

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

FORM 8-K

CURRENT REPORT

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

September 22, 2008

Date of Report (Date of earliest event reported)

SAFESTITCH MEDICAL, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State of Other Jurisdiction
of Incorporation)

0-19437
(Commission File Number)

11-2962080
(I.R.S. Employer
Identification Number)

4400 Biscayne Boulevard, Suite 670, Miami, Florida
(Address of principal executive offices)

33137
(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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

Item 7.01 Regulation FD Disclosure

The slides and additional financial information attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Presentation"), which is incorporated by reference in this Item 7.01, is initially being presented by certain members of management of SafeStitch Medical, Inc. (the "Company") on September 22, 2008 at the UBS Global Life Sciences Conference.

Additionally, attached to this Current Report on Form 8-K as Exhibit 99.2 and incorporated by reference in this Item 7.01 is a letter to stockholders, dated September 19, 2008 (the "Stockholder Letter"). The Company anticipates mailing the Stockholder Letter on or about September 26, 2008 to stockholders of record as of September 17, 2008.

The information in this report (including Exhibits 99.1 and 99.2) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act. This report shall not be deemed an admission as to the materiality of any information herein (including Exhibits 99.1 and 99.2).

Statements contained in the attached Presentation and Stockholder Letter are made pursuant to the Safe Harbor for forward-looking statements described in the Private Securities Litigation Reform Act of 1995. In these communications, the Company may make certain statements that are forward-looking, such as statements regarding the Company's future results and plans, and anticipated trends in the industry and economies in which the Company operates. These forward-looking statements are the Company's expectations on the date of the Presentation and the Stockholder Letter, respectively, and the Company will make no efforts to update these expectations based on subsequent events or knowledge. These forward-looking statements are based on the Company's current expectations and are subject to a number of risks, uncertainties and assumptions, including that the Company's revenue may differ from that projected; that the Company may be further impacted by slowdowns, postponements or cancellations in the Company's clients' businesses, or deterioration in the financial condition of the Company's clients; that the Company's targeted service markets may not expand as the Company expects; that the Company may experience delays in the awarding of customer contracts; that the Company's reserves and allowances may be inadequate, or the carrying value of the Company's assets may be impaired; that the Company may experience increased costs associated with realigning the Company's business, or may be unsuccessful in those efforts and any of the other risks in the Company's Annual Report on Form 10-KSB, as amended, for the year ended December 31, 2007. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from the results expressed or implied in any forward-looking statements made by the Company in these communications. These and other risks, uncertainties and assumptions are detailed in documents filed by the Company with the Securities and Exchange Commission. The Company does not undertake any obligation to revise these forward-looking statements to reflect future events or circumstances.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation materials.
99.2	Letter to Stockholders dated September 19, 2008

SIGNATURES

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

SAFESTITCH MEDICAL, INC.

By: /s/ Adam S. Jackson
Name: Adam S. Jackson
Title: Chief Financial Officer

Date: September 22, 2008

Exhibit Index

Exhibit Number

Description

99.1	Presentation materials.
99.2	Letter to Stockholders dated September 19, 2008

SAFESTITCH

MEDICAL

Where Safety Meets Innovation

Endoscopic and Minimally Invasive Surgical Devices

www.SafeStitch.com

OTCBB: SFES

Safe Harbor Statement

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

Founded in 2005

- ▶ **Charles J. Filipi M.D.**
 - Multiple commercially successful medical devices
- ▶ **Phillip Frost M.D.**
 - Former Chairman and CEO of IVAX; Chairman, CEO and President of Opko Health; The Frost Group
- ▶ **Jane Hsiao Ph.D.**
 - Former Vice-Chairman of IVAX; Vice Chairman and CTO of Opko Health; The Frost Group
- ▶ **Jeffrey G. Spragens**
 - Co-founder and Director of North American Vaccine

Big Markets

- ▶ Obesity
- ▶ GastroEsophageal Reflux Disorder (GERD)
- ▶ Barrett's Esophagus
- ▶ Inguinal Hernia

Management Team

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

- Founder and Business Manager of SafeStitch LLC; Former Founder and Director of North American Vaccine Corporation; Co-Founder and Director of Foundation for Peace; Co-Founder of Mint Management and Development

▶ **Stewart B. Davis M.D. – Chief Operating Officer and Secretary**

- Chief Operating Officer of SafeStitch LLC; Managing Partner and Medical Director of Parasol International; Former Asst. Medical Director of Innovia LLC, InnFocus LLC, InnoGraft LLC and InnCardia LLC

▶ **Adam S. Jackson – Chief Financial Officer**

- Former Senior Vice President, Finance and Senior Vice President, Controller of Levitt Corporation; Former Chief Financial Officer of Romika-USA, Inc.

