Patient Safety Technologies, Inc
Form 10-K
April 14, 2011

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

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2010

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: 001-09727

PATIENT SAFETY TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	13-3419202
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Venture Plaza, Suite 350 Irvine CA, 92618
(Address of principal executive offices Zip Code)

Registrant's telephone number, including area code: (949) 387-2277

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $0.33 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such 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 ¨ No ¨

Indicate by check mark, if disclosure of delinquent filers in response 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. ¨

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 ¨ (Do not check if smaller reporting company)	Smaller Reporting Company x

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

The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant based on the last reported sale price of the common stock as reported on the OTC Bulletin Board on June 30, 2010 was approximately $13.9 million.

The number of outstanding shares of the registrant’s common stock, par value $0.33 per share, as of April 1, 2011 was 33,514,394.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of this Annual Report on Form 10-K is either incorporated from the Registrant's Proxy Statement for the 2011 Annual Meeting of Stockholders, or will be filed in a future amendment to this Annual Report on Form 10-K, in either case to be filed with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PATIENT SAFETY TECHNOLOGIES, INC.

FORM 10-K FOR THE YEAR
ENDED DECEMBER 31, 2010

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K (this "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Our forward-looking statements relate to future events or our future performance and include, but are not limited to, statements concerning our business strategy, future commercial revenues, market growth, capital requirements, new product introductions, expansion plans and the adequacy of our funding. Other statements contained in this Report that are not historical facts are also forward-looking statements. You can sometimes identify forward-looking statements by our use of forward-looking words like "may," "will," "could," "should," "expects," "intends," "plans," "ant "believes," "estimates," "seeks," "predicts," "potential," or "continue" or the negative of these terms and other similar expres and terminology.

We caution investors that any forward-looking statements presented in this Report, or that we may make orally or in writing from time to time, are based on the beliefs of, assumptions made by, and information currently available to, us. Although we believe that the plans, objectives, expectations and intentions reflected in or suggested by our forward-looking statements are reasonable, those statements are based only on the current beliefs and assumptions of our management and on information currently available to us and, therefore, they involve uncertainties and risks as to what may happen in the future. Accordingly, we cannot guarantee that our plans, objectives, expectations or intentions will be achieved. Our actual results, performance (financial or operating) or achievements could differ from those expressed in or implied by any forward-looking statement in this report as a result of many known and unknown factors, many of which are beyond our ability to predict or control, and those differences may be material. Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include the following:

- the early stage of adoption of our Safety-Sponge® System and the need to expand adoption of our Safety-Sponge® System;
- the impact on our future revenue and cash flow from the ordering patterns of our exclusive distributor, Cardinal Health;
- our need for additional financing to support our business;
- our reliance on third-party manufacturers, some of whom are sole-source suppliers, and on our exclusive distributor; and
- any inability to successfully protect our intellectual property portfolio

For further discussion of these and other factors see, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in this Report. This Report and all other written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in or referred to in this section.

Our forward-looking statements speak only as of the date they are made and should not be relied upon as representing our plans, objectives, expectations and intentions as of any subsequent date. Although we may elect to update or revise forward-looking statements at some time in the future, we specifically disclaim any obligation to do so, even if our plans, objectives, expectations or intentions change.

HELPFUL INFORMATION

As used throughout this annual report on Form 10-K, the terms the “Company,” “the registrant,” “we,” “us,” and “our” me
Patient Safety Technologies, Inc., a Delaware corporation, together with our consolidated subsidiary, SurgiCount Medical Inc., a California corporation, unless the context otherwise requires.

Unless otherwise indicated, all statements presented in this annual report on Form 10-K regarding the medical patient safety market, the market for our products, our market share, the cumulative number of Safety-Sponges® used and number of procedures in which the Safety-Sponge® System have been used are internal estimates only.

Safety-Sponge®, SurgiCounter™ and Citadel™, among others, are registered or unregistered trademarks of Patient Safety Technologies, Inc. (including its subsidiary).

