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SafeStitch Medical, Inc. Is Well Positioned For Future Growth With The Recent Commercialization Of Their AMID Stapler For Inguinal Hernia Surgery And Their Trans-Oral Endoscopic Device For Delivering Medical Tools During Surgery For The Outpatient Treatment Of GERD And Obesity Ready To Enter The FDA Approval Process

**Healthcare
Medical Instruments & Supplies
(SFES-OTC: BB)**

**SafeStitch Medical, Inc./
SafeStitch, LLC**

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1987 to 1993, he was one of three founding board of directors members of North American Vaccine which was a public company acquired by Baxter International in 1999. Mr. Spragens also has previous experience as a developer and attorney.

**Stewart Davis, M.D.
Chief Operating Officer**

Dr. Davis has served as SafeStitch's Chief Operating Officer since June 2007. Prior to that and from July 2003, Dr. Davis was Assistant Medical Director for

and percutaneous heart valves. Since 2006, he has also been managing partner and medical director of Parasol International, LLC, a privately-owned global healthcare advisory firm. Dr. Davis has approximately ten peer-reviewed articles and three NIH grants and has published a book. Dr. Davis graduated from the University of Miami School of Medicine in 2003.

Company Profile:

SafeStitch Medical, Inc., a developmental stage medical device company, focuses on the development and sale of medical devices. The company offers 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. Its products include the AMID Stapler™, which is specifically designed for the repair of inguinal (groin) and ventral (abdominal) hernias; the SMART Dilator™, which is used to treat the narrowing of the esophagus; and standard and airway bite blocks, which are used to protect

Executive Bios:

**Jeffrey G. Spragens
Chief Executive Officer and
President**

Mr. Spragens has served as SafeStitch's President and Chief Executive Officer and as a member of our Board of Directors since September 2007, and 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, Mr. Spragens 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



Innovia LLC, a privately-held bio medical device company in Miami, Florida, and its affiliates, including InnFocus LLC, InnoGraft LLC and InnCardia LLC. Innovia and its affiliates design implantable medical devices focusing on ophthalmology implants, vascular grafts

endoscopes and other instruments used in trans-oral gastrointestinal procedures. SafeStitch Medical product candidates include intraluminal gastroplasty device for obesity and GERD; and the Barrett's excision and ablation device for the

treatment and diagnosis of Barrett's esophagus. Its product candidates also include devices for Natural Orifice Trans-luminal Endoscopic Surgery, a method of operating in the abdominal cavity without making an incision in the abdominal wall; and a T fastener gun, which delivers small metal fasteners at the end of an endoscope. The company was founded in 2005 and is based in Miami, Florida.

**Interview conducted by:
Lynn Fosse, Senior Editor**

CEO CFO: Mr. Spragens, what was the vision when you founded SafeStitch Medical and where are you today?

Mr. Spragens: We founded the company in August of 2005, with Dr. Phillip Frost, Dr. Jane Hsiao and Dr. Charles Filipi. The vision of the company was to develop an affordable medical device for the safe, efficacious and durable trans-oral outpatient treatment of GERD and Obesity.

CEO CFO: Why the decision to look at those areas?

Mr. Spragens: One of the reasons we decided to look at Gastro Esophageal Reflux Disorder, (GERD) and obesity was because Dr. Filipi had been involved in those areas for at least fifteen years prior to August of 2005. These earlier attempts centered around trying to put some instruments on the tip of an endoscope to manipulate tissue in the esophagus and in the stomach. All of those efforts were coming up short, and Dr. Filipi called me and said, "I think I know why they are not working. We are trying to do too much with too little". So the vision of SafeStitch was to safely deliver, trans-orally, through the esophagus, the medical tools needed, which in our experience are excision, suture, injection, and suction capabilities, as-well-as visualization with an endoscope. These tools have to be part of the package and are critical to perform effective surgery, and do it through the mouth.

CEO CFO: Where are you in the development process?

Mr. Spragens: We will be doing our first surgeries with our device in the next sev-

eral weeks. We have our first in-human surgery; and that will be abroad. We have pre-IDE applications pending for clinical trials in the U.S. to use our devices both for GERD and Obesity. We anticipate that those FDA trials will start late this year.

CEO CFO: Would you explain more about what happens with the GERD products?