▶ **Charles J. Filipi M.D. – Medical Director**

- Founder and Medical Director of SafeStitch LLC; Professor of Surgery at Creighton University School of Medicine; Former President of the American Hernia Society

▶ **Christian Martin – Director, Product Development**

- Former Vice President of Engineering Axiotec Inc., Former Principal Engineer Syntheon LLC, 17 plus years of engineering experience

▶ **Mario Arbesu – Director, Quality Assurance and Regulatory Affairs**

- Former Quality and Regulatory Consultant, Former Director Product Assurance Syntheon LLC, 13 plus years of engineering, quality and regulatory affairs experience

Board of Directors

- ▶ **Jane Hsiao Ph.D.** – Chairman of the Board
- ▶ **Jeffrey G. Spragens**
- ▶ **Charles J. Filipi M.D.**
- ▶ **Steven Rubin**
 - Executive Vice President of Opko Health, The Frost Group, Former Senior Vice President, General Counsel and Secretary of IVAX
- ▶ **Richard Pfenniger, Jr.**
 - CEO and President of Continucare Corporation
- ▶ **Kevin Wayne**
 - Associate Professor of Business Administration at Rivier College, Co-founder and Former Vice President of Onux Medical, Inc
- ▶ **Kenneth Heithoff M.D.**
 - Founder and Director of Center for Diagnostic Imaging

Medical Advisory Board

- ▶ **Richard Rothstein M.D.**
 - Dartmouth University; World Renowned Gastroenterologist; Expert in GERD, Barrett's Esophagus and NOTES
- ▶ **Raul Rosenthal M.D.**
 - Cleveland Clinic; World Renowned Bariatric Surgeon
- ▶ **Lee Swanstrom M.D.**
 - Oregon Clinic; World Renowned Laparoscopic and Endoscopic Surgeon; First Surgeon to perform Transoral NOTES Cholecystectomy in the US
- ▶ **Glen Lehman M.D.**
 - Indiana University; World Renowned Gastroenterologist; Expert in Endoscopic GERD Treatment and ERCP
- ▶ **Tom DeMeester M.D.**
 - University of Southern California (Chairman of Surgery); World Renowned Esophageal Surgeon; Expert in Barrett's Esophagus
- ▶ **Jeff Peters M.D.**
 - University of Rochester (Chairman of Surgery); World Renowned GERD Surgeon; Expert in Barrett's and esophageal dilation

