price.

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.

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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 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.

More information about us may be found at our website: www.SafeStitch.com. Information contained on our website is not incorporated by reference and does not comprise a part of this Annual Report on Form 10-K. Please refer to page 19 for a glossary of certain medical terms used in this Annual Report on Form 10-K.

General

We were originally incorporated in August 1988 as NCS Ventures Corp. under the laws of the State of Delaware, after which our name changed to Cellular Technical Services Company, Inc. On September 4, 2007, we acquired SafeStitch LLC, and, in January 2008, we changed our name to SafeStitch Medical, Inc.

Company Overview

We are a developmental stage FDA-registered medical device company focused on the development of medical devices that manipulate tissues for the treatment of hernia formation, obesity, gastroesophageal reflux disease (GERD), 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 AMID Stapler®, SMART Dilator™, and standard and airway bite blocks. 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. Preliminary clinical trials for our gastroplasty product candidates began in the third quarter of 2010 and are expected to continue in the second half of 2012. In February 2012, we received Special 510K clearance for the AMID Stapler®, and, on March 28, 2012 we introduced the AMID Stapler® to the participants attending the joint meeting of the 2012 American Hernia Society and the European Hernia Society in New York.

Our objective in designing surgical devices is to accomplish one or more of the following surgical goals:

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

We believe that we can attain 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.

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Dr. Charles J. Filipi, our Chief Medical Officer, has been a pioneer in laparoscopic surgery and endoluminal surgery at Creighton University and is past president of the American Hernia Society. He has been the lead physician responsible for the development of our product candidates, and he has relationships with a number of physicians who are experts in these fields. We believe that Dr. Filipi will be able to utilize his expertise and these relationships to facilitate device development and the opportunities mentioned above. Some 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;
- Increasing need 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 the treatment of obesity patients. The incidence of obesity (defined as a body mass index (BMI) greater or equal to 30 and/or 100 pounds overweight) is increasing, despite increased public awareness of the health risks associated with obesity and the growth of the diet and fitness industries. The Centers for Disease Control and Prevention (CDC) reports that in 2009 2010, 35.7% of U.S. adults were obese and 16.9% of U.S. children and adolescents were obese. The CDC reports that this includes over 78 million U.S. adults and approximately 12.5 million children and adolescents that were obese. Some estimates project that 100 million Americans, or approximately 38% 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 world-wide, including in newly industrialized countries such as China and India.

Current treatment options for obesity include exercise and dieting, prescription drugs, new but unproven endoscopic procedures and bariatric surgical alternatives. 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. An estimated 350,000 to 400,000 bariatric surgical procedures are performed annually worldwide. Bariatric surgery is usually recommended for those people with a 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 the gastric sleeve. Gastric bypass combines the creation of a small stomach pouch to restrict food intake and the construction of a duodenal bypass, thereby decreasing the body s ability to absorb nutrients from food. In gastric banding procedures, 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. The FDA has approved an indication for use of the gastric band in procedures on people with a BMI of 30 or higher with co-morbidities. In the gastric sleeve procedure, the stomach volume is significantly reduced, which accelerates the flow of food through the stomach. These procedures are expensive and require abdominal wall incisions. It has been reported that at least 20% of gastric band patients require the removal of the gastric band within the first year following surgery. Some of the reported problems associated with the gastric band include erosion, migration, intolerance, leakage, and slippage.

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Our lead product candidates can also be used to treat GERD and GERD-related complications such as Barrett s Esophagus. 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. A significant portion of the adult population in the United States suffers from GERD symptoms. Left untreated for a prolonged period of time, GERD can lead to complications such as Barrett s Esophagus, a precancerous change to the lining of the esophagus. Barrett s Esophagus can develop into an often fatal form of cancer of the esophagus. Worldwide, there are approximately 200,000 GERD surgical procedures performed annually. None of the currently available outpatient endoscopic procedures has 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. Endoscopies require a bite block to protect both the endoscope and the patient s teeth. We have developed an airway bite block, described below, that can be used during an endoscopy and is intended to prevent a low oxygen level during the procedure due to a restricted airway.

Our AMID Stapler® is designed for use in open surgical repair of both inguinal (groin) and ventral (abdominal) hernias and for the approximation of tissue, including skin. We received Special 510K clearance for the AMID Stapler® in February 2012. Hernias impact approximately 1% of the world s population, and roughly 800,000 inguinal hernias are repaired annually in the United States. Greater than 60% of the inguinal hernia repairs performed in developed countries are performed using the Lichtenstein technique popularized by Dr. Amid. During the repair, mesh is affixed to tissues to prevent hernia recurrence. Hernias are also repaired through open incision without affixing mesh, and laparoscopically with mesh reinforcement.

Products

The AMID Stapler®

We developed the AMID Stapler® in cooperation with Dr. Parviz Amid, a pioneer of and renowned expert in the Lichtenstein Hernia Repair. This stapler uses non-absorbable titanium staples to repair inguinal (groin) or ventral (abdominal) hernias. The staples are used to fix mesh in place, which helps prevent the recurrence of a hernia. In November 2009, we received FDA clearance to market the AMID Stapler® in the United States as a Class II device, and, in February 2010, we received CE Mark approval to market the stapler in the European Union and other countries requiring CE mark. After we commenced production of the AMID Stapler® in 2010, we voluntarily suspended sales in order to implement several improvements and a more robust and reliable commercial manufacturing process. Thereafter, we submitted a Special 510(k) to the FDA that was cleared in February 2012. This clearance allows us to market the AMID Stapler® in the United States and we expect to begin commercial sales in the United States in the second quarter of 2012. Additionally, we will supplement our Technical File prior to marketing the AMID Stapler® in the European Union.

SMART Dilator™

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. Approximately 800,000 dilations are performed in the United States each year. 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. Untreated perforation of the esophagus is fatal, usually within two days. Research indicates that, during dilation, the physician should place no greater than two pounds of pressure on the dilator. Our SMART Dilator™ 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 Dilator™ 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 Dilator™.

In February 2009, we received FDA clearance to market the SMART Dilator™ in the United States as a Class II device, and we continue to evaluate commercialization options.

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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 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 to test for comfort during endoscopic procedures in human patients. This is a Class I 510(k)-exempt device that requires no preclearance from the FDA prior to marketing.

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. The Airway Bite Block was tested following Institutional Review Board (IRB) approval at Creighton University Medical Center in 2008. The Airway Bite Block will come in two sizes. This is a Class I 510(k)-exempt device that requires no preclearance from the FDA prior to marketing.

We continue to evaluate commercialization options for the Standard and Airway Bite Blocks.

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 intralumenal surgery.

Intralumenal 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 operations are generally performed through an external abdominal incision, and sometimes laparoscopically. Traditional surgery has the potential for significant complications and often requires an in-patient hospital stay, which is expensive.

The Gastroplasty Device is the most tested of our product candidates, and has demonstrated its potential for effectiveness. In animal tests and *ex vivo* human testing, the Gastroplasty Devices have been successful in obesity surgeries for suturing and excising tissue and reducing stomach size. We successfully tested our first investigational devices in five patients in Hungary, and follow up observations were reviewed in March 2012, which was approximately 18 months following the initial procedures. At the 18 month follow-up, we observed, through endoscopic visualization, that the operative site showed significant scar tissue as intended, with the scar forming a restrictive ring for weight loss or, in the case of GERD, a barrier to prevent acid from refluxing into the esophagus. We also observed that the weight loss and esophageal monitoring was satisfactory and as expected. We expect to continue *in vivo* human testing of this device in the United States in 2013. We are preparing separate GERD and obesity clinical trial protocols for this device and anticipate submitting the final investigational device exemption (IDE) trial plans to the FDA for review in 2013. We intend to apply to the FDA for clearance of the Gastroplasty Device for the GERD indication and approval for the obesity indication.

Barrett s Excision Device for Treatment and Diagnosis (Barrett s Device)

Barrett s Esophagus, which is 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, malignancy and death. Our Barrett s Device is designed to assist in both the diagnosis of and treatment of Barrett s Esophagus.

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. No incision will be required, and the procedure will be an outpatient procedure. We expect this device to be more effective and less costly than existing procedures.

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In more than ten *in vivo* and *ex vivo* animal tests and five *ex vivo* human tests, the Barrett s Device has successfully excised tissue with the desired width, length, depth and contour. We expect to conduct the first human testing of the Barrett s Device in late 2013, following submission and review by FDA of an IDE for trials of this device.

T Fasteners for Upper GI Bleeding (T Fastener Gun)

The T Fastener Gun delivers small metal fasteners at the end of an endoscope. We believe that our T Fastener Gun can provide full-thickness stomach wall suturing for control of gastric bleeding. Existing devices apply energy or clips that are often too superficial, resulting in rebleeding. The T Fastener suture end is tightened, and because 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 is a Class II 510(k) device that will require IDE clinical data to support a premarket notification for FDA clearance.