PART I

ITEM 1. BUSINESS

Overview

Patient Safety Technologies, Inc., focuses on the development, marketing and sale of products designed to improve patient outcomes and reduce costs in the healthcare industry. We conduct our business through our wholly owned subsidiary, SurgiCount Medical, Inc. Our proprietary Safety-Sponge® System is a patented solution designed to eliminate one of the most common errors in surgery, retained surgical sponges, and the human and economic costs associated with this surgical mistake. The Safety-Sponge® System is comprised of a line of uniquely identified surgical sponges and towels and a turnkey hardware and software offering integrated to form a comprehensive accounting and documentation system. Over an estimated 45.4 million of our Safety-Sponges® have been successfully used in more than 2.1 million surgical procedures. We sell our Safety-Sponge® System to hospitals through our direct sales force and by leveraging the sales and marketing capabilities of our distribution partners. Our proprietary line of surgical sponges and towels are manufactured for us by our exclusive manufacturer, A Plus International Inc. ("A Plus"), a leading, China-based manufacturer of disposable medical and surgical supplies. Our sponge and towel products are distributed through Cardinal Health, Inc. ("Cardinal Health"), who provides us sales, marketing and logistics support and the fulfillment of our products to our end-user hospitals by both delivering our products directly to our end-user hospitals and where appropriate through alternative distributors. We currently have over 60 hospitals using the Safety-Sponge® System, all of which are located in the U.S. During 2010 the number of hospitals using our Safety-Sponge® System more than doubled and we lost no customers. Although not necessarily proportionally related to future revenue, growth in the number of hospitals using our products is a good indicator of our underlying business. Once implemented, the vast majority of our end-user hospitals use the Safety-Sponge® System across all of their relevant surgical and OB/GYN procedures.

Subsequent to the resignation of our previous President and Chief Executive Officer and four other board members, during the third quarter of 2010 newly appointed management implemented a comprehensive restructuring program focused on a number of initiatives, including the reduction of operating expenses and aggressively managing the Company to achieve positive operating income and operating cash flow. Restructuring activities included the elimination of certain job positions, lowering executive and employee cash compensation levels, refining and enforcing expense and travel policies and initiating spend measurement systems and accountability across various functional areas. As a result of a number of factors, primarily the continued growth of the Company's revenues from both delivery of Cardinal Health's stocking inventory (as discussed in "Cardinal Health – Exclusive U.S. Distributor" below), the increased number of hospitals using the Company's products and the impact on operating expenses from the recent restructuring initiatives, the Company reported positive operating income of $925 thousand during the quarter ended September 30, 2010, the first period of positive reported operating income in the history of the Company's ownership of SurgiCount since 2005 and the first reporting period under newly appointed management.

We generated revenues of $14.8 million and $4.5 million during the fiscal years ended December 31, 2010 and 2009, respectively. Our 2010 revenues of $14.8 million include approximately $8.9 million of revenues from the partial fulfillment of a $10.0 million stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health (the "Forward Order"). Also during 2010 we generated an additional approximately $5.9 million of revenue, separate from the Forward Order, from the delivery of products to Cardinal Health to meet immediate demand from end-user hospitals. Under certain circumstances the Forward Order may negatively impact our 2012 revenues and cash flows. See "Management's Discussion and Analysis of Financial Condition and Results of Operations— Factors Affecting Future Results—Cardinal Health Supply Agreement".

Patient Safety Industry

The U.S. patient safety market is a multi-billion dollar industry that includes a wide range of medical devices, technologies and equipment. We estimate there are approximately 32 million surgical procedures annually in the U.S. in which our products can be used and that our average revenue per procedure opportunity is currently approximately $14 to $16 dollars, implying an immediate market opportunity in the U.S. for us of more than $450 million. In addition, we estimate that the total applicable procedures for our products outside the U.S. to be approximately two times those done domestically, bringing the worldwide market opportunity for us to be over $1.3 billion.

We believe that the U.S. healthcare industry is increasingly receptive to products like our Safety-Sponge® System that can enable providers to increase their standards of patient care and lower their costs. We believe drivers of this demand include growing evidence as to the clinical efficacy and cost effectiveness of products like ours, an increased focus by both federal and state level regulatory agencies to hold hospitals more accountable for preventable errors, increasing legal costs associated with these events and the underlying desire by providers to provide improved outcomes for their patients and protect their staff from the ramifications of these event.

Our Safety-Sponge® System

Before and after most surgical procedures are performed, surgical staff manually count most of the items used inside a patient in an effort to prevent these objects from being unintentionally left inside a patient after surgery. Due to number of contributing factors, including the quantity typically used in a procedure, the nature of their use and their physical properties, surgical sponges prove to be one of the most difficult and time consuming to account for and are one of the most common items unintentionally retained inside patients. Our proprietary Safety-Sponge® System is designed to prevent surgical sponges and towels from being unintentionally left in patients after surgical procedures by allowing for a more accurate accounting of these individual items prior to the patient being closed.