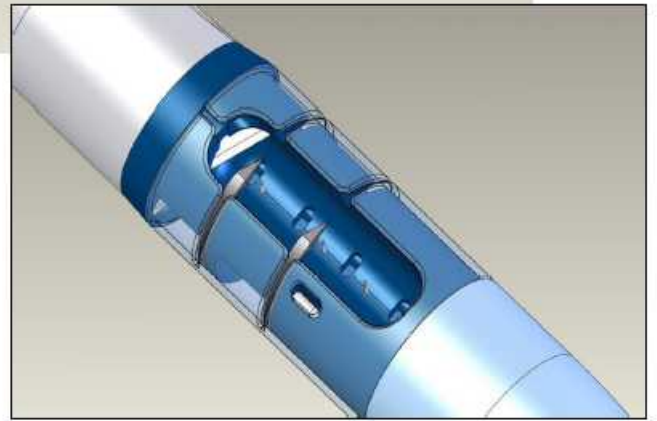
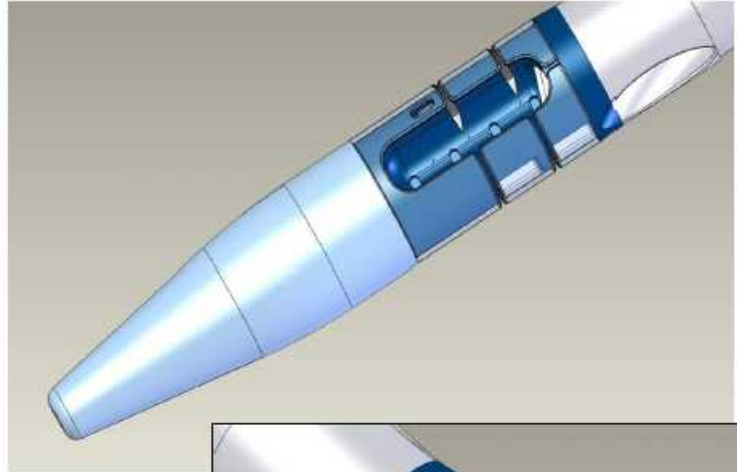
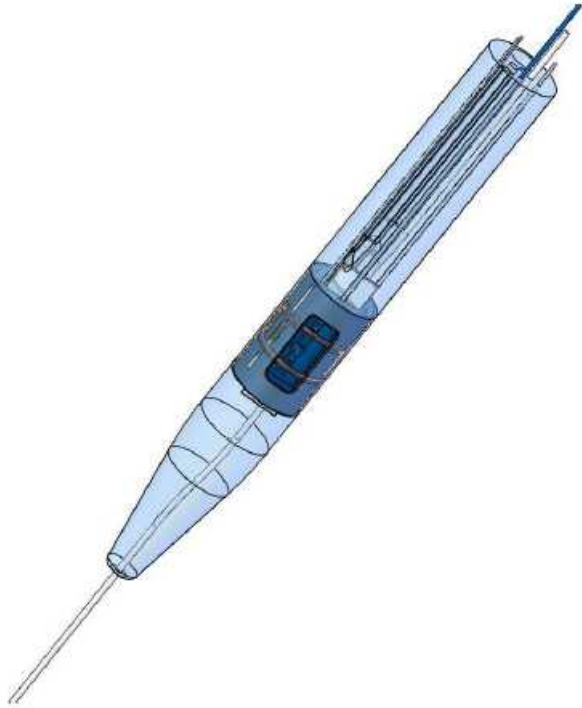
Company Highlights

- ▶ License agreement with Creighton University
- ▶ September 4, 2007 – Share exchange with Cellular Technical Services Company (OTCBB: CTSC)
- ▶ Access to \$4M Line of Credit
- ▶ January 2008 – Name Change to SafeStitch Medical, Inc. and Symbol Change to SFES
- ▶ May 2008 – Raised \$4M in a PIPE
- ▶ Strong pipeline of products
- ▶ Some products anticipated to launch in 2008, others in clinical trials in 2008 & 2009

SafeStitch Pipeline

- ▶ Intraluminal Gastroplasty Device
 - For Obesity
 - For GERD
- ▶ Barrett's Excision and Ablation Device
- ▶ Hernia Device / Novel Surgical Fasteners
- ▶ SMART Dilator
- ▶ Standard Bite Block
- ▶ Airway Bite Block
- ▶ T Fastener
- ▶ Novel Devices for Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Intraluminal Gastroplasty Device



The obesity crisis

Continued from Page One

go up. The associated chronic health conditions cost the NHS an estimated £1.5 billion a year, more than just the amount of that they cost in terms of the NHS in the country.

The Government's chief scientific adviser, Professor John Pebody, says we have the ability to change our diets. Food and health officials have said that it is not inevitable that we will become obese. It is a choice we make.

Food critics Professor David King, the Government's chief scientific adviser, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."

The Government's chief scientific adviser, Professor John Pebody, said: "We want to see the nation take the national obesity challenge. We want to see individual and corporate responsibility."



It's a very sad situation. We've become so obese we can't get into it.

OBESITY BY NUMBERS

- 90%** of type 2 diabetes sufferers have a body mass index (BMI) of 30 or more.
- 80%** of type 2 diabetes sufferers are associated with a BMI of 35 or more.
- 2.4** times higher risk of coronary heart disease and stroke for obese women and 1.6 for men.
- 10%** of all cancers among non-smokers are linked to obesity.
- 17%** of stroke and circulatory disease and 10% of cancer deaths are linked to obesity.
- 17%** of stroke and circulatory disease and 10% of cancer deaths are linked to obesity.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

It's a very sad situation. We've become so obese we can't get into it.

Being fat can knock 13 years off your life

PRINTED IN AMERICA WEDNESDAY

OBESITY: DEADLIER THAN SMOKING

OBESITY is more dangerous than smoking and will dramatically shorten the lives of millions, a landmark study has found.

While smoking reduces life by an average of ten years, the research says being even mildly overweight can cut the

of children in the UK will be chronically obese - so fat that their health is in danger. At present around a quarter of adults are obese.