Novel Devices for Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Natural Orifice Transluminal Endoscopic Surgery or NOTES is a 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 University for a patent application for a magnetic gallbladder retractor that would enable improved operative exposure for gallbladder removal, as well as other devices to assist in NOTES procedures. 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 University for most of our products and 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 and the T Fastener Gun. In addition, we have certain rights to other Creighton University intellectual property that we have not yet defined as product candidates. In total, we have eight patent applications pending in the United States, including those that are exclusively licensed from Creighton. We are also pursuing several of these applications in other countries, and three such foreign patents have been issued.

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

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

Licenses and Collaborative Relationships; Research and Development

Our strategy is to develop a portfolio of product candidates through a combination of internal development and external partnerships. Collaborations are key to our strategy, and, on May 26, 2006, we entered into the Creighton Agreement, which grants us the right to license and sublicense most of our product candidates and associated know-how, including the exclusive right to manufacture, use and sell the product candidates. The foregoing license is exclusive even with respect to Creighton University. Pursuant to the Creighton Agreement, we are obligated to pay Creighton University, 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.

Creighton University provides all necessary facilities, including animal research laboratories, to accommodate Dr. Filipi s research and development of licensed products and product candidates, and we compensate Creighton University for the use of such facilities in accordance with the Creighton Agreement. We recorded expenses for 2011 and 2010 of $45,000 and $52,000, 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 located within 100 miles of Omaha, Nebraska. Also pursuant to the agreement, the university agreed that Dr. Filipi would initially devote at least 90% of his working time during the four-year period that began May 26, 2006 and ended May 26, 2010 and would thereafter devote at least 50% of his time for the subsequent two years towards the research and development of any licensed product or product candidate 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.

Pursuant to the Creighton 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 incurred in connection with the Creighton Agreement, we have incurred research and development costs and expenses of $3.4 million and $2.7 million for the years ended December 31, 2011 and 2010, respectively.

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In January 2007, we signed a consulting agreement with Dr. Parviz Amid to help us develop a stapler for hernia repair. Dr. Amid is past president of the American Hernia Society and a pioneer of and renowned expert in the Lichtenstein hernia repair. Under this agreement, we have agreed to pay Dr. Amid a 4% royalty based on the worldwide net sales of any product developed by us with his assistance, including the AMID Stapler®, for a period of ten years from the first commercial sale of each such product.

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. The following table sets forth some of the companies whose products we expect to compete with our products and product candidates:

Product or Product Candidate	Significant Competitor(s)
Gastroplasty Device	USGI Medical, Endo Gastric Solutions, Inc., ValenTx, Inc., GI Dynamics, Inc. and Medigus, Ltd.
Barrett s Device	Olympus Medical Equipment Services America, Inc. and BARRX Medical, Inc.
AMID Stapler®	Covidien.
SMART Dilator™	Boston Scientific Corporation, Cook Medical Supply, Inc., and Miller Medical Specialties.
Standard and Airway Bite Blocks	C.R. Bard, Inc, ConMed Corporation, U.S. Endoscopy, Omni Medical Supply, Inc. and Olympus Medical Equipment Services America, Inc.
T Fastener Gun	Cook Medical Supply, Inc. and Olympus Medical Equipment Services America, Inc.

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 products 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.

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.

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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 Self- Referral Law (commonly referred to as the Stark Law), 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, by the Department of Veterans Affairs under, among other laws, the Veterans Health Care Act of 1992, by the Public Health Service within HHS under the Public Health Service Act, by the Department of Justice through the Federal False Claims Act and various criminal statutes, and by 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 articles 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 clearance or 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 Predicate Device (a device first marketed prior to May 28, 1976 or a device marketed after that date which was substantially equivalent to a pre-May 28, 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 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. The FDA permits certain low risk medical devices to be marketed without requiring the manufacturer to submit a premarket notification. In other instances, the FDA may not only require that a premarket notification be submitted, but also that such notification 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 IDE regulations for clinical trials performed in the United States. The FDA review process for premarket notifications submitted pursuant to section 510(k) should take about 90 days on average, but it can take substantially longer if the agency has concerns. Furthermore, 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. There is not 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 (a) not substantially equivalent to a Predicate Device or (b) 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.

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We intend to continue in discussions with the FDA regarding the appropriate regulatory approval pathway for our Gastroplasty Device for the treatment of GERD and for the treatment of obesity. We have not yet sought final FDA approval to conduct any clinical studies of any of our licensed products in the United States. 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 or cleared 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. The interim results of a study may also 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 or 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 either (i) safe and effective, a prerequisite for FDA approval of a PMA, or (ii) 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 require PMA post market surveillance and extended clinical follow up, 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 which could affect the device s 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 and other federal export requirements and possible restrictions.

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 Union, we will be required to maintain certain International Organization for Standardization (ISO) certifications in order to sell products and we and/or our manufacturers must undergo periodic inspections by notified bodies to obtain and maintain these certifications. These regulations require us and 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.

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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 , by way of example, 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.

Recently Enacted Health Care Reform Legislation

Congress passed health care reform legislation that President Obama signed into law on March 23, 2010 and March 30, 2010. The package signed into law by the President is considered by some to be the most dramatic change to the country s health care system in decades.

The principal aim of the law as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The law s most far-reaching changes do not take effect until 2014, including a requirement that most Americans carry health insurance. The effect of these significant coverage expansions on the sales of the Company s products is unknown and speculative at this point.

The enacted legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer will have to pay an excise tax (or sales tax) in an amount equal to 2.3 percent of the price for which such manufacturer sells its medical devices. This tax applies to all medical devices, including the Company s products and product candidates.

The legislation as enacted also provides for increased enforcement of the fraud and abuse regulations discussed below.

It should be noted that the constitutionality of certain provisions of the health care reform law, including the mandate to purchase insurance, are before the Supreme Court of the Unites States, which is expected to reach some decision on or before June 25, 2012.

Third-Party Payments, Especially Payments by Medicare and Medicaid

A. Medicare and Medicaid Coverage

Because some 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 frameworks are 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, either directly or through one of its contractors, 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.

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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 and the surgical procedure is of a type expressly approved by CMS.

There can be no assurance that bariatric surgery relying 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. Reimbursement Levels

Even if Medicare and other third-party payor programs cover the procedures that use our devices, the level of reimbursement may not be sufficient for commercial success. The Medicare reimbursement levels for covered procedures are determined annually through three sets of rulemakings, one for outpatient departments of hospitals under the Outpatient Prospective Payment System (OPPS), another for the inpatient departments of hospitals under the Inpatient Perspective Payment System (IPPS), and the third 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 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.

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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, Sections 1877 and 1903(s) 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 under a federal program (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/or Medicaid payments or exclusion from the Medicare and/or Medicaid programs. 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 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 regularly subject 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.

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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 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 based on our current business model, it is likely that we 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 HITECH Act provisions of the American Recovery and Reinvestment Act of 2009 increase the duties of business associates and covered entities with respect to protected health information, thereby subjecting them to direct government regulation, increasing their compliance costs and their exposure to civil monetary penalties and other government sanctions. While the law does not alter the definition of a business associate, it makes it more likely that covered entities with whom we are likely to do business will require us to enter into business associate agreements.

Manufacturing

We are currently modifying our prototype lab, located in Miami, Florida, to accommodate the commercial manufacture of the AMID Stapler®, which we intend to launch in the second quarter of 2012. In addition, we intend to continue to use this facility for the manufacture of prototypes and non-commercial components, device prototypes and non-commercial finished devices of certain of our product candidates for testing, including for limited use in animal or human clinical testing. 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 (cGMPs) or ISO certifications where applicable, and to the extent laboratory analysis is involved, current good laboratory practices (cGLPs), where applicable.

Sales & Marketing

We currently have limited sales, marketing and distribution personnel. We have recently hired six direct sales representatives, under the management of our Director of Sales, and a Director of Marketing. In order to commercialize any products that are approved or cleared for commercial sale, we must continue to build a sales and marketing infrastructure, collaborate with third parties possessing sales and marketing experience and/or utilize a combination of internal and third party resources. We intend to build our sales and marketing infrastructure to market some of our product or product candidates, and we may collaborate with companies established in this industry to market and sell certain of our products, if cleared or approved, as the case may be. Such collaborations could take the form of joint ventures or sales, marketing or distribution agreements. We intend to distribute our products, including our AMID Stapler®, through our own sales and marketing organization and through independent contractor and distribution agreements with companies possessing established sales and marketing operations in the medical device industry, but there can be no assurance that we will successfully be able to build a sales and marketing infrastructure or be able to enter into independent contractor and distribution agreements on terms acceptable to us or at all.

Employees

As of December 31, 2011, we had 29 full-time employees, six of whom hold advanced degrees. 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.

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Executive Officers of the Registrant

Jeffrey G. Spragens. Mr. Spragens, 70, has served as our President and Chief Executive Officer and as a member of our Board of Directors since our acquisition of SafeStitch LLC 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, Mr. Spragens 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, an American Stock Exchange listed company sold to Baxter International in 1999. Mr. Spragens also has previous experience as a developer and attorney.

Charles J. Filipi M.D. Dr. Filipi, 71, has served as our Chief Medical Officer (f/k/a Medical Director) and a member of our Board of Directors since our acquisition of SafeStitch LLC 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. Dr. Filipi has also served as president of the American Hernia Society, editor of the Journal Hernia and has published approximately 100 peer-reviewed articles and fifty-one book chapters. He has been the inventor of over twenty provisional or utility patents. His primary areas of interest are intralumenal surgery for the correction of gastroesophageal reflux disease, Barrett s Esophagus, and obesity.