The Safety-Sponge® System is a patented system of uniquely identified surgical sponges and towels and a turnkey hardware and software offering integrated to form a comprehensive accounting and documentation system. Over an estimated 45.4 million of our Safety-Sponges® have been successfully used in more than 2.0 million surgical procedures. We currently have over 60 hospitals using the Safety-Sponge® System, all of which are located in the U.S. Each of our Safety-Sponge® surgical sponges and towels are affixed with a soft, pliable label on which an individually unique identifier is printed. These unique identifiers are printed in both human readable and machine readable form. When used with our handheld mobile computer, scanner and software (the SurgiCounter™) the system is designed to eliminate the incorrect counting of sponges by greatly reducing the human error involved with manually counting these items. Because each Safety-Sponge® has an individually unique, machine readable identifier, the SurgiCounter™ is designed to only count each item “in” once and “out” once. Our solution is intended to be used in conjunction with a manual count being concurrently performed by surgical staff to ensure the safest possible clinical practice and to prevent any technology dependence.

Surgical sponges and towels are typically delivered to a hospital in one of two formats, either in stand-alone, sterilized packages (most often with five or ten of the same type of item to each package, we call this format “Single Sterile”) or within larger packages of various disposable surgical products that are custom built for a specific procedure at a specific hospital. These larger customized packages of disposable surgical products are often called “Custom Procedure Trays.” We estimate the overall usage of surgical sponges and towels to be approximately 65% from inside Custom Procedure Trays and 35% from Single Sterile packages. Our Safety-Sponge® line of surgical sponges and towels are available in both of these formats. We typically deliver our sponges and towels to providers of Custom Procedure Trays in a non-sterilized, non-packaged format we call “Bulk Non Sterile”. Once our Bulk Non Sterile products are placed within a larger Custom Procedure Tray along with other disposable products, the Custom Procedure Trays are typically sealed and the entire Custom Procedure Tray is sterilized.

In addition to providing surgical staff with a more accurate intra-operative account of all individual sponges and towels used during a procedure through the use of our SurgiCounter™ with our Safety-Sponges®, our Citadel™ software application is designed to provide hospitals with an evidence-based outcome and compliance audit capabilities through the generation of an electronic report of that particular procedure. These procedure reports includes information such as the exact time each individual sponge was scanned and accounted for before and after use, as well as other procedure specific information such as patient identification, procedure performed and the surgical staff in that procedure. The Citadel™ application can be used for post-operative documentation and compliance monitoring for individual cases as well as to review aggregate data such as product usage and other information. This information can be pushed to other databases within the hospital such as electronic medical records and has been designed with future applications in mind including additional patient safety, convenience, asset tracking, data management and product utilization applications and features.

Customers and Distribution

Our business model includes an outsourced manufacturing and partnered distribution strategy. We sell our Safety-Sponge® System to hospitals through our direct sales force and by leveraging the sales and marketing capabilities of our distribution partners. Our proprietary line of surgical sponges and towels are manufactured for us by our exclusive manufacturer, A Plus. Our sponge and towel products are distributed through Cardinal Health, who provides us sales, marketing and logistics support and the fulfillment of our products to our end-user hospitals by both delivering our products directly to our end user hospitals and where appropriate through alternative distributors. Once implemented, the vast majority of our end-user hospitals use the Safety-Sponge® System across all of their relevant surgical and OB/GYN procedures.

We currently target our sales efforts primarily to the approximately 5,700 acute care hospitals in the United States. We are currently initiating efforts to actively pursue hospitals in other countries. Our sales process typically involves making contact with multiple stakeholders within a hospital including executives, surgeons, medical and nursing personnel, risk management and various administrators. We believe it is important that all of these stakeholders evaluate not only the economics, but also the clinical effectiveness and other benefits of our Safety-Sponge® System. As part of the sales process, hospitals considering the adoption of the Safety-Sponge® System often conduct a limited trial of the product in order to gain a better understanding of the functionality and benefits of our Safety-Sponge® System.

Although some customers decide to adopt our Safety-Sponge® System prior to a trial, we generally sign up new hospital customers following such an evaluation event. Once a customer has agreed to adopt our Safety-Sponge® System by executing a purchase contract, we then typically provide the hardware used in our system, including our SurgiCounter™, to the hospital and make our personnel and materials available to provide technical and clinical support for our hardware and systems integration (see "—Sales and Clinical Support" below). Although we occasionally have a customer hospital who prefers to purchase our hardware, we typically offer the hardware used in the Safety-Sponge® System at no cost to the hospital in exchange for certain commitments to purchase our Safety-Sponge® line of disposable sponges and towels.

Cardinal Health – Exclusive U.S. Distributor

In November 2006, we began an exclusive distribution relationship with Cardinal Health to supply hospitals with our Safety-Sponge® line of disposable sponges and towels. This original agreement had a term of 36 months, and automatically renewed for successive 12 month periods unless terminated early in accordance with its terms.