Dr. Davis: Our plan is not creating a new procedure, but to do a procedure that is currently being done, either open or laparoscopically, with our instrumentation. So we are developing the instrumentation to enable it to be done trans-orally, which means through the mouth. It doesn't have any outside incisions. We

The AMID Stapler has a big need. There are approximately a million inguinal hernias done a year and at least 600,000 to 700,000 of them are good candidates to use our AMID Stapler. Using our stapler instead of the traditional hand suturing can potentially lead to a faster, safer procedure with significantly less post-operative pain in the first weeks after the surgery. Secondly, we believe our product for Obesity and GERD is going to be an outstanding product. It certainly will bring another tool to doctors fighting this Obesity and GERD epidemic.

- Jeffrey G. Spragens

are going down the esophagus and creating a gastroplasty, which is the manipulating of tissue. For GERD, we go down and tighten up the area around the gastric esophageal junction. What has happened in most patients that have reflux disorder is the lower esophageal sphincter loosens up and causes acid to reflux up. So, in layman's terms we are going down and tightening things up. It is more complicated than that, but that is the simple way to put it. For obesity we go down and create something similar to the gastric bands (lap bands). What we do with our device is to create an internal band using a patient's own anatomy as opposed to putting an implant in. We create that same type of restrictive procedure that is created in a gastric band procedure.

CEO CFO: Has the medical community been actively looking for solutions in this area?

Dr. Davis: They are actively looking. Most patients that suffer from morbid obesity really are poor candidates for traditional obesity procedures whether that is a gastric bypass or a lap band procedure. This is because of all of their comorbidities. People that are overweight are more of a risk of having trouble during the surgery. So many doctors are reluctant to operate on them because of the chances of having other problems during the procedure that have nothing to do with the actual obesity procedure. Doctors are after something that is less invasive, so they can operate on patients that wouldn't otherwise be candidates for surgery.

CEO CFO: Is there much competition in developing new methods?

Dr. Davis: There is definitely a decent amount of competition out there. I think many companies realize that not enough people are getting treated for obesity, so they really need it to be less invasive. However, there are a few companies that have devices that have been able to enable procedures like this. So far, they have not achieved the durability that we expect with our device.

Mr. Spragens: We think that we bring a little more focus and ability to do the complete

procedure with our device and with a lot of our intellectual property. The main point is that there couldn't be enough companies working on this problem. The fact is in the United States we are looking at an obesity problem that is approaching 27%, so almost 30% of the population are candidates for this procedure. The American Diabetes Foundation has recently concluded after a long study that the only effective way to counter the onset of type II diabetes brought about by obesity is bariatric surgery of some kind. They went through all the other weight-loss methods in their study and the only one that has been effective to counter the epidemic of type II diabetes is bariatric surgery. The market is so large that it needs to be attacked by as many people as possible. Studies are now showing that for the first time since these records have

been kept today's children are not projected to live as long as their parents. This is really a significant change in our future when we are saying that for the first time that children are not going to live as long as their parents.

Dr. Davis: Yes exactly. Worldwide obesity has the highest cost of any disease in society, because of the general diseases related to obesity and then all of the spectrum of diseases that it causes, whether it is type II diabetes or coronary artery disease, high blood pressure, high cholesterol are all related to obesity. The cost to society is extremely high. Therefore, more and more patients are going to need these types of procedures to better their overall health. In some cases, patients may be a candidate for one and not the other. So competition is going to create multiple opportunities, which is good. Our biggest plus in the population and what the community feels about our procedure is that we may have the procedure that is the most durable of the available procedures out there.

Mr. Spragens: Durability has been one of the failings of the other products that are trying to come on to the market. We feel that we have solved that problem. Since August of 2005, durability was a prime focus because Dr. Filipi stated that the work he had been involved in with other companies, had failed because of durability. I would like to reiterate some of Dr. Davis' points about the need for more and better products to combat obesity. I have a report on the 'Fattest Countries in the World', and the United States is third. Number one is Samoa, followed by China. Recently a study in China reported the obesity rate was in the high 20% range, and lap band companies are applying for approval and clearance to start selling there. We certainly will be looking to that market and the wide market.

CEOCFO: Speaking of the market, what is the timetable on eventual commercialization?

Mr. Spragens: The commercialization will come in several phases. There are two indications that we are looking at for first approval, one for treatment of GERD, and one for treatment of Obesity. We anticipate that commercialization within the United States will begin somewhere in the middle of late 2012 or early 2013. In Europe and the rest of the world, it should be a year earlier than that.

CEOCFO: Are you going to do this alone or bringing in a partner; what is your business strategy?