James J. Martin, C.P.A. Mr. Martin, 45, has served as our Chief Financial Officer since January 2011, and, from July 2010 through January 2011, Mr. Martin served as our Controller. Mr. Martin has served as Vice President of Finance for Aero Pharmaceuticals, Inc. (Aero) a privately-held pharmaceutical distributor and Chief Financial Officer of Non-Invasive Monitoring Systems, Inc.(NIMS), a publicly-held medical device company since January 2011. From July 2010 through January 2011, Mr. Martin served as Controller of NIMS and Aero. Prior to joining SafeStitch, from 2008 through 2010, Mr. Martin served as Controller of AAR Aircraft Services-Miami, a subsidiary of AAR Corp, an aerospace and defense company in which he was responsible for all financial reporting and inventory logistics. From 2005-2008, Mr. Martin served as Controller of Avborne Heavy Maintenance, a commercial aircraft maintenance repair and overhaul company. In addition to his career in finance and accounting, Mr. Martin served five years in the United States Navy as an Operations Specialist.

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 the surgical manipulation of gastric (stomach) tissue.

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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.

Inguinal refers to the groin area or lower lateral region of the abdomen.

Intralumenal refers to 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 across the intestinal wall.

Ventral refers to the side of the body opposite the dorsal spine.

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.

Risks Related to our Business

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

We are a medical device company with a limited operating history. We remain a developmental stage enterprise, and 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 the second quarter of 2012. Three of our products 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, 2011 and 2010 were $5.7 million and $5.3 million, respectively, and we had an accumulated deficit of $22.8 million as of December 31, 2011. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we prepare for clinical trials of our product candidates and begin to commercialize our 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.

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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:

- the costs associated with establishing a sales force and commercialization capabilities;
- the costs associated with the expansion of our manufacturing capabilities;
- our need to expand our research and development activities;
- the rate of progress and cost of our clinical trials;
- 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, scientific, medical and sales and marketing 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.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. As discussed above in Item 1. Business , Congress passed health care reform legislation that President Obama signed into law in March 2010. While the most immediate impact on device manufacturers is the imposition of a 2.3 percent tax beginning in 2013, the other effects of the law on our business and sector remain uncertain. Over the next few years, the administration can be expected to issue rules implementing the new reforms and those regulations could have adverse consequences for device manufacturers.

In addition to the legislation discussed above, various healthcare reform proposals have also emerged at the state level. We cannot predict what additional healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any such future legislation or regulation will have on us. In addition to the taxes imposed by the new federal legislation, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and materially adversely affect our business, financial condition and results of operations.

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Continued worldwide economic and 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.

Worldwide economic conditions 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 and preferred stock and through borrowings under credit facilities available to us from stockholders and other individuals, including our existing $4.0 million line of credit which will mature in June 2013. Any 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. Our inability to raise additional working capital on acceptable terms would materially and adversely affect our liquidity and could materially adversely affect our ability to continue our operations.

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

We are engaged in the research and development of intralumenal 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.

Some 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 clinical experience with our devices and devices similar to those that we are developing 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 early clinical experience with the test articles or 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).

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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. 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. 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 products and product candidates, and we cannot give any assurance that our product candidates will receive regulatory clearance or that any of our products or future products will be successfully commercialized.

We are highly dependent on the success of our products and product candidates, especially the Gastroplasty Device and the AMID Stapler®. We cannot give any assurance that the FDA will permit us to clinically test or grant regulatory clearance for the Gastroplasty Device, nor can we give any assurance that the Gastroplasty Device or any of our other products will 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 products and future products, 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, Satiety, EndoGastric Solutions, Inc., Medigus, Ltd., C.R. Bard, Inc, ValenTx, Inc., GI Dynamics, Inc., Medical Equipment Services America, Inc., BARRX Medical, Inc., Covidien, Boston Scientific Corporation, ConMed Corporation, Cook Medical Supply, Inc., Miller Medical Specialties, U.S. Endoscopy 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;

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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 products or future products, or that reach the market sooner than our product candidates, 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 other planned clinical trials will be completed on schedule, or at all, and we cannot guarantee that our planned clinical trials will begin on time or at all. The commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

limited number of, and competition for, suitable patients that meet the protocol s inclusion criteria and do not meet any of the exclusion criteria;

limited number of, and competition for, suitable sites to conduct our clinical trials, and delay or failure to obtain FDA approval, if necessary, to commence a clinical trial;

delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;

requirements to provide the medical device required in our clinical trial at cost, which may require significant expenditures that we are unable or unwilling to make;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and

delay or failure to obtain 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.

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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. We intend to continue discussions with the FDA regarding the appropriate regulatory approval for our Gastroplasty Device for the treatment of GERD and for the treatment of obesity. Obtaining approval of any PMA can be a lengthy, expensive and uncertain process. While the FDA normally reviews and clears a premarket notification in 90 days, there is no guarantee that our future product candidates 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.

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, uncertain 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 device lawfully marketed either as a grandfathered device or one that was cleared through the 510(k) premarket notification process;
- 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.

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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 our trials. 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.

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 products and 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, either before or after clearance or approval, or 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.

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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, or third-party payors, including government payors, may not provide coverage for our products or for procedures using our products, which could undermine our financial viability.

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;
- physician training in the use of our products;
- 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.

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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, marketing 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 and Dr. Charles J. 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 organization.

We have scientific, regulatory 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 and begin commercializing our products, 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 utilize in-licensing as a source of 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.

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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.

Because our manufacturing capabilities are limited, we will rely on third parties to manufacture and supply substantially all of our product candidates, and an inability to find additional or alternate sources for our products could materially and adversely affect our financial condition and results of operations.

We currently operate a manufacturing facility for the commercial production of the AMID Stapler®. In the future, we may choose to use a third party manufacturer for the AMID Stapler® as well as our other products and product candidates. Currently, a significant number of our AMID Stapler® component parts come from third-party suppliers. If these manufacturing partners are unable to produce our products or component parts 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.

Our product candidates require precise, high quality manufacturing. We and our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with QSR, cGMP and other applicable government regulations and corresponding standards. If we or 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 by us or on the part of our contract manufacturers could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our products and future products, 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 products. Such approval may 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 a limited sales, marketing and 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 limited marketing, sales and distribution capabilities. We intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our products and 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. We intend to distribute our products, including our AMID Stapler®, through our own sales and marketing organization and through independent contractor and distribution agreements with companies possessing established sales and marketing operations in the medical device industry, but there can be no assurance that we will successfully be able to build a sales and marketing infrastructure or be able to enter into

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independent contractor and distribution agreements on terms acceptable to us or at all. 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 products and product candidates. If we are not successful in commercializing our existing and future products, 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.

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.

We rely heavily on licenses from third parties, particularly our license with Creighton, and any loss of our rights under such license agreements could materially adversely affect our business prospects.

Most of the patent applications in our patent portfolio are not owned by us, but are licensed from Creighton and other third parties. 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.

Most of our patent rights are licensed to us from Creighton. If we or Creighton University do not properly maintain or enforce the patent applications underlying this license, or if we lose our rights under this license, our competitive position, business prospects and results of operations will be materially adversely affected.

Our success will depend in part on the ability of us or Creighton University to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights. We or Creighton University may not successfully prosecute the patent applications which are licensed to us. Even if patents issue in respect of these patent applications, we or Creighton University 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 necessary to obtain an acceptable outcome from any such litigation. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and results of operations.

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If we or our licensors are unable to obtain and enforce patent protection for our products and product candidates, 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 numerous patent applications are in process, we presently do not hold any issued U.S. patents, and to our knowledge none of the technology we license has been patented in the U.S. 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 develop and use information that we regard as proprietary.

The issuance of a patent provides a presumption, but does not guarantee that it is valid. Any patents we have obtained, or obtain in the future, may be challenged or potentially circumvented. Moreover, the United States Patent and Trademark Office (the USPTO) may commence interference proceedings involving our patents or patent applications. Any such challenge to 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, future court decisions may introduce uncertainty in the enforceability or scope of any patent, including those owned by medical device companies.

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

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

If we or our licensors 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

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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.

Some jurisdictions may require us or our licensors 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, any of which could materially adversely affect our liquidity, business prospects and results of operations.

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.

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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 (DME), they may be subject to distribution under Medicare s Competitive Acquisition regulations, which 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 products and product candidates in non-U.S. markets. In order to market our existing and future products 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 products 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 products. 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.

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

Our business is subject to risks associated with conducting business domestically and internationally, in part due to some 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 U.S. and non-U.S. laws and regulations;
- changes in U.S. and 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.

Risks Related to Our Common Stock

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

For the two years ended December 31, 2011, the market price of our common stock has fluctuated from a high of $2.20 per share to a low of $0.45 per share. The market price of our common stock may continue to 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. The volatility of our common stock is further exacerbated due to its low trading volume. 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 and the loss of some or all of your investment.