In November 2009, we renewed our distribution relationship with Cardinal Health through the execution of a new Supply and Distribution Agreement (the "Supply and Distribution Agreement"). This new agreement has a five-year term to 2014 and names Cardinal Heath as the exclusive distributor in the United States, Puerto Rico, and Canada of the current products used in our proprietary Safety-Sponge® System. Though Cardinal Health is our exclusive distributor in these geographical areas, the terms of our agreement with Cardinal Health do not limit the sales of our products to direct customers of Cardinal Health only. Our products are available to any hospital that wishes to purchase them through their existing distribution relationships. In the event an end-user hospital customer of ours does not have a distribution relationship with Cardinal Health, Cardinal Health distributes our products directly to the alternative distributor that works with that hospital.

In connection with the execution of the Supply and Distribution Agreement in November 2009, Cardinal Health issued a $10.0 million stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of stocking inventory over a 12-month period (the "Forward Order"). Cardinal Health paid us $8.0 million as partial pre-payment of the Forward Order, and agreed to pay $2.0 million directly to A Plus, to pay for product when A Plus invoices the Company. Cardinal Health also agreed to place a second $5.0 million stocking purchase order prior at the end of the third quarter of 2010, based on whether the Company achieved certain conditions, including a minimum targeted customer sales threshold. Both Cardinal Health and the Company jointly agreed in late 2010 not to go forward with this second stocking purchase order. Cardinal Health also agreed to maintain normal ordering patterns and volumes for purchasing our Safety-Sponge® products throughout 2010 and not to use any of the inventory delivered under the Forward Order to meet immediate hospital demand. In late 2010 Cardinal Health requested to change the product mix of the Forward Order. We agreed to this change because the products Cardinal Health requested were not immediately available, and Cardinal agreed to take delivery of the remaining inventory on a modified schedule. As of December 31, 2010 we had delivered approximately $8.9 million of the Forward Order and we anticipate delivering the remaining $1.1 million of Forward Order inventory in the first half of 2011. The net effect is we did not realize the full $10.0 million of Forward Order revenue in 2010, and we will recognize $1.1 million of Forward Order revenue in 2011.

Significant Subsequent Event Update

In March 2011, we and Cardinal Health signed an amendment to the Supply and Distribution Agreement (the "Amended Supply and Distribution Agreement"). The Amended Supply and Distribution Agreement revised a number of terms and conditions of the previous agreement, including but not limited to extending the termination date of the agreement from November 19, 2014 to December 31, 2015 and adding certain terms and provisions regarding setting target inventory levels and defining a formula for determining what excess inventory is of our products held by Cardinal Health. Cardinal Health has agreed to not sell any of the Forward Order inventory until calendar year 2012, and we have agreed to a methodology for how Cardinal Health will sell this inventory to our customers, so there is a more orderly release throughout the 2012 year that more reasonably minimizes its impact to the Company's revenues and cash flow during 2012. For a discussion on the effects that this agreement is expected to have on our financial condition and results of operations, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors Affecting Future Results - Cardinal Health Supply Agreement."

Our agreement with Cardinal Health also gives them minimum gross margins on all sales of our Safety-Sponge® disposable surgical sponge and towel products. The minimum gross margin amounts vary depending on the format of

the product sold (Single Sterile or Bulk Non Sterile) and depending on the distribution of that product to the end-user hospital (directly by Cardinal Health or through alternative distributors). In addition, for Bulk Non Sterile products included in Cardinal Health's custom procedure kits the guaranteed minimum gross margins are based on a formula that varies depending on certain sales performance results during specific time periods.

Warrant Purchase and Registration Rights Agreement

In connection with the Supply and Distribution Agreement entered into in November 2009, we entered into a Warrant Purchase and Registration Rights Agreement, dated effective November 19, 2009, pursuant to which we issued Cardinal Health warrants to purchase 1,250,000 shares of our common stock at $2 per share, and 625,000 shares of our common stock at $4 per share. These warrants have a term of five-years (expiring November 2014), but are subject to early expiration in certain circumstances. In addition, the Company granted Cardinal Health a right of first refusal for an initial one year term with respect to certain issuances of common stock. This right of first refusal expired in November 2010. We also granted Cardinal Health certain registration rights with respect to the shares of our common stock issuable upon exercise of the warrants pursuant to a Registration Rights Agreement dated November 19, 2009.