The research, written by 300 leading scientists, says Britain's obesity crisis is an epidemic that would limit its own life expectancy to reverse.

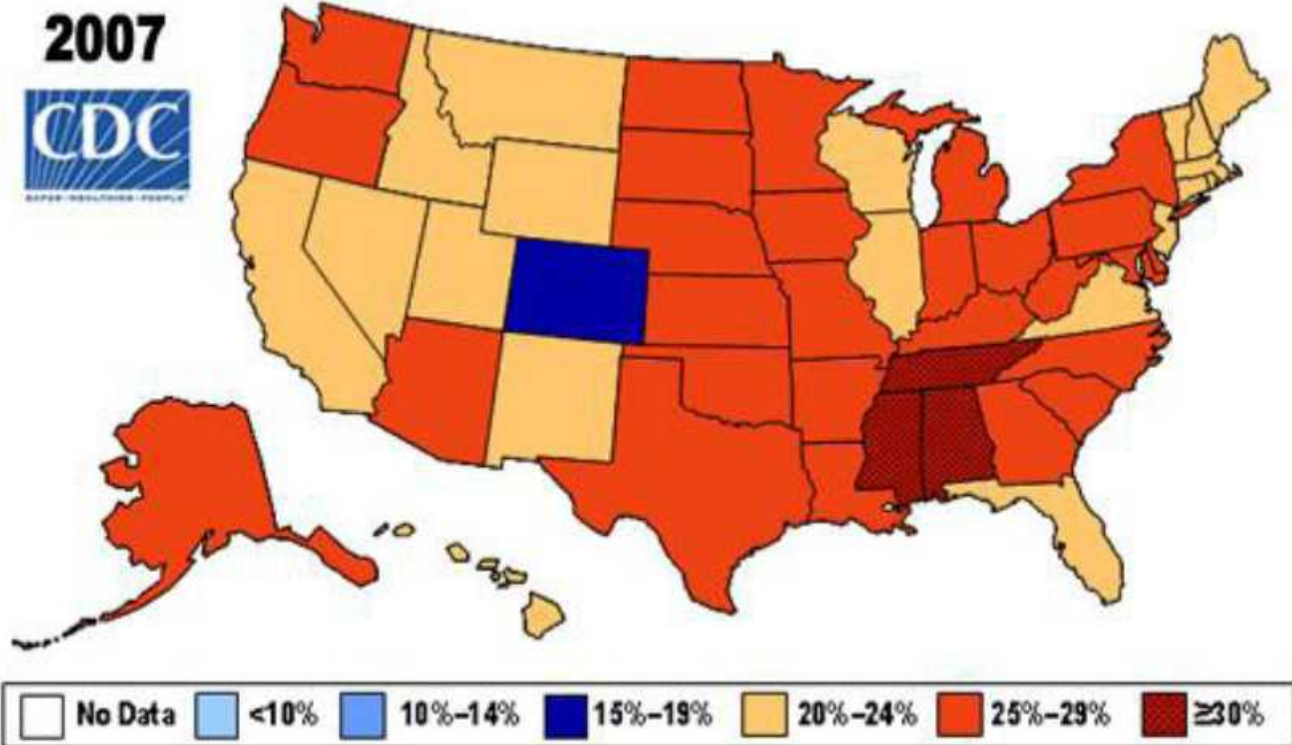
If current trends continue, by 2036 about 60 per cent of men, 60 per cent of women and 25 per cent

The epidemic of this so far mainly young will be devastating. The report expects type 2 diabetes to rise by 78 per cent, stroke to rise by 60 per cent and, if not curbed, to continue to rise. The cancer death toll will also

Turn to Page 4

Obesity Trends in the U.S.

(*BMI ≥ 30 , or ~ 30 lbs overweight for 5' 4" person)