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Some or all of the restricted shares of our common stock held by our stockholders, including, but not limited to, shares issued in connection with (i) our acquisition of SafeStitch LLC, (ii) our 2008, 2010 and 2012 private placements and (iii) the 2010 conversion into common stock of all outstanding shares of our preferred stock, may be offered from time to time in the open market pursuant to an effective registration statement under the Securities Act of 1933, as amended, or without registration pursuant to Rule 144 promulgated thereunder, and these sales may have a depressive effect on the market price of our common stock.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price.

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. As of December 21, 2011, approximately 62% of the issued and outstanding shares of our common stock are held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock.

These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public 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, if at all.

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, and you may lose all or a portion of your investment in our common stock.

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 SEC. This risk-disclosure 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.

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

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, over 62% of our outstanding voting securities as of December 21, 2011. 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, 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 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 and manufacturing facility 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 lease approximately 6,800 square feet under the lease agreement, which is for a five-year term that began on January 1, 2008.

Additionally, we lease approximately 462 square feet of office space in Omaha, Nebraska. This facility includes one administrative office used by Dr. Filipi, who is based in Omaha, Nebraska and is our Chief Medical Officer and one of the members of our Board of Directors. We also lease approximately 1,200 square feet of warehouse space in Miami, Florida which is used as our prototype lab.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

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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. During the period from February 22, 2011 to August 25, 2011, our common stock was quoted on the OTCQB 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 OTCQB or the OTCBB, as applicable. The bid prices represent inter-dealer transactions, without adjustments for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

	Bid Prices	
	High	Low
2011		
First Quarter	$ 1.70	$ 0.81
Second Quarter	1.38	0.46
Third Quarter	0.90	0.50
Fourth Quarter	1.01	0.45
2010		
First Quarter	$ 1.95	$ 1.02
Second Quarter	1.70	1.02
Third Quarter	2.20	1.50
Fourth Quarter	2.05	1.14

As of March 28, 2012, there were approximately 208 record holders 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, 2011 and 2010, 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 Jeffrey G. Spragens, our Chief Executive Officer and President and a director, and 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, which provides for up to $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.

Item 6. Selected Financial Data.

As a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the Exchange Act), we are not required to include information otherwise required by this item.

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Item 7. Management s Discussion an40d Analysis of Financial Condition and Results of Operations.

This Annual Report on Form 10-K contains certain forward-looking statements about our expectations, beliefs or intentions regarding our product development and commercialization 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 and our other filings with the SEC. We do not undertake any obligation to update forward-looking statements, except as required by applicable law. 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, FDA-registered medical device company focused on the development of medical devices that manipulate tissues for the treatment of 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 AMID Stapler®, SMART Dilator™, and standard and airway bite blocks. 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. Preliminary clinical trials for our gastroplasty product candidates began in the third quarter of 2010 and are expected to continue in the second half of 2012. Sales of our AMID Stapler® are anticipated to begin in the second quarter of 2012.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our audited 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, 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 net loss totaled $22.8 million for the period from September 15, 2005 (inception) through December 31, 2011. Such loss included $5.7 million and $5.3 million for the years ended December 31, 2011 and 2010, respectively. We do not currently generate revenues from any of our products, including those already cleared for commercial marketing by the FDA. While we anticipate generating revenue in 2012, we expect to continue to generate net losses in connection with the commercial launch of such FDA-cleared 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 we will likely continue to incur net losses for the near future.

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Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Research and Development (R&D) costs and expenses were $3.4 million for the year ended December 31, 2011, as compared to $2.7 million for the year ended December 31, 2010. This $0.7 million increase resulted primarily from the addition of R&D and manufacturing staff and increased expenditures for contract engineering services, pre-clinical testing, research equipment, controlled environment infrastructure, the manufacturing of devices and components to be used in clinical trials of our gastroplasty device, and costs associated with the redesign and testing of the AMID Stapler®.

Selling, General and Administrative (SG&A) costs and expenses were $2.3 million for the year ended December 31, 2011 as compared to $2.6 million for the year ended December 31, 2010. This $0.3 million decrease is primarily related to a decrease in stock-based compensation expense due to a change in the forfeitures experience, professional and legal fees, sales and accounting payroll costs, advertising fees, travel and trade show expenses related to the initial commercialization of the AMID Stapler®. These decreases were offset in part by increases in payroll costs from the addition of quality, regulation and engineering personnel, obsolete inventory disposals, increased rent and other costs associated with our efforts to develop a more reliable manufacturing process. SG&A costs and expenses consist primarily of salaries and other related costs, including stock-based compensation expense. Other SG&A costs and expenses include facility-related costs not otherwise included in R&D costs and expenses, and professional fees for legal and accounting services. We expect that our SG&A costs and expenses will increase in 2012 in connection with our intended commercialization activities for the AMID Stapler® beginning in the second quarter of 2012.

Other income totaled $0 and $0.2 million for the years ended December 31, 2011 and 2010, respectively. This $0.2 million decrease resulted from the awarding of a tax grant in 2010 under the U.S. Government s Qualifying Therapeutic Discovery Project (QTDP) program for research related to development of the AMID Stapler® and the related Simplified Stapled Lichtenstein Procedure (SSLP) for hernia repair. The QTDP program was created by Congress on May 21, 2010 under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act. The QTDP program provides support for innovative projects that are determined by the U.S. Department of Health and Human Services to have reasonable potential to result in a new therapy, reduce health care costs, or significantly advance the goal of curing cancer. The grant was received in 2010 and was not taxable income for federal tax purposes.

Interest income was negligible for the years ended December 31, 2011 and 2010. Interest expense totaled $48,000 for the year ended December 31, 2011, as compared to $0 for the year ended December 31, 2010. The 2011 interest expense was due to outstanding balances under our credit facility.

Liquidity and Capital Resources

As a result of our significant R&D expenditures and the lack of any product sales revenue, we have generated operating losses since inception. We do not expect to have any source of revenues before the second quarter of 2012 at the earliest, and we expect to incur losses from operations for the foreseeable future. We expect to incur increasing R&D costs and expenses, including expenses related to hiring new personnel and conducting clinical trials. We expect that SG&A costs and expenses will also increase as we expand our regulatory compliance and administrative staff and add sales and marketing personnel and infrastructure.

To date, we have funded our operations primarily with proceeds from private placement of common and preferred stock and our $4.0 million credit facility. 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, among other things, any 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, uncertain economic conditions could 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.

On February 17, 2012, we sold 20,794,000 shares of our common stock in a private placement at a price of $0.40 per share, with net proceeds to the Company of $8.3 million. Approximately 54% of the shares offered were purchased by our officers, directors and significant shareholders. A portion of the proceeds was used to pay off all amounts outstanding under the credit facility.

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We have received FDA clearance to begin marketing the AMID Stapler® in the United States and we are preparing to commence clinical trials of our Gastroplasty Device. We expect to begin commercial sales of the AMID Stapler® in the second quarter of 2012. Commencing such commercialization and clinical trial activities is anticipated to significantly increase our cash requirements for 2012 and into the foreseeable future. Our management believes that the $8.3 million in proceeds received by the Company from the sale of the 20,794,000 shares of common stock in February 2012, together with the availability under our existing line of credit, which matures in June 2013, is sufficient to fund our current cash flow requirements through December 31, 2012. However, in order to fund all planned operations, including the commercialization of certain of our products and the anticipated expansion of clinical trials for certain of our product candidates, we anticipate that additional external financing will be required. 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 commercialization efforts and clinical trials.

Our actual future capital requirements will depend on many factors, including sales of the AMID Stapler®, 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 R&D 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.

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Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

SafeStitch Medical, Inc.

We have audited the accompanying consolidated balance sheets of SafeStitch Medical, Inc. and subsidiaries (a development stage company) (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders equity and cash flows for the years ended December 31, 2011 and 2010 and for the period from September 15, 2005 (inception) through December 31, 2011. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2011 and 2010, and the consolidated results of their operations and cash flows for the years ended December 31, 2011 and 2010 and for the period from September 15, 2005 (inception) through December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York

March 29, 2012

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SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONSOLIDATED BALANCE SHEETS

(in 000s, except share data)

	December 31, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 298	$ 3,032
Other receivable related-party	66	64
Prepaid expenses	143	117
Inventory		91
Total Current Assets	507	3,304
FIXED ASSETS		
Property and equipment, net	470	337
OTHER ASSETS		
Security deposits	2	2
Deferred financing costs, net	14	51
Total Other Assets	16	53
TOTAL ASSETS	**$ 993**	**$ 3,694**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 469	$ 221
Notes payable		49
Total Current Liabilities	469	270
Stockholders loans, including accrued interest	2,523	
Commitments and contingencies (Note 9)		
STOCKHOLDERS (DEFICIT) EQUITY		
Preferred stock, $0.01 par value per share, 25,000,000 shares authorized 10% Series A Cumulative Convertible Preferred Stock, 4,000,000 shares authorized, no shares issued and outstanding as of December 31, 2011 and 2010; liquidation preference $0 as of December 31, 2011 and 2010		
Common stock, $0.001 par value per share, 225,000,000 shares authorized, 28,003,755 shares issued and outstanding as of December 31, 2011 and 2010	28	28
Additional paid-in capital	20,762	20,427
Deficit accumulated during the development stage	(22,789)	(17,031)
Total Stockholders (Deficit) Equity	(1,999)	3,424
TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY	**$ 993**	**$ 3,694**