Manufacturing

All of our sponge and towel products are currently manufactured for us by our exclusive manufacturing partner, A Plus International Inc. ("A Plus"). In 2005, we entered into an exclusive supply agreement with A Plus to provide us with sponge and towel products for use with our Safety-Sponge® System (the "A Plus Supply and Manufacturing Agreement"). Wenchen ("Wayne") Lin, a member of our Board of Directors, is a founder and significant beneficial owner of A Plus. In January 2007, we entered into a successor supply agreement with A Plus and, in May 2008, we entered into our current exclusive A Plus Supply and Manufacturing Agreement. The current A Plus Supply and Manufacturing Agreement grants A Plus the exclusive, world-wide license to manufacture and import the sponge and towel products used in our Safety-Sponge® System, including the right to sublicense to the extent necessary. A Plus manufactures our products in its FDA approved facilities, primarily those in China, which are subject to periodic site inspections by the FDA. In addition to manufacturing our products, A Plus provides packaging, sterilization, logistics and related quality and regulatory compliance support. A Plus has agreed not to manufacture, import or otherwise supply any bar coded surgical products for any other third party. Under the current A Plus Supply and Manufacturing Agreement, we agreed to negotiate the pricing schedule annually to reflect changes in manufacturing costs, taking into account changes in cotton prices and Chinese currency exchange rates. While we believe the manufacturing capacity of A Plus is sufficient to meet our expected demand, in the event A Plus cannot meet our requirements, the agreement allows us to retain additional manufacturers as needed. The successor agreement has an initial term of ten years and will expire in May 2018 unless terminated early in accordance with its terms.

In conjunction with the execution of the January 2007 A Plus Supply and Manufacturing Agreement, we entered into a subscription agreement with A Plus, pursuant to which we sold A Plus 800,000 shares of our common stock and warrants to purchase 300,000 shares of our common stock at an exercise price of $2.00 per share, which have a term of five years. We received gross proceeds of $500,000 in cash and a $500,000 credit against future shipments (which has been fully utilized). A Plus was also granted certain right to participate in future financings and was granted certain director designation rights, pursuant to which Wayne Lin, currently a member of our Board of Directors was given the opportunity for this role. In addition, we agreed not to undertake certain transactions (such as incurring certain indebtedness or engaging in certain transactions with respect to our intellectual property) without first obtaining the A Plus designated director's approval.

A Plus has also purchased additional shares of our Series B Convertible Preferred Stock in June 2010 and Wayne Lin and family members purchased shares of our common stock in March 2011 in previously disclosed private placements.

We do not directly engage in the manufacturing of the hardware used in our Safety-Sponge® System (such as our SurgiCounters™). We purchase these items from certain third-party vendors on a purchase order basis. We also utilize third party developers to create, document and test our proprietary software.

Sales and Clinical Support

Our sales efforts focus on establishing relationships with various stakeholders within targeted institutions including executives, surgeons, nurses and various administrators and fostering a consultative approach to communicating the value proposition of our offering. We provide extensive education, support and training both prior to and after implementation of the Safety-Sponge® System. The length of our sales cycle can vary substantially customer by customer, depending on a number of variables including but not limited to the number of retained sponges a hospitals has historically experienced, the timing of those events, the severity of the patient complications and extent of financial damages and the budgeting process at that particular institution. Our sales and support efforts are augmented by our team of full-time and part-time clinical specialists. Our clinical team is comprised primarily by specialists with extensive nursing backgrounds. Our clinical team plays an essential role in our sales, education, implementation and

on-going support process.

Indemnification Program

In the third quarter of 2009 we launched an indemnification program to provide our customers with added assurance regarding the reliability of our Safety-Sponge® System and the financial benefits of its use. We indemnify customers in the program using the Safety-Sponge® System up to $1 million per incident should they experience a retained sponge using the solution. To qualify for the indemnification program customers agree to certain stipulations, including but not limited to using only our sponge and towel products, using our Citadel™ software application and maintaining a concurrent manual count of the sponges and towels used in a procedure. We maintain insurance to cover the potential liability to us from this program as well as to provide additional assurance to our customers in the program of our ability to meet any obligations there under. To date, there have been no claims under this program.

Intellectual Property

Patents, trademarks and other proprietary rights are an important element of our business. Our policy is to file patent applications and trademark registrations and to protect our technology, inventions and improvements to inventions that are commercially important to the development of our business, in particular, as it pertains to the technology used in our proprietary Safety-Sponge® System, including our Safety-Sponges®, SurgiCounters™, and all of our software applications.

We currently hold numerous patents issued by the United States Patent and Trademark Office as well by the appropriate agencies in various other countries. We also own a number of registered and unregistered trademarks, including Safety-Sponge®, SurgiCounter™, and Citadel™.