Mr. Spragens: At the moment, we are moving forward by ourselves. Our first product, the AMID Stapler™ for inguinal hernia repair was cleared by the FDA late

Our plan is not creating a new procedure, but to do a procedure that is currently being done, either open or laparoscopically, with our instrumentation. So we are developing the instrumentation to enable it to be done trans-orally, which means through the mouth. It doesn't have any outside incisions. We are going down the esophagus and creating a gastroplasty, which is the manipulating of tissue. For GERD, we go down and tighten up the area around the gastric esophageal junction... For obesity we go down and create something similar to the gastric bands (lap bands). What we do with our device is to create an internal band using a patient's own anatomy as opposed to putting an implant in. - Stewart Davis, M.D.

last year and received CE Mark early this year. We have started shipping the AMID Stapler to doctors around the country. To back that up we have built a sales force led by Caron D'Ambruso, who is our Vice President of Sales and Marketing and by JC Campbell, who is our National Sales Manager. We have hired and trained eight experienced medical device sales people, two in California, one in Texas, one in Atlanta, one in Florida, one out of the New York area, one out of the Boston area, and one in the Chicago area. So we have already developed a sales team to sell the AMID Stapler this year, and that sales force can start moving into the GERD and Obesity device markets as the indications for use of our GERD and obesity devices should be ready for com-

mmercialization in early 2013. As a general use indication for fixation and excisions, the devices may be cleared and ready within the next nine months. Dr. Davis will run through the list of general use for the devices.

CEOCFO: Do you anticipate quick adoption of the later devices by the medical community?

Mr. Spragens: Well, the real strategy and reason is that we have been actually pushed by the medical community to get these devices out to use by doctors.

Dr. Davis: Doctors have been clamoring for these devices, so the approach is to bring devices out as a general indication for excision and fixation trans-orally

through the esophagus; then later on for GERD and Obesity. With the current indications, the reason they are clamoring for these products is you have a lot of patients undergoing obesity procedures that need to have these procedures revised. There are thousands of those happening every year, and our instruments will enable them to revise these procedures more easily and in an expeditious manner. Then there are a handful of other applications for our devices including repairs of fistulas throughout the GI Tract, whether it is esophageal, gastric fistulas, small intestine or large intestine fistulas. They

will also use them in excising polyps throughout different parts of the gastrointestinal tract, closing up gastrostomy holes for different procedures, taking care of the different bleeders in gastrointestinal bleeding disorders and also acute gastrointestinal bleeds. So, there is a large list of other uses for this device and general uses that would not require reflux disorder or obesity indications from the FDA. That is our double pathway. We hope to be cleared for these general indications by the end of this year.

CEOCFO: Development is always expensive; what is the financial picture for SafeStitch today?

Mr. Spragens: We just successfully completed a \$5 million PIPE that closed in June 2010 and we have cash of about \$6 million, which is sufficient to get us into the trials. Furthermore, we have access to a \$4 million line of credit and we may pursue additional financing activities in 2011 to complete the financing necessary to fund trials for the GERD and Obesity indications. We are in the process of applying to the NYSE/AMEX for listing on their exchange; we are listed on the bulletin board stock exchange (OB: SFES) today. We look forward to having a listing on one of the major exchanges so that more investors and institutions can follow us.

CEOCFO: So the investment community is starting to pay attention?

Mr. Spragens: Exactly!

CEOCFO: Why should potential investors pay attention to SafeStitch?

Mr. Spragens: Number one, we have an exciting product in the AMID Stapler that has gone through a several million dollar development, and the launching of an impressive sales force. We have completed the successful manufacturing of the first large lot of this product. The AMID Stapler has a big need. There are approximately a million inguinal hernias done a year and at least 600,000 to 700,000 of them are good candidates to use our AMID Stapler. Using our stapler instead of the traditional hand suturing can potentially lead to a faster, safer procedure with significantly less post-operative pain in the first weeks after the surgery. Secondly, we believe our product for Obesity and GERD is going to be an outstanding product. It certainly will bring another tool to doctors fighting this Obesity and GERD epidemic. A recent study published in The Journal of Medicine has brought forth some pretty compelling evidence that the extended use of proton pump inhibitors (PPI) to treat

GERD is causing some severe problems with increased risk of fractures. People are concerned with being on a lifelong regimen of something that works aggressively in the stomach to prevent the symptoms of GERD. It doesn't prevent GERD, it just neutralizes the hydrochloric acid so one isn't necessarily feeling the impact of GERD. However, we believe that continuing to have the kind of stomach secretions coming up into the esophagus, no matter if some has been neutralized, there are still dangers to the esophagus. So that is what compelled us to come up with what we believe to be an outpatient 45-minute conscious sedation procedure for GERD. So in other words, our procedure will allow you to get off of a lifelong commitment to the PPI's based on what we have learned. In the future, you will be in the doctor's office for a couple of hours, similar to having a colonoscopy procedure.



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