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

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SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

(in 000s, except per share amounts)

	Years Ended December 31,		September 15, 2005 (Inception) to December 31,
	2011	2010	2011
Revenues	$	$	$
Costs and expenses			
Research and development	3,367	2,728	12,938
Selling, general and administrative	2,306	2,617	8,995
Total costs and expenses	5,673	5,345	21,933
Loss from operations	**(5,673)**	**(5,345)**	**(21,933)**
Other income and (expense)			
Other income		244	1,147
Interest income		2	79
Amortization of deferred financing costs	(37)	(204)	(1,970)
Interest expense	(48)		(112)
Total other income and (expense)	(85)	42	(856)
Loss before income tax	**(5,758)**	**(5,303)**	**(22,789)**
Provision for income tax			
Net loss	**$ (5,758)**	**$ (5,303)**	**$ (22,789)**
Loss attributable to common stockholders and loss per common share:			
Net loss	$ (5,758)	$ (5,303)	$ (22,789)
Deemed dividend Series A Preferred Stock Issuance		(500)	(700)
Deemed dividend Series A Preferred Stock Conversion		(4,301)	(4,301)
Declared/Accrued Dividends Series A Preferred Stock		(278)	(366)
Loss attributable to common stockholders	**(5,758)**	**(10,382)**	**(28,156)**
Weighted average shares outstanding, basic and diluted	28,004	22,230	
Net loss per basic and diluted share	**$ (0.21)**	**$ (0.47)**	

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

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SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

FOR THE PERIOD SEPTEMBER 15, 2005 (INCEPTION) THROUGH DECEMBER 31, 2011

(in 000s)

	Preferred Stock		Common Stock		Additional	Deficit Accumulated During the	
	Shares	Amount	Shares	Amount	Paid-in Capital	Development 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 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			1,862	2	3,986		3,988
Issuance of common shares as repayment of stockholder note December 30, 2008 at $1.22 per share			8		10		10
Stock-based compensation					239		239
Net loss						(5,185)	(5,185)
Balance at December 31, 2008		**$**	**17,963**	**$ 18**	**$ 10,817**	**$ (9,362)**	**$ 1,473**
Issuance of Series A Preferred Stock in July 2009 at $1.00 per share, net of offering costs	2,000	20			1,962		1,982
Fair value of beneficial conversion feature of Series A Preferred Stock					200		200

Deemed dividend to Series A Preferred Stockholders, charged to additional paid-in capital in the absence of retained earnings					(200)		(200)
Stock-based compensation					195		195
Net loss						(2,366)	(2,366)
Balance at December 31, 2009	**2,000**	**$ 20**	**17,963**	**$ 18**	**$ 12,974**	**$ (11,728)**	**$ 1,284**
Issuance of Series A Preferred Stock in January 2010 at $1.00 per share, net of offering costs	2,000	20			1,978		1,998
Fair value of beneficial conversion feature of Series A Preferred Stock					500		500
Deemed dividend to Series A Preferred Stockholders, charged to additional paid-in capital in the absence of retained earnings					(500)		(500)
Issuance of common shares in private offering			4,978	5	4,969		4,974
Conversion of 4,000 shares of Series A Preferred Stock and accumulated dividends into 4,366 shares of Common Stock in September 2010	(4,000)	(40)	4,366	4	36		
Issuance of 697 shares of Common Stock as Consideration Shares in September 2010			697	1	(1)		
Intrinsic value of 5,063 aggregate shares of Common Stock issued on conversion of Series A Preferred Stock					4,301		4,301
Dividend paid to Series A Preferred Stockholders on conversion, charged to additional paid-in capital in the absence of retained earnings					(4,301)		(4,301)
Stock-based compensation					471		471
Net loss						(5,303)	(5,303)
Balance at December 31, 2010		**$**	**28,004**	**$ 28**	**$ 20,427**	**$ (17,031)**	**$ 3,424**
Stock-based compensation					335		335
Net loss						(5,758)	(5,758)
Balance at December 31, 2011		**$**	**28,004**	**$ 28**	**$ 20,762**	**$ (22,789)**	**$ (1,999)**

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

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SAFESTITCH MEDICAL, INC.

(A Developmental Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in 000s)

	Years Ended December 31,		September 15, 2005 (Inception) to December 31,
	2011	2010	2011
OPERATING ACTIVITIES			
Net loss	$ (5,758)	$ (5,303)	$ (22,789)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred finance costs	37	204	1,970
Stock-based compensation expense	335	471	1,305
Stock-based compensation expense related to Share Exchange			77
Depreciation and amortization	140	87	342
Loss from disposal of assets	20		20
Gain on sale of TruePosition investment			(903)
Inventory disposals	86	53	139
Changes in operating assets and liabilities			
Other current assets	(28)	(29)	(189)
Inventory	5	(144)	(139)
Other assets			(2)
Accounts payable and accrued liabilities	248	128	185
Accrued interest	48		48
NET CASH USED IN OPERATING ACTIVITIES	**(4,867)**	**(4,533)**	**(19,936)**
INVESTING ACTIVITIES			
Purchase of equipment	(293)	(277)	(832)
Proceeds from sale of TruePosition investment			903
Payment received under Rule 16b			4
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	**(293)**	**(277)**	**75**
FINANCING ACTIVITIES			
Net cash provided in connection with the acquisition of SafeStitch LLC			3,192
Issuance of Common Stock, net of offering costs		4,974	8,962
Issuance of Preferred Stock, net of offering costs		1,998	3,980
Capital Contributions			1,431
Proceeds from notes payable		70	141
Repayment of notes payable	(49)	(71)	(141)
Proceeds from stockholders loans	2,475		5,335
Repayment of stockholders loans			(2,776)
Exercise of options			35
NET CASH PROVIDED BY FINANCING ACTIVITIES	**2,426**	**6,971**	**20,159**

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,734)	2,161	298
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,032	871	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 298	$ 3,032	$ 298
Supplemental disclosures:			
Cash paid for interest	$	$	$ 64
Non cash activities:			
Non-cash dividend upon issuance and conversion of Preferred Stock	$	$ 4,801	$ 5,001
Dividends	$	$ 366	$ 366
Stockholder loans contributed to capital	$	$	$ 84
Warrants issued in connection with credit facility	$	$	$ 1,985

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

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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).

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, 2011, the Company has accumulated a deficit of $22.8 million, including a net loss of $5.8 million for the year ended December 31, 2011, 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, the $8.3 million in proceeds received from the issuance of shares of common stock in February 2012 (see Note 14), 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 (the Credit Facility), and by monitoring its discretionary expenditures, management believes that the Company will be able to fund its existing operations through December 31, 2012. However, in order to fund all planned operations, including the commercialization of certain of the Company s products, including the AMID Stapler®, and the anticipated expansion in 2012 of clinical trials for certain of the Company s product candidates, the Company anticipates that additional external financing will be required. 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.

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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, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents. We consider all highly liquid investments 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, and includes overnight repurchase agreements collateralizing its depository bank accounts (sweep accounts) in its cash balances. Balances in excess of Federal Deposit Insurance Corporation (FDIC) limitations may not be insured.

Allowances for Doubtful Accounts. The Company provides an allowance for receivables it believes it may not collect in full. Receivables are written off when they are deemed to be uncollectible and all collection attempts have ceased. The amount of bad debt recorded each period and the resulting adequacy of the allowance for doubtful accounts at the end of each period are determined using a combination of customer-by-customer analysis of the Company s accounts receivable each period and subjective assessments of the Company s future bad debt exposure.

Inventories. Inventories are stated at lower of cost or market using the weighted average cost method. Provisions for potentially obsolete or slow-moving inventory are made based on management s analysis of inventory levels, obsolescence and future sales forecasts. Obsolete inventory aggregating $86,000 was disposed of during 2011.

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.

Revenue Recognition. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, the goods are shipped and title has transferred, the price is fixed or determinable, and the collection of the sales proceeds is reasonably assured.

Advertising Costs. The Company expenses all costs of advertising as incurred. Advertising and promotional costs are included in selling, general and administrative (SG&A) costs and expenses for all periods presented, and totaled $73,000 and $61,000, respectively, for the years ended December 31, 2011 and 2010.

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.

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Stock-based compensation. The Company accounts for all share-based payments, including grants of stock options, as operating expenses, based on their grant date fair values. 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. Stock-based compensation is included in general and administrative costs and expenses for all periods presented.

Therapeutic discovery project tax credit. The Company records the therapeutic discovery project tax credit on the accrual basis when approved by the government agency which is reported as other income in the accompanying statements.

Fair value of financial instruments. The carrying amounts of cash and cash equivalents, accounts payable, and accrued expenses approximate fair value based on their short-term maturity.

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, 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 it is more likely than not 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). Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company s comprehensive net loss is equal to its net loss for all periods presented.