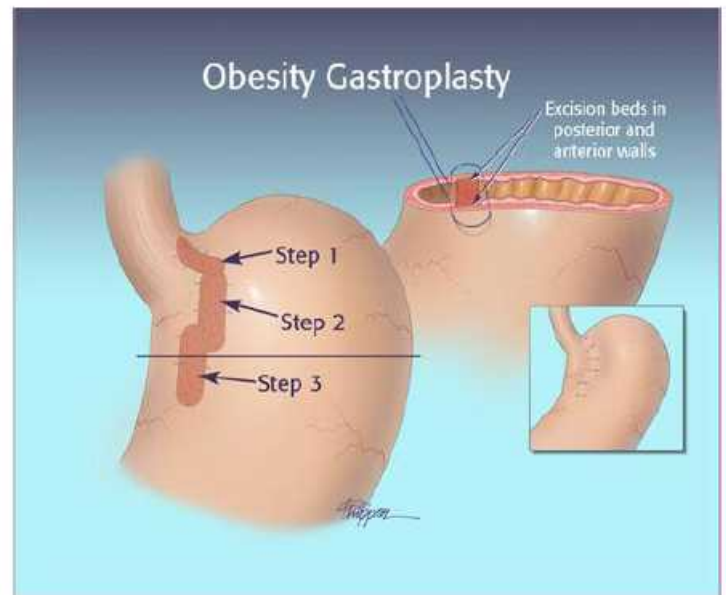


Obesity

- ▶ Linked to heart disease, diabetes and many other health issues
- ▶ Current procedures for obese patients have become household terms (gastric bypass, stomach stapling, lap band)
- ▶ All existing procedures involve abdominal surgery
- ▶ High risk patients, with high morbidity and mortality for these procedures
- ▶ Currently, 350,000 – 400,000 bariatric procedures are performed Worldwide, each year
- ▶ Procedures cost \$15,000 to \$70,000

SafeStitch Obesity Procedure

- ▶ Advantages:
 - Outpatient procedure
 - Safer
 - Faster recovery
 - Durability of effect
 - Significant cost reduction
- ▶ Clinical trials expected to begin in early 2009
- ▶ Non-U.S. Sales anticipated Q4 2010, U.S. Q1 2011

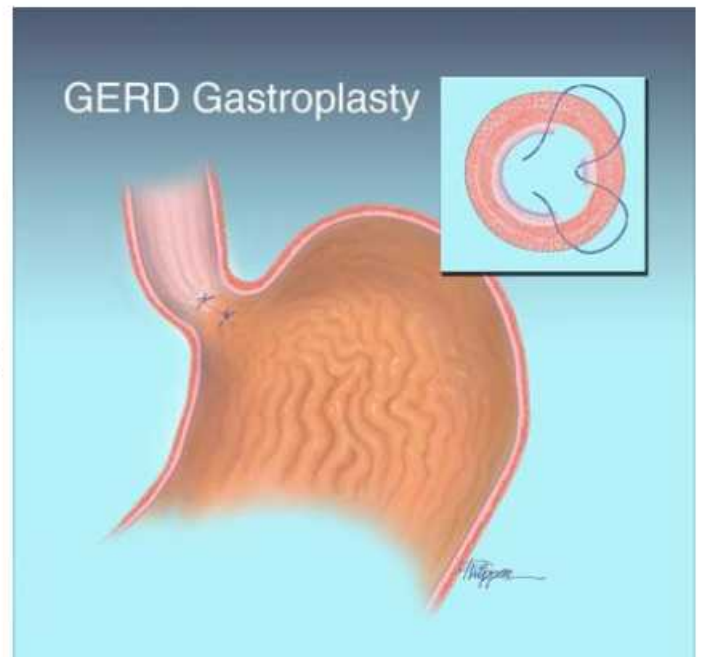


GERD

- ▶ GastroEsophageal Reflux Disorder (GERD)
 - Heartburn, indigestion
- ▶ Multibillion market in pharmaceuticals alone
- ▶ GERD can lead to Barrett's Esophagus, which may lead to cancer
- ▶ 200,000 to 250,000 GERD procedures are currently performed Worldwide, each year

SafeStitch GERD Procedure

- ▶ Same design
- ▶ Advantages:
 - Outpatient procedure
 - Safer
 - Easier and Quicker
 - Durability of effect
 - Significant cost reduction
- ▶ Clinical trials expected to begin in early 2009
- ▶ Non-U.S. Sales anticipated Q4 2010, U.S. Q1 2011

