
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

Date of Report (Date of Earliest Event Reported):

February 10, 2010

SafeStitch Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware

0-19437

11-2962080

(State or other jurisdiction
of incorporation)

(Commission
File Number)

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

4400 Biscayne Blvd., Suite A-100, Miami, Florida

33137

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

305-575-4145

Not Applicable

Former name or former address, if changed since last report

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:

- 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 (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On February 10, 2010, SafeStitch Medical, Inc. (the "Company") issued a press release announcing that the Company had received CE Mark authorization for European Economic Community marketing of its AMID Stapler™ for use in general surgery procedures for fixation of mesh, in the repair of hernia defects and in other surgical specialties for the approximation of tissues, including skin. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" with the Securities and Exchange Commission 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 incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act. This Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information contained herein, including Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number Description

99.1 Press release dated February 10, 2010.

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 hereunto duly authorized.

SafeStitch Medical, Inc.

February 10, 2010

By: */s/ Adam S. Jackson*

Name: Adam S. Jackson

Title: Chief Financial Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated February 10, 2010

SafeStitch Medical, Inc. Receives CE Mark for the AMID Hernia Stapler

MIAMI—(BUSINESS WIRE)—SafeStitch Medical, Inc. (OTCBB: SFES) announced today that it has received CE Mark authorization to commercialize its AMID Stapler™ in the European Economic Community. The new stapler is to be used for fixation of mesh in the repair of hernia defects and also for the approximation of tissues, including skin. The AMID Stapler™ is the first surgical stapler designed specifically for use in inguinal hernia repairs using the Lichtenstein method, in which mesh is implanted for reinforcement. SafeStitch announced in November 2009 that it had received 510(k) clearance from the Food and Drug Administration for sale of the AMID Stapler™ in the U.S. market.

SafeStitch designed the stapler in collaboration with Dr. Parviz Amid, a pioneer of and renowned expert in the Lichtenstein repair. Dr. Charles J. Filipi, SafeStitch's Medical Director and former President of the American Hernia Society, noted that "approximately one million hernia repairs are performed in the U.S. each year and the Lichtenstein repair is used in as many as 70% of inguinal hernia repairs worldwide. Based on clinical experience to date, we believe the AMID Stapler™ will make the Lichtenstein repair faster and more attractive to surgeons presently affixing mesh and closing incisions with sutures."

"The AMID Stapler™ is angled for safety and better visibility and its patented mesh manipulators permit easy and safe mesh placement. Its 17 box-shaped, sharp-tipped titanium staples are designed specifically for this repair" explained Dr. Stewart Davis, SafeStitch's COO.

Jeffrey Spragens, SafeStitch's President and CEO, noted that, "this CE Mark and FDA clearance marks the completion of the development phase for SafeStitch's first four products: the SMART Dilator™, Standard BiteBlock, Airway BiteBlock and the AMID Stapler™. We continue our commercialization efforts for these products, starting with the launch of the AMID Stapler™. Our product development efforts are now fully focused on SafeStitch's minimally invasive gastroplasty devices for obesity and GERD procedures. We have successfully completed our pre-clinical laboratory studies with these gastroplasty devices, and are preparing IDE applications for FDA clearance to conduct multicenter clinical trials."

About SafeStitch Medical, Inc.

Miami-based SafeStitch Medical, Inc. is a medical device company primarily developing endoscopic and minimally invasive surgical devices. SafeStitch's product portfolio includes endoscopic gastroplasty devices for bariatric (obesity) surgery and repair of gastroesophageal reflux disorder (GERD), as well as the AMID Stapler™, Standard BiteBlock, Airway BiteBlock and SMART Dilator™. SafeStitch has also started development of devices for excision and diagnosis of Barrett's esophagus and natural orifice transluminal endoscopic surgery (NOTES). Information about the Company may be found on its website at: www.safestitch.com.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding our product development and commercialization efforts, and our ability to significantly improve clinical outcomes in patients, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors, including those described in our filings with the Securities and Exchange Commission, could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include that the design of the AMID Stapler™ may not have the versatility to perform as anticipated or make the hernia repair procedure easier, faster or safer, or reduce post-operative pain, that we may not receive clearance to market the AMID Stapler™ in areas outside of the U.S. and the European Economic Community, that the commercialization and launch of the AMID Stapler™ or any of our other devices may be delayed or may be unsuccessful, that we will be unable to successfully develop and commercialize our minimally invasive gastroplasty devices for obesity and GERD procedures, that our devices under development may not achieve the expected results or effectiveness and may not generate data that would support their approval or marketing, that others may develop products and devices, including other devices for hernia repair, obesity or GERD procedures, which are superior to our devices, and that our devices may not have advantages over presently marketed products or devices or products or devices under development by others. In addition, forward-looking statements may also be adversely affected by risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, 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. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Contact: SafeStitch Medical, Inc., Miami

Dr. Stewart B. Davis, 305-575-4145