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Estimated Useful lives	December 31, 2011	December 31, 2010
Machinery and equipment	5 years	$ 660,000	$ 452,000
Furniture, fixtures and leasehold improvements	3-5 years	81,000	50,000
Software	3-5 years	57,000	37,000
		798,000	539,000
Accumulated depreciation and amortization		(328,000)	(202,000)
Property and equipment, net		**$ 470,000**	**$ 337,000**

Depreciation of fixed assets utilized in research and development activities is included in research and development costs and expenses. All other depreciation is included in general and administrative expense. Depreciation and amortization expense was $140,000 and $87,000 for the years ended December 31, 2011 and 2010, respectively.

NOTE 4 STOCK-BASED COMPENSATION

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. For the years ended December 31, 2011 and 2010, the Company recorded stock-based compensation expense of $0 and $34,000, respectively, for these options, which is included in general and administrative expense.

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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), which was amended on June 6, 2011 to increase the number of shares of Common Stock available for issuance thereunder from 2,000,000 to 3,000,000. 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 3,000,000 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 twelve 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 562,500 and 750,000 stock options under the 2007 Plan during the years ended December 31, 2011 and 2010, respectively. The options granted during 2011 were issued at an exercise price of $1.12 per share and had an estimated aggregate grant date fair value of $502,000. The options granted during 2010 were issued at exercise prices between $1.10 and $2.00 per share and had an estimated aggregate grant date fair value of $697,000. The weighted average grant date fair value of the options granted during 2011 and 2010 was $0.89 per share and $0.93 per share, respectively. At December 31, 2011, a total of 1,372,000 shares of Common Stock remained available for issuance under the 2007 Plan.

Total stock-based compensation recorded for the years ended December 31, 2011 and 2010 was $335,000 and $471,000, respectively, and is included in general and administrative expense. The stock-based compensation recorded for the year ended December 31, 2011 included a credit of $113,000 for a change in the forfeitures experience. 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. The risk-free interest rate for periods within the contractual life of the stock option award is based on the yield of U.S. Treasury bonds on the grant date with a maturity equal to the expected term of the stock option. The expected life of stock option awards is based upon the simplified method for plain vanilla options described in SEC Staff Accounting Bulletin No. 107, as amended by SEC Staff Accounting Bulletin No. 110. Forfeiture rates are based on management s estimates. The fair value of each option granted are estimated on the date of their grant using the Black-Scholes option pricing model using the following assumptions.

	Year ended December 31, 2011	Year ended December 31, 2010
Expected volatility	76.91% 102.63%	87.09% 108.28%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.25% 3.25%	.88% 3.11%
Expected life	5.5 10.0 years	4.0 7.0 years
Forfeiture rate	0% 5%	0% 5%

The following summarizes the Company s stock option activity for the year ended December 31, 2011:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	1,334,667	$ 1.41	5.74	
Granted	562,500	$ 1.12	9.20	
Exercised				
Canceled or expired	(269,000)	$ 1.19	4.88	
Outstanding at December 31, 2011	1,628,167	$ 1.35	6.26	$
Exercisable at December 31, 2011	864,917	$ 1.50	4.98	$
Vested and expected to vest at December 31, 2011	1,585,098	$ 1.35	6.23	$

68,000 of the 562,500 options granted during the year ended December 31, 2011, were vested as of December 31, 2011. At December 31, 2011, there was $242,000 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 1.74 years.

No options were exercised during the years ended December 31, 2011 and 2010.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.

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NOTE 5 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 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 (Frost Gamma), a trust controlled by Dr. Phillip Frost, the largest beneficial holder of the issued and outstanding shares of Common Stock, Dr. Jane H. Hsiao, the Company s Chairman of the Board, and Steven D. Rubin, a director. The Credit Facility provides up to $4.0 million in total available borrowings, consisting of up to $3.9 million from The Frost Group and up to $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 outstanding 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 on four occasions to extend the maturity date, which is now June 30, 2013.

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 is being amortized over the life of the Credit Facility. The Company recorded amortization expense of $37,000 and $204,000 related to these deferred financing costs for the years ended December 31, 2011 and 2010, respectively.

The Company borrowed $2,475,000 under the Credit Facility during the year ended December 31, 2011. The Company recognized interest expense related to the outstanding borrowings under the Credit Facility for the years ended December 31, 2011 and 2010 of $48,000 and $0, respectively. As of December 31, 2011 there was a balance outstanding under the Credit Facility of $2,523,000 (see Note 14), including accrued interest of $48,000, and there was no balance outstanding at December 31, 2010.

NOTE 6 CAPITAL TRANSACTIONS

2010 Private Placement of Common Stock. On June 15, 2010, the Company entered into a stock purchase agreement (the 2010 Stock Purchase Agreement) with 20 investors (the 2010 PIPE Investors) pursuant to which the 2010 PIPE Investors agreed to purchase an aggregate of 4,978,000 shares of Common Stock (the PIPE Shares) at a price of $1.00 per share for aggregate consideration of $4,978,000. Among the 2010 PIPE Investors who purchased a portion of the PIPE Shares were Hsu Gamma Investments, L.P. (Hsu Gamma), an entity of which Dr. Jane Hsiao, the Company s Chairman of the Board, is general partner, Frost Gamma, as well as Grandtime Associates Limited (Grandtime), a Taiwan-based investment company. Each of Hsu Gamma, Frost Gamma and Grandtime purchased 1,300,000 PIPE Shares. The Company issued the PIPE Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the Securities Act), and Rule 506 of Regulation D promulgated thereunder.

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10.0% Series A Cumulative Convertible Preferred Stock. In June 2009, the Company authorized a new series of preferred stock, designated as 10.0% Series A Cumulative Convertible Preferred Stock, par value $0.01 per share (Series A Preferred Stock). Holders of the Series A Preferred Stock are entitled to receive, when, as and if declared by the Company s Board of Directors, dividends on each share of Series A Preferred Stock at a rate per annum equal to 10.0% of the sum of (a) $1.00, plus (b) any and all declared and unpaid and accrued dividends thereon, subject to adjustment for any stock split, combination, recapitalization or other similar corporate action (the Liquidation Amount). Holders of the Series A Preferred Stock also have the right to receive notice of any meeting of holders of Common Stock or Series A Preferred Stock and to vote (on an as-converted into Common Stock basis) upon any matter submitted to a vote of the holders of Common Stock or Series A Preferred Stock. With respect to dividend distributions and distributions upon liquidation, winding up or dissolution of the Company, the Series A Preferred Stock ranks senior to all classes of Common Stock and to each other class of the Company s capital stock existing now or hereafter created that are not specifically designated as ranking senior to or *pari passu* with the Series A Preferred Stock. The Company may not issue any capital stock that is senior to or *pari passu* with the Series A Preferred Stock unless such issuance is approved by the holders of at least 66 2/3% of the issued and outstanding Series A Preferred Stock voting separately as a class.

Upon the occurrence of a Liquidation Event (as defined in the Series A Preferred Stock s Certificate of Designation, which is referred to as the Certificate of Designation), holders of Series A Preferred Stock are entitled to be paid, subject to applicable law, out of the assets of the Company available for distribution to its stockholders, an amount in cash (the Liquidation Payment) for each share of Series A Preferred Stock equal to the greater of (x) the Liquidation Amount for each share of Series A Preferred Stock outstanding, or (y) the amount for each share of Series A Preferred Stock the holders would be entitled to receive pursuant to the Liquidation Event if all of the shares of Series A Preferred Stock had been converted into Common Stock as of the date immediately prior to the date fixed for determination of stockholders entitled to receive a distribution in such Liquidation Event. Such Liquidation Payment will be paid before any cash distribution will be made or any other assets distributed in respect of any class of securities junior to the Series A Preferred Stock, including, without limitation, Common Stock. The holder of any share of Series A Preferred Stock may at any time and from time to time convert such share into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the share by (B) the conversion price, which was initially $1.00, subject to adjustment as provided in the Certificate of Designation. To the extent it is lawfully able to do so, the Company may redeem all of the then outstanding shares of Series A Preferred Stock by paying in cash an amount per share equal to $1.00 plus all declared or accrued unpaid dividends on such shares, subject to adjustment for any stock dividends or distributions, splits, subdivisions, combinations, reclassifications, stock issuances or similar events with respect to the Common Stock.

2009 Issuance of Series A Preferred Stock. On July 21, 2009, the Company entered into a securities purchase agreement with a private investor (the 2009 Investor), pursuant to which the 2009 Investor agreed to purchase an aggregate of up to 2,000,000 shares (the 2009 Shares) of the Series A Preferred Stock at a purchase price of $1.00 per share. On July 22, 2009, the Company closed on the issuance of the 2009 Shares for aggregate consideration of $2.0 million. A portion of the proceeds from the issuance was used to repay all principal and interest outstanding under the Credit Facility.