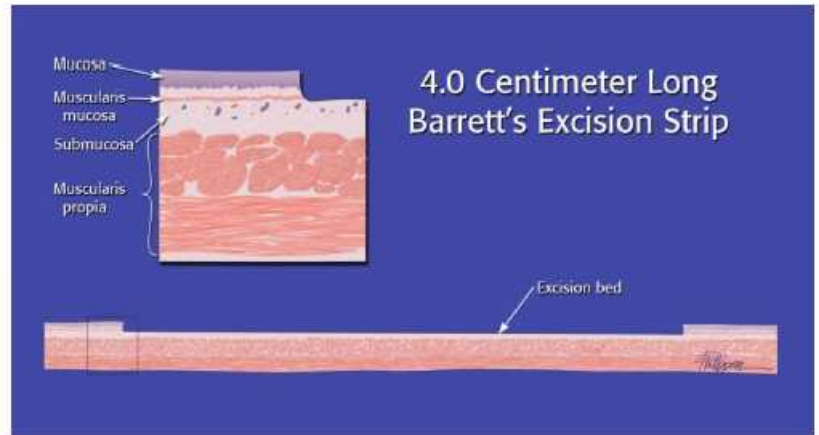


Barrett's Excision and Strip Mucosal Device

- ▶ For treatment and diagnosis of Barrett's Esophagus
 - Condition in which the esophagus changes so that some of its lining is replaced by a type of tissue similar to that normally found in the intestine, intestinal metaplasia
 - GERD is most common cause
 - May lead to esophageal cancer
- ▶ Conservatively, ~1 million patients in U.S., more Worldwide

Barrett's Excision and Strip Mucosal Device

- ▶ Advantages:
 - Large piece of tissue excised; can be sent for histology
 - Clean margins
 - Easier and Quicker
 - Cost reduction
- ▶ Clinical trials expected to begin in 2009



AMID Stapler

Hernia Device / Novel Surgical Fasteners

- ▶ Can be used for Hernia repair and other surgical procedures (skin stapling)
- ▶ Hernia market is 800,000 to 1 million inguinal surgeries per year in the U.S.
- ▶ Worldwide, incidence is consistent with U.S. percentages
- ▶ Device is being developed with Parviz Amid MD
 - UCLA; World Renowned Inguinal Hernia Surgeon; Popularized Lichtenstein (mesh) repair (90% of hernia repairs worldwide are done by this method)

AMID Stapler

Hernia Device / Novel Surgical Fasteners

- ▶ New type of stapler and staple will replace current hand-suturing procedure
- ▶ For Lichtenstein repair, The Amid stapler will:
 - Make the procedure easier, faster and safer
 - Reduce post-operative pain
 - Allow skin closure with the same device
- ▶ Clinical Evaluations expected in 2009
- ▶ Sales anticipated Q1 2010



SMART Dilator

- ▶ 800,000 dilations of esophageal strictures are performed annually in the U.S.; ~2 million Worldwide
- ▶ Perforation Rate: ~1.1%
- ▶ Important Features
 - Visual feedback force gauge handle
 - Tapered tip
 - Endoscope channel through entire device
 - Disposable: other disposable dilators sell for \$150 – \$250
- ▶ 510(k) FDA approval anticipated Q4 2008
- ▶ IRB approved clinical evaluation to begin in Q3 2008
- ▶ Commercialization anticipated early 2009

SMART Dilator



Standard Bite Block

- ▶ Approximately 18 – 20M upper endoscopies done per year Worldwide and all procedures need bite blocks to prevent injury to endoscopes and the patients' teeth
- ▶ Class I, 510(k) exempt device
- ▶ Advantages:
 - Harder to expel from mouth
 - Softer material
 - Superior crush resistance
 - Larger working inner diameter
- ▶ Clinical evaluation completed in Q3 2008 and marketing plans are being developed



Airway Bite Block

- ▶ Approximately 5M upper endoscopies done worldwide each year, on obese patients
- ▶ The majority of these patients have airway problems during procedure, which require some intervention
- ▶ Class I, 510(k) exempt device
- ▶ Advantages:
 - Novel design integrating Standard Bite Block and Oral-Pharyngeal airway
 - Softer Material
 - Superior crush resistance
 - Larger working inner diameter
- ▶ IRB approved clinical evaluation began in Q3 2008 and marketing plans are being developed



Manufacturing

- ▶ Standard and Airway Bite Blocks are being manufactured in Taiwan
 - Injection molding
- ▶ SMART Dilator
 - Injection molding and extrusion being done using contract manufacturers

▶ T Fastener

- For Upper GI Bleeding and closing gastrotomies following NOTES
- T Fastener can be placed using multi-firing endoscopic device
- High mortality rate due to Upper GI bleeding
 - Needs to be treated quickly and effectively

▶ Novel Devices for NOTES

- IP for multiple devices:
 - Magnetic retractors
 - Device for closing gastrotomies following NOTES
 - NOTES access platforms