Competition

With our core Safety-Sponge® System offering, we face competition from both technology based products and from non technology based solutions, namely the approach of relying solely on the manual counting of sponges. Partly because the vast majority of acute care hospitals do not currently use any technology based solution in an effort to prevent retained sponges, we view the competition we face from a solely manual counting approach as significantly as we do technology based solutions. From a technology standpoint, there are multiple competing products available to our customers, including products offered by RF Surgical Systems, Inc. and ClearCount Medical Solutions. Both of these technology competitors utilize different approaches and underlying technologies. We believe we compare favorably to these technology competitors across a variety of categories including but not limited to relative cost, safety, evidence of clinical efficacy, support by independent clinical research, simplicity, ease of use, existing users, clinical support, size of required footprint in the operating room, ability to complement existing recommended clinical practices and scalability to provide additional features and applications beyond just preventing retained sponges.

Government Regulation

Our products and research and development activities are regulated by numerous governmental authorities, principally the U.S Food and Drug Administration, or FDA, and corresponding state and foreign regulatory agencies. Any device manufactured or distributed by us is subject to continuing regulation by the FDA. The Food, Drug and Cosmetics Act, or FDC Act, and other federal and state laws and regulations govern the clinical testing, design, manufacture, use and promotion of medical devices, such as our Safety-Sponge® System.

In the United States, medical devices are classified into three different classes, Class I, II and III, on the basis of controls deemed reasonably necessary to ensure the safety and effectiveness of the device. Class I devices are subject to general controls, such as labeling, pre-market notification and adherence to the FDA's good manufacturing practices, and quality system regulations. Class II devices are subject to general as well as special controls, such as performance standards, post-market surveillance, patient registries and FDA guidelines. Class III devices are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness, such as life-sustaining, life-supporting and implantable devices, or new devices that have been found not to be substantially equivalent to existing legally marketed devices. All of our currently available products are classified as Class I devices. In the future we may consider introducing products that may be classified differently.

Under the FDC Act, most medical devices must receive FDA clearance through the Section 510(k) notification process, or the more lengthy premarket approval process (commonly referred to as PMA). Some Class I devices are also "exempt" from the 510k requirement subject to certain limitations. Our Safety-Sponge® System is within a defined device group that is specifically denoted as "exempt" from the 510(k) process, however, a 510(k) for the Safety-Sponge® System was filed and received FDA clearance through the 510(k) notification process.

The FDA's quality system regulations also require companies to adhere to current good manufacturing practices requirements, which include testing, quality control, storage, and documentation procedures. Compliance with applicable regulatory requirements is monitored through periodic site inspections by the FDA. Our exclusive manufacturer, A Plus manufactures our products in FDA registered facilities and is subject to such periodic site inspections. In addition, we are required to comply with FDA requirements for labeling and promotion. The Federal Trade Commission also regulates medical device advertising for appropriate claims of effectiveness. We are also subject to the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997, which requires additional reporting requirements for users and distributors in the event of an incident involving serious illness, injury or death caused by a medical device.

Organizational History

Patient Safety Technologies, Inc. is a Delaware corporation that currently conducts its operations through a single, wholly-owned subsidiary, SurgiCount Medical, Inc., a California corporation. Today our sole focus is providing hospitals with products focused on improving patient outcomes and reducing healthcare costs. We were incorporated on March 31, 1987 and from July 1987 through March 2005, operated as an investment company registered pursuant to the Investment Company Act of 1940, as amended. In February 2005, we began operations in our current field, the medical patient safety market, through the acquisition of SurgiCount Medical, Inc., the developer of our proprietary Safety-Sponge® System, and in April 2005 changed our name from Franklin Capital Corporation to Patient Safety Technologies, Inc. to more appropriately reflect the focus of our operations.

Investments

The Company's legacy business prior to 2005 was as an investment company. As of the date of this annual report on Form 10-K, our investment portfolio is comprised solely of one remaining non-core asset, shares of Series F Convertible Preferred Stock of Alacra Corporation, which we acquired in April, 2000. The Series F Convertible Preferred Stock gives us the right, subject to Alacra having legally available funds, to have it redeemed by Alacra over a period of three years for face value plus accrued dividends (if any) beginning on December 31, 2006. We notified Alacra of our exercise of this right in December 2006 and Alacra completed the redemption of one-third of our preferred stock in December 2007. Since that time, Alacra has not redeemed any more of our Series F Convertible Preferred Stock. Based on discussions with Alacra management, we had anticipated redemption and subsequent receipt of funds for all of our remaining shares of Alacra Series F Convertible Preferred Stock (50% in each) in the fourth quarters of 2009 and 2010, respectively. However, despite our active dialogue with Alacra management

throughout 2010, they have not paid any of the remaining redemption amounts owed to us. Accordingly, we currently intend to proceed with all legal remedies available to us to obtain performance by Alacra of its redemption obligations, however no guarantee can be made as to the outcome of any such legal proceedings. As a result, during the fourth quarter of 2010 we recorded an impairment charge of $667 thousand to reduce the carrying value of this investment at December 31, 2010 to $0. For more information, see Note 8 to our Consolidated Financial Statements, appearing elsewhere in this annual report on Form 10-K.