2010 Issuance of Series A Preferred Stock. On July 21, 2009, the Company entered into a second securities purchase agreement (the Future Purchase Agreement) with certain private investors (the Future Investors, together with the 2009 Investor, the Preferred Investors), pursuant to which the Future Investors agreed to purchase, at the Company s election upon ten days written notice delivered to the Future Investors by the Company, an aggregate of up to 2,000,000 shares of Series A Preferred Stock (the Future Shares, together with the 2009 Shares, the Preferred Shares) at a purchase price of $1.00 per share. On December 30, 2009, the Company provided notice to the Future Investors that the Company intended to consummate the sale of the Future Shares on January 12, 2010, and on January 12, 2010, the Company closed on the issuance of 2,000,000 Future Shares under the Future Purchase Agreement for aggregate consideration of $2.0 million. Among the Future Investors who purchased an aggregate of 995,000 Future Shares were Hsu Gamma, Frost Gamma and Mr. Spragens, each of whom is the beneficial owner of more than 10% of the Common Stock.

The Company issued the Preferred Shares in reliance upon the exemption from registration under Section 4(2) of the Securities Act. On July 22, 2009 and January 12, 2010, the closing prices of the Common Stock on the OTCBB were $1.10 and $1.25, respectively, resulting in beneficial conversion features of $0.10 and $0.25 per share of Series A Preferred Stock on the respective issue dates. The $200,000 and $500,000 aggregate beneficial conversion features of the Series A Preferred Stock on the issue dates were deemed discounts on the issuance of the Preferred Shares and were recorded as increases to additional paid-in capital in the consolidated financial statements. Because the Series A Preferred Stock was immediately convertible by the holders thereof into Common Stock, the $200,000 and $500,000 aggregate intrinsic value was deemed a dividend paid to the Preferred Investors on the relevant closing date. In the absence of retained earnings, such deemed dividends were recorded as reductions of additional paid-in capital and, for calculating net loss per common share, as increases in losses attributable to common stockholders (see Note 7).

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2010 Conversion of Series A Preferred Stock. Effective September 10, 2010 (the Conversion Date), the Preferred Investors elected to convert an aggregate of 4.0 million shares of the Series A Preferred Stock pursuant to the terms of the Certificate of Designation. Following conversion of the Series A Preferred Stock, the Company had no issued and outstanding shares of any class of preferred stock. On the Conversion Date, for each converted share of Series A Preferred Stock, the holder thereof became entitled to receive one share of Common Stock, plus all accrued and unpaid dividends (Unpaid Dividends) thereon through the Conversion Date, which Unpaid Dividends were paid in shares of Common Stock in accordance with the Certificate of Designation. Approximately $366,000 of Unpaid Dividends had accumulated through the Conversion Date and an aggregate of 365,575 shares of Common Stock were issued as a result of the Unpaid Dividends (the Dividend Shares), of which 29,709 Dividend Shares were issued to each of Hsu Gamma and Frost Gamma, and 6,638 Dividend Shares were issued to Mr. Spragens.

To encourage the Preferred Investors to voluntarily convert their respective shares of Series A Preferred Stock, the Company offered to each Preferred Investor who converted his or her shares of Series A Preferred Stock on or prior to the Conversion Date the number of shares of Common Stock (the Consideration Shares) equal to the difference between (a) the number of shares of Common Stock issuable pursuant to a holder-initiated conversion of Series A Preferred Stock on March 31, 2012 and (b) the number of shares of Common Stock issuable pursuant to a holder-initiated conversion of Series A Preferred Stock on the Conversion Date, each as calculated in accordance with the Certificate of Designation. The Preferred Investors voluntarily elected to convert all of their respective shares of Series A Preferred Stock, and an aggregate of 697,462 Consideration Shares were issued, of which 76,261 Consideration Shares were issued to each of Hsu Gamma and Frost Gamma, and 17,042 Consideration Shares were issued to Mr. Spragens.

On September 10, 2010, the closing price of the Common Stock on the OTCBB was $1.85, resulting in an intrinsic value of $0.85 per share for the 4,000,000 shares of Common Stock issued upon conversion of the Series A Preferred Stock and the 365,575 shares of Common Stock issued as Dividend Shares. These 4,365,575 shares of Common Stock had an aggregate intrinsic value of $3.7 million on the Conversion Date, which was considered a deemed dividend. The 697,462 Consideration Shares issued on the Conversion Date had an aggregate market value of approximately $1.3 million, which was also considered a deemed dividend on the Conversion Date. In the absence of retained earnings, the $366,000 accumulated dividends and the $5.0 million aggregate deemed dividends were recorded as reductions of additional paid-in capital and, for calculating net loss per common share, as increases in losses attributable to common stockholders (see Note 7).

NOTE 7 BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss attributable to common stockholders 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 and conversion of preferred stock. In computing diluted net loss per share for the years ended December 31, 2011 and 2010, no adjustment has been made to the weighted average outstanding common shares as the assumed exercise of outstanding options and warrants and conversion of preferred stock would be anti-dilutive.

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

	December 31, 2011	December 31, 2010
Stock options	1,628,167	1,334,667
Stock warrants	805,521	805,521
Series A Preferred Stock	0	0
Total	**2,433,688**	**2,140,188**

Under applicable SEC accounting guidance, the difference between (a) the fair value of the consideration transferred to the Preferred Investors upon conversion of the Series A Preferred Stock and (b) the carrying amount of the Series A Preferred Stock on the Company s balance sheet is required to be added to the Company s net loss to arrive at loss available to common stockholders in the calculation of loss per share. As discussed in Note 6 above, during the year ended December 31, 2010, the Preferred Investors received an aggregate dividend of $5.4 million, consisting of $0.4 million accumulated dividends and $5.0 million aggregate deemed dividends. This $5.4 million aggregate dividend was recorded as a $4.4 million increase in losses attributable to common stockholders on the Conversion Date, after giving effect to the $0.7 million beneficial conversion feature and $0.3 million cumulative dividends recorded as increases in losses attributable to common stockholders in prior periods.

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NOTE 8 COMMITMENTS AND CONTINGENCIES

The Company is obligated under various operating lease agreements for office space expiring in 2012. 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 $199,000 and $164,000 for the years ended December 31, 2011 and 2010, respectively. At December 31, 2011, the Company was obligated under non-cancellable operating leases to make future minimum lease payments (excluding sales taxes) as follows:

Year Ending December 31,	
2012	$ 217,000
	$217,000

The Company is obligated to pay royalties to Creighton University (Creighton) on the sales of products licensed from Creighton pursuant to an exclusive license and development agreement (see Note 9). The Company is also obligated under an agreement with Dr. Parviz Amid to pay a 4% royalty to Dr. Amid on the net sales of any product developed with Dr. Amid s assistance, including the AMID Stapler®, for a period of ten years from the first commercial sale of such product. No royalties were incurred for, or paid during the years ended December 31, 2011 and 2010.

The Company has placed orders with various suppliers for the purchase of certain tooling, inventory and contract engineering and research services. Each of these orders has a duration or expected completion within the next twelve months. The Company currently has no material commitments with terms beyond twelve months.

NOTE 9 AGREEMENT WITH CREIGHTON UNIVERSITY

On May 26, 2006, SafeStitch entered into an exclusive license and development agreement (the Creighton Agreement) with 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 Creighton 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 Creighton Agreement, less certain amounts including, without limitation, chargebacks, credits, taxes, duties and discounts or rebates. Also pursuant to the Creighton Agreement, the Company 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 excluded the first $150,000 of costs related to the prosecution of patents, which the Company invested outside of the Creighton 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. For the years ended December 31, 2011 and 2010, the Company paid Creighton $45,000 and $52,000, respectively, in satisfaction of the 20% facility reimbursement obligation.

Pursuant to the Creighton 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 Creighton 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.

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NOTE 10 INCOME TAXES

The Company accounts for income taxes using the asset and liability method, the objective of which is to establish deferred tax assets and liabilities for the temporary differences between the financial reporting and the tax bases of the Company s assets and liabilities at enacted tax rates expected to be in effect when such amounts are realized or settled. A valuation allowance related to deferred tax assets is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

At December 31, 2011, we have approximately $ 11.8 million of federal net operating loss carryforwards to offset future taxable income and $7.0 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, 2011 we have approximately $476,000 of research and development tax credit carryforwards. The net operating loss and research and development credit carryforwards expire through 2031.

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:

	December 31, 2011	December 31, 2010
Income tax benefit at the federal statutory rate	34.00%	34.00%
State income taxes, net of effect on federal taxes	3.51%	3.49%
Research and development credit	2.84%	2.71%
Other	0.56%	0.25%
Increase in valuation allowance	(40.91%)	(40.45%)
Provision for income tax	0%	0%

The deferred tax asset at December 31, 2011 and 2010 consists of the following:

	2011	2010
Net operating loss carryforward	$ 4,419,000	$ 3,121,000
Deferred start up costs	2,658,000	1,916,000
Research and development credit carryforward	477,000	290,000
Stock-based compensation	520,000	394,000
Other	(13,000)	(16,000)
	8,061,000	5,705,000
Less: Valuation allowance	(8,061,000)	(5,705,000)
Net deferred tax asset	$	$

The change in the valuation allowance from December 31, 2010 to December 31, 2011 amounted to approximately $2,356,000. 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.

The Company recognizes interest and penalties related to uncertain tax positions in general and administrative expense. As of December 31, 2011, the Company has no unrecognized tax position, including interest and penalties.

The tax years 2008-2010 remain open to examination by the major tax jurisdictions in which the Company operates.