Summary

- ▶ Large, important and growing markets
 - Obesity, GERD, Barrett's and Inguinal Hernia
 - Multibillion markets, currently
- ▶ Unique devices
 - Outpatient and minimally invasive
- ▶ Reduce cost to society from obesity and obesity-related diseases

SAFESTITCH

MEDICAL

Where Safety Meets Innovation

▶ **Contact:**

Jeffrey Spragens - CEO & President

Stewart Davis M.D. - COO

4400 Biscayne Boulevard

Suite 670

Miami, FL 33137

(305) 575-6000

(305) 575-4130 Fax

www.SafeStitch.com



September 19, 2008

Dear Fellow Stockholder:

It has been a year since Cellular Technical Services Company, Inc. and SafeStitch LLC combined to form SafeStitch Medical, Inc. In that time, we have strengthened SafeStitch's financial position and infrastructure while continuing to develop exciting and innovative medical devices to provide new and better treatment options for the millions of people suffering from obesity, gastroesophageal reflux disorder (GERD), esophageal diseases and hernias. Our pipeline of product candidates includes three devices that we anticipate will be ready to market by the end of this year, as well as several candidates for which we expect to launch clinical trials in 2009.

PRODUCT DEVELOPMENT

Three Products Anticipated to be Ready to Market by the end of 2008

We expect three of our products - the Standard Bite Block, the AIRWAY BITEBLOCK™ and the SMART DILATOR™ - to be fully tested, FDA approved and ready to market by the end of this year. The Standard Bite Block is designed to be harder for the patient to expel from his or her mouth and will be made from softer materials, yet will have superior crush resistance properties as compared to bite blocks now on the market. Bite blocks are used to prevent injury to endoscopes and patient teeth in the approximately 18-20 million upper endoscopies performed worldwide each year.

Our AIRWAY BITEBLOCK™ is the first Bite block specifically designed for the approximately 5 million endoscopies performed on obese patients each year. The SafeStitch AIRWAY BITEBLOCK™ combines the performance of our Standard Bite Block with an oral-pharyngeal airway to help reduce airway problems associated with obesity.

Finally, our SMART DILATOR™ will be the first dilator designed to help reduce the incidence of esophageal perforations in the more than 2 million dilations of esophageal strictures performed worldwide each year. Dr. Charles Filipi, our Medical Director, has studied the growing rate of potentially fatal perforations associated with these dilations, and you can find his study (published in Journal of the American College of Surgeons) reprinted on our website, www.SafeStitch.com. The SMART DILATOR™ gives visual feedback through its patented force gauge handle, and has a tapered tip, which reduces the number of devices required for a single dilation.

Obesity and GERD Device

Our flagship product is the Intraluminal Gastroplasty Device, which is being designed to perform both obesity and GERD procedures. There are currently 350,000-400,000 obesity procedures and 200,000 to 250,000 GERD procedures performed worldwide each year. We believe that significant expansion in both of these markets could be realized by introducing a safer, simpler outpatient procedure. The SafeStitch gastroplasty device should allow these procedures to be performed on an outpatient basis, reducing surgical and recovery times, adverse events and costs.

We have successfully lab-tested this device in canine, porcine and primate models, and we plan to continue testing improvements and perfecting the surgical techniques needed to use the device. Based on this primate work and in reviewing our sequencing of procedural steps, it appears that the speed of the procedure may be enhanced by using a variation of our Barrett's excision device in conjunction with our Gastroplasty device. We will seek to confirm this enhancement in one more round of primate survival tests in late 2008 and plan to begin clinical trials in early 2009. If the trials go according to plan, we expect approval for European and other international sales by late 2010 and FDA approval for US sales in early 2011.

The Amid Hernia Stapler

With the help of UCLA's Dr. Parviz Amid, a world renowned inguinal hernia surgeon who popularized the Lichtenstein hernia repair, we are developing a new type of stapler and staple for the more than 1.5 million inguinal hernia repairs performed worldwide each year. We anticipate that the Amid stapler will have multiple safety advantages and will make the hernia operation easier, faster and safer, while also allowing the surgeon to close the incision with the same device.

We anticipate clinical evaluations of the Amid stapler in 2009, with the subsequent commercialization beginning in Europe and elsewhere outside the US in late 2009 and in the US in early 2010.

Barrett's Excision and Strip Mucosal Device

Barrett's Esophagus is a condition affecting over 1 million people in the U.S. and many more worldwide in which the esophagus changes so that some of its lining is replaced by a type of tissue similar to that normally found in the intestine. GERD is the most common cause of Barrett's Esophagus, which may lead to esophageal cancer. The Barrett's Excision and Strip Mucosal Device is designed to excise large pieces of tissue containing the Barrett's lesion, which can be sent for histology, giving a precise diagnosis. The device is designed to simplify the procedure and allow it to be performed at a substantially lower cost.

We expect clinical trials of this device to begin in late 2009 and commercialization in mid 2011.

Other Products

Natural Orifice Transluminal Endoscopic Surgery, or NOTES, is one of today's most talked about surgical advances. SafeStitch is uniquely positioned to participate in this potentially revolutionary market through the intellectual property we control for NOTES access platforms, magnetic retractors and devices for closing gastrotomies following NOTES surgery. These intellectual property rights were acquired through our license with Creighton University; however, further development is required and no clinical trials are planned at this time.

The intellectual property for our T-Fastener, which was originally developed by Dr. Filipi working with Ethicon EndoSurgery (J&J) and Creighton University, was also acquired through our license with Creighton. The T-Fastener is a multi-firing device mounted on the tip of an endoscope that can rapidly fire small fasteners to treat upper GI bleeding and close gastrotomies following NOTES surgery. Like the NOTES devices, the T-Fastener needs further development and no clinical trials are currently scheduled.

Competition

The market for obesity and other gastrointestinal products remains highly competitive and will likely continue to attract new entrants. There are already a large number of products competing for market share, and significant levels of commercial resources are being utilized to promote those products and develop new ones. We expect to differentiate our products on the basis of enhanced safety, effectiveness and efficiency, as well as improved patient outcomes and lower cost.

FINANCIAL AND ORGANIZATIONAL ENHANCEMENTS**Private Offering, Capital Position and American Stock Exchange Application**

On May 28, 2008, we completed the private placement of almost 1.9 million shares of our common stock at a price of \$2.15 per share. In addition to adding approximately \$4.0 million to our cash position, this offering increased the number of shares of our common stock held by non-affiliates from 3.3 million to 4.8 million, or about 26% of our total outstanding shares. We greatly appreciate the support of those persons who participated in this offering, helping to broaden our unaffiliated stockholder base, which has helped us take the first steps toward listing our common stock on the American Stock Exchange (AMEX). The AMEX maintains rigid financial, market capitalization and governance standards for new listings, and we believe that we will be in position to apply for listing once we begin sales of our bite blocks and Smart Dilator, and commence clinical trials of the gastroplasty device and the Amid hernia stapler.

Building a Complete Medical Device Development Company

When Drs. Filipi, Phillip Frost, Jane Hsiao and I started SafeStitch LLC three years ago, all of our product engineering was outsourced, and our operation consisted of an animal lab at Creighton University and a small office staffed by Dr. Filipi, an assistant and an animal technician.

In May of 2007, Dr. Stewart Davis joined us as Chief Operating Officer and spearheaded the effort to bring our research and engineering activities in-house and build a top flight medical device development company. In December 2007, we acquired a machine shop and prototype lab in Miami with full manual and computer numerical control (CNC) machining, lathing and injection molding capabilities. This lab gives us more control over prototype development for quicker, more efficient and cost-effective prototype production, and improved quality and regulatory control. We plan to expand our prototype lab operation in the next six months to include wet lab, assembly lab and small scale manufacturing with a clean room. Dr. Filipi's four-person research team in Omaha is now supported by a seven-person product engineering and prototype development team in Miami. Our in-house R&D group anticipates that it will continue to augment its work by selectively outsourcing certain activities, but we are excited that we now have the majority of our R&D work under our direct supervision and control.

Our Miami staff also includes a solid quality control and regulatory compliance function, and we are implementing a quality system, as well as document control and ISO-compliant policies and procedures. New policies and procedures are also being implemented in administration and finance as we enhance our corporate governance, SEC reporting and Sarbanes-Oxley compliance activities under the direction of our new Chief Financial Officer, Adam Jackson, and his accounting team.

We are pleased with the progress we have made in the last year, and we are excited about SafeStitch's prospects in the arenas we have entered. We appreciate your continued support as we build and expand SafeStitch Medical and look forward to continuing to report to you with our progress and developments as they occur. In the meantime, please visit our website, www.SafeStitch.com for regular updates on our filings, medical articles, and other news and announcements.

Very truly yours,

/s/ Jeffrey Spragens

Jeffrey G. Spragens

President and Chief Executive Officer

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