Employees

As of December 31, 2010, we had approximately 13 full-time employees, which consisted of two executive officers, a supply chain executive, four sales focused employees, a corporate controller, three senior management level positions supporting our product development, quality and regulatory affairs, field and clinical support, along with an officer manager and administrative staff. As part of our proactive effort to optimize our cost structure, we regularly use a significant number of outside consultants for clinical support, implementation support, product development and other outside services. We intend to hire limited, additional personnel as our business grows, including converting some of the consultants used into employee positions when such actions are appropriate and cost justified. Utilizing this outside consultant approach allows us to minimize our fixed costs without significantly limiting the breadth or capabilities of our operations. Our employees are not represented by a labor union nor covered by a collective bargaining agreement. We believe that relations with our employees are very good.

13D Event and Subsequent Restructuring

On April 9, 2010 our current President and Chief Executive Officer, co-founder of our wholly-owned operating subsidiary SurgiCount Medical and co-inventor of our Safety-Sponge® System, Brian E. Stewart, filed a Form 13D with the Securities and Exchange Commission ("SEC") on behalf of himself and certain other shareholders of the Company. The shareholders represented included two of the Company's existing directors and the other co-founder of SurgiCount Medical and co-inventor of the Safety-Sponge® System and collectively represented a sufficient number of shares of the Company's stock outstanding to demand that the Company call a special meeting of stockholders with the express purpose of effecting significant and immediate change by removing five of the then standing directors of the board, including the then President and Chief Executive Officer. As a direct result of this shareholder effort, on June 24, 2010, the five designated members of the board of directors resigned and Brian E. Stewart was appointed as President and Chief Executive Officer and as a Director of the Company. Concurrently, the Company closed a financing consisting of approximately $6.1 million of convertible preferred stock (the "Series B Convertible Preferred"). Buyers of the Series B Convertible Preferred (each of whom is an accredited investor, as defined under Rule 501(a) of Regulation D of the Securities Act of 1933), consisted of A Plus, JMR Capital Ltd. and Catalysis Partners, LLC. Wayne Lin, a member of our Board of Directors is a founder and significant beneficial owner of A Plus and John P. Francis, a member of our Board, has voting and investment control over securities held by Francis Capital Management, LLC, which acts as the investment manager for Catalysis Partners, LLC (see the "Management's Discussion and Analysis of Financial Conditions and Results of Operations—Financial Condition, Liquidity and Capital Resources" and Note 12 to our Consolidated Financial Statements, in this annual report on Form 10-K for further background on the Series B Convertible Preferred stock financing). In connection with the resignation of the five directors, the Company entered into a Separation and Mutual General Release with each director ("Directors Release"), which provided that each director would not sue the Company and each gave a waiver of unknown claims and agreed to a two year non-disparagement clause. In addition, we extended the vesting and exercise periods in certain circumstances with respect to options held by the former directors and officers. See the Company's Current Report on Form 8-K filed June 29, 2010 for additional information.

Subsequent to the resignation of our previous President and Chief Executive Officer and four other board members, during the third quarter of 2010 newly appointed management implemented a comprehensive restructuring program focused on a number of initiatives, including the reduction of operating expenses and aggressively managing the Company to achieve positive operating income and operating cash flow. Restructuring activities included the elimination of certain job positions, lowering executive and employee cash compensation levels, refining and enforcing expense and travel policies and initiating spend measurement systems and accountability across various functional areas. As a result of a number of factors, primarily the continued growth of the Company's revenues from both delivery of Cardinal Health's stocking inventory (as discussed in "Cardinal Health – Exclusive U.S. Distributor" above), increased number of hospitals using the Company's products and the impact on operating expenses from the restructuring initiative, the Company reported positive operating income of $925 thousand during the quarter ended September 30, 2010, the first period of positive reported operating income in the history of the Company's ownership of SurgiCount since 2005 and the first reporting period under newly appointed management.

Available Information

Our periodic and current reports, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are available free of charge on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

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Other Information

Our principal executive offices are located at 2 Venture Plaza, Suite #350, Irvine, CA 92618 and our telephone number is (949) 387-2277. Our website is www.surgicountmedical.com. Our website and the information contained therein or connected thereto are not intended to be incorporated into this annual report on Form 10-K. The inclusion of our website address in this report does not include or incorporate by reference into this report any information on our website.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this annual report on Form 10-K, we have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Related to Our Business

We have a history of losses, expect future losses and cannot assure you that we will remain consistently profitable or generate consistent positive cash from operations.

Historically, the Company has incurred significant losses and has had negative cash flows from our operations. While we saw a significant improvement in the business results during the second half of 2010, as of December 31, 2010, our accumulated deficit was $56.6 million because of losses generated throughout the Company's history. While the Company generated its first reported operating profit since the Company's ownership of SurgiCount Medical in the third quarter of 2010, continued improved results at this level or better depends on continued customer acceptance and sales growth of our Safety-Sponge® System, managing our expenses in relative proportion to gross profits generated, and having the ability to raise capital to support our growth and future investment in technology development. In addition, as we work to expand adoption of our Safety-Sponge® System, because of how our sales cycle works (see "Business - Customers and Distribution"), our cash outlays typically increase before we begin to generate cash from selling to new customers. During the years ended December 31, 2010 and 2009, we had revenues of $14.8 million and $4.5 million respectively. 2010 reported revenues included $8.9 million of Forward Order related sales to Cardinal Health, our exclusive distributor, in accordance with the terms of our exclusive distributor arrangement (see "Management Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Results—Cardinal Health Supply Agreement"). If we are not successful in generating sufficient growth in revenues from sales of products used in our Safety-Sponge® System or we are unable to obtain sufficient capital to fund our efforts to further develop our technology and expand adoption of our Safety-Sponge® System, there can be no assurance that we will be able to maintain adequate liquidity to allow us to continue to operate our business or prevent the possible impairment of our assets. If this were to occur, investors could be at risk of losing all or part of their investment in our company.

We may need additional financing to maintain and expand our business, and such financing may not be available on favorable terms or not available at all.

While results achieved during the second half of 2010 suggests that our current level of revenues from the sales of products used in our Safety-Sponge® System may be sufficient to generate cash flow from operations, we have historically had to finance our negative cash flow from operating activities through additional cash proceeds from the sale of debt and equity securities. We believe that our existing liquidity, which includes $7.1 million of proceeds at the closing of a private placement on March 29 and 30, 2011 (see Note 21 to our consolidated financial statements

appearing elsewhere in this annual report on Form 10-K), along with our expected future cash flows from operations during 2011, are expected to be sufficient to meet our operating and capital requirements through at least the next 12 months. However, if projected cash flows from operations are not achieved as planned, or if capital requirements needed to expand our business exceed available cash balances, additional debt or equity financing may be required. At present we do not have any bank credit, and have historically relied upon selling equity to investors to raise cash. If additional debt or equity financing were to be raised in the future, it could require us to grant lenders a security interest in all or a portion of our assets and or to issue warrants to acquire our equity securities, resulting in dilution to our stockholders. In addition, any such debt financing could involve restrictive covenants, including limitations on our ability to incur additional debt, limitations on our ability to acquire or assign intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If additional equity financing is raised in the future, it would dilute our current shareholder's holdings in our company.

Future additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital when required or on acceptable terms, there can be no assurance that we will be able to maintain adequate liquidity to allow us to continue to operate our business, or prevent the possible impairment of our assets. If this were to occur, investors could lose all or part of their investment in our company.

Growth of our business is critical to our success. However, failure to properly manage our potential growth would be detrimental to our business.

We need to grow our business and expand adoption of our Safety-Sponge® System to succeed. However, substantial growth in our operations will place a significant strain on our existing resources available (including cash) and increase demands on our management, our operational and administrative systems and controls. In addition, because of how our sales cycle typically works (see "Business - Customers and Distribution"), any growth in our customer base typically requires the investment of a significant amount of cash and resources prior to generating any cash from such customers. There can be no assurance that our existing personnel, systems, procedures or controls or available financial resources will be adequate to support our growth in the future or that we will be able to successfully implement appropriate measures consistent with our growth strategy. While we have made significant progress during the last six months, we need to continually implement and maintain our operational and financial systems, policies, procedures and controls to expand, train and manage our employee base. We will also need to continue to attract, retain and integrate qualified personnel in all areas of our business. We cannot guarantee that we will be able to do so, or that if we are able to do so, we will be able to successfully integrate changes into our existing operations. Failure to manage our growth effectively could have a material adverse effect on our business, financial condition and results of operations.

Cardinal Health's right to use any excess inventory it holds to partially meet customer demand beginning in January of 2012 could have a material negative impact to our revenues and cash flows.

In