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NOTE 11 CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In connection with the acquisition of SafeStitch LLC, the Company entered into the Credit Facility with 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, 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. As of December 31, 2011 there was balance outstanding under the Credit Facility of $2,523,000, including $48,000 of accrued interest, and there was no balance outstanding at December 31, 2010 (See Note 5).

The Company entered into a five-year lease for office space in Miami, Florida with a company controlled by Dr. Frost. The non-cancelable lease, which commenced January 1, 2008, provides for a 4.5% annual rent increase over the life of the lease. The Miami office lease was amended in July 2011 to include additional office space in the same building, and current rental payments under the lease are approximately $19,000 per month. The Company recorded $199,000 and $127,000 of rent expense related to the Miami lease for the years ended December 31, 2011 and 2010, respectively.

Dr. Hsiao, Dr. Frost and director Steven Rubin are each significant stockholders and/or directors of Non-Invasive Monitoring Systems, Inc. (NIMS), a publicly-traded medical device company, Aero Pharmaceuticals, Inc. (Aero), a privately-held pharmaceutical distribution company that dissolved in December 2011, Tiger X Medical, Inc. (Tiger X) (formerly known as Cardo Medical, Inc.), a publicly-traded medical device company, and SearchMedia Holdings Limited (SearchMedia), a publicly-traded media company operating primarily in China, and Sorrento Therapeutics, Inc. (Sorrento), a publicly-traded development stage biopharmaceutical company. Director Richard Pfenniger is also a shareholder of NIMS. The Company s Chief Financial Officer also serves as the Chief Financial Officer and supervises the accounting staffs of NIMS and, until its dissolution, Aero, under a Board-approved cost sharing arrangement whereby the total salaries of the accounting staffs of the three companies are shared. Aero has not participated in the cost sharing arrangement since June 30, 2011 and was dissolved in December 2011. Since December 2009, the Company s Chief Legal Officer has served under a similar Board-approved cost sharing arrangement as Corporate Counsel of SearchMedia and as the Chief Legal Officer of each of NIMS and Tiger X, and since June 2011, as Corporate Counsel for Sorrento. The Company has recorded reductions to SG&A costs and expenses for the years ended December 31, 2011 and 2010 of $78,000 and $114,000, respectively, to account for the sharing of accounting costs under this arrangement. The Company has recorded $178,000 and $186,000 of reductions to SG&A costs and expenses for the year ended December 31, 2011 and 2010, respectively, to account for the sharing of legal costs under this arrangement. Aggregate accounts receivable from NIMS, Tiger X, Sorrento and SearchMedia were approximately $66,000 as of December 31, 2011 and are included in other receivable related party.

NOTE 12 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 $39,000 and $39,000, respectively, for the years ended December 31, 2011 and 2010.

NOTE 13 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 banks and financial institutions it considers to be of high credit quality; however the Company s cash deposits may at times exceed the FDIC insured limit. The Company s deposits at banks in excess of the FDIC insured limit are maintained in sweep accounts that are collateralized by overnight repurchase agreements. The Company has not experienced losses on these accounts, and management believes that the Company is not exposed to significant risks on such accounts.

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NOTE 14 SUBSEQUENT EVENTS

In February 2012, the Company granted to directors, officers, existing employees and consultants an aggregate of 813,500 options to purchase the Company s common stock under the 2007 Plan. The options were granted at exercise prices of $0.65 and $0.85 per share.

On February 17, 2012, the Company entered into a stock purchase agreement (the 2012 Stock Purchase Agreement) with 35 investors (the Investors) pursuant to which the Investors agreed to purchase an aggregate of 20,794,000 shares of Common Stock (the Shares), at a price of $0.40 per share, with net proceeds to the Company of $8.3 million. A portion of the proceeds was used to pay off $3.1 million outstanding under the Credit Facility, and the balance of the proceeds will be used for continued research, development and commercialization of the Company s products and product candidates. Among the Investors purchasing Shares were Frost Gamma, Dr. Jane Hsiao, the Company s Chairman of the Board, Jeffrey Spragens, the Company s President and Chief Executive Officer and Richard Pfenniger, a member of the Company s Board of Directors. Frost Gamma and Dr. Hsiao each purchased 4,500,000 shares, Mr. Spragens purchased 250,000 shares, and Mr. Pfenniger purchased 125,000 shares.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures.
Disclosure 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, 2011. 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.

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, 2011, 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, 2011, 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

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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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011.

Item 11. Executive Compensation.
The information required by this Item is incorporated by reference to the definitive proxy statement for our 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011.

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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011.

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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011.

Item 14. Principal Accounting Fees and Services.
The information required by this Item is incorporated by reference to the definitive proxy statement for our 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2011.

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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 29, 2008 and incorporated by reference herein.
3.3	Certificate of Designation of Series A Preferred Stock, filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 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 29, 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.
4.3	Specimen Certificate for Series A Preferred Stock, filed as Exhibit 4.2 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 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, 2007, by and among the Company, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on September 10, 2007 and incorporated by reference herein.
10.3	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 29, 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.

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Exhibits:

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	First 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, filed as Exhibit 10.8 to our Annual Report on Form 10-K filed with the SEC on March 27, 2009 and incorporated by reference herein.
10.9	Form of Current Securities Purchase Agreement, filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
10.10	Form of Future Securities Purchase Agreement, filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on July 23, 2009 and incorporated by reference herein.
10.11	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.
10.12+	Form of Employee Stock Option Agreement pursuant to the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, filed as Exhibit 10.12 to our Annual Report on Form 10-K filed with the SEC on March 31, 2010 and incorporated by reference herein.
10.13+	Form of Non-Employee Stock Option Agreement pursuant to the SafeStitch Medical, Inc. 2007 Incentive Compensation Plan, filed as Exhibit 10.13 to our Annual Report on Form 10-K filed with the SEC on March 31, 2010 and incorporated by reference herein.
10.14	Second Amendment to Note and Security Agreement, dated March 29, 2010, by and among the Company, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.14 to our Annual Report on Form 10-K filed with the SEC on March 31, 2010 and incorporated by reference herein.
10.15	Stock Purchase Agreement, dated as of June 15, 2010, by and between SafeStitch Medical, Inc. and the purchasers party thereto, filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 17, 2010 and incorporated by reference herein.
10.16	Confidential General Release of All Claims, dated November 24, 2010, by and between Stewart Davis and SafeStitch Medical, Inc., filed as Exhibit 10.1 to our Current Report on Form 8-K filed on December 1, 2010 and incorporated by reference herein.
10.17	Consulting Agreement, dated November 24, 2010 and effective November 12, 2010, by and between Stewart Davis and SafeStitch Medical, Inc., filed as Exhibit 10.2 to our Current Report on Form 8-K filed on December 1, 2010 and incorporated by reference herein.
10.18	Confidential General Release of All Claims, dated January 14, 2011, by and between Adam Jackson and SafeStitch Medical, Inc., filed as Exhibit 10.1 to our Current Report on Form 8-K filed on January 14, 2011 and incorporated by reference herein.
10.19	Consulting Agreement, effective January 10, 2011, by and between Adam Jackson and SafeStitch Medical, Inc., filed as Exhibit 10.2 to our Current Report on Form 8-K filed on January 14, 2011 and incorporated by reference herein.
10.20	Third Amendment to Note and Security Agreement, dated March 28, 2011, by and among the Company, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.20 to our Annual Report on Form 10-K filed with the SEC on March 30, 2011 and incorporated by reference herein.

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Exhibits:

10.21	Fourth Amendment to Note and Security Agreement, dated August 10, 2011, by and among the Company, SafeStitch LLC, The Frost Group, LLC and Jeffrey G. Spragens, filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on August 12, 2011.
10.22	Form of Stock Purchase Agreement dated February 17, 2012, filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 21, 2012 and incorporated by reference herein.
14.1	Code of Ethics Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002 filed as Exhibit 14.1 to our Annual Report on Form 10-K filed with the SEC on March 31, 2010 and incorporated by reference herein.
21.1*	Subsidiaries of the Registrant
23.1*	Consent of EisnerAmper LLP
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
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document**
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document**
101.LAB	XBRL Taxonomy Extension Label Linkbase Document**
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document**

* Filed herewith

** Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Act of 1934 and otherwise not subject to liability.

\+ Compensation Plan or Arrangement or Management Contract

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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 30, 2012

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, President and Director (Principal Executive Officer)	March 30, 2012
/s/ Jane H. Hsiao, Ph.D. Jane H. Hsiao, Ph.D.	Chairman of the Board of Directors	March 30, 2012
/s/ Dr. Charles J. Filipi Dr. Charles J. Filipi	Chief Medical Officer and Director	March 30, 2012
/s/ Dr. Chao C. Chen Dr. Chao C. Chen	Director	March 30, 2012
/s/ Steven D. Rubin Steven D. Rubin	Director	March 30, 2012
/s/ Richard C. Pfenniger, Jr. Richard C. Pfenniger, Jr.	Director	March 30, 2012
/s/ Kevin T. Wayne Kevin T. Wayne	Director	March 30, 2012
/s/ James J. Martin James J. Martin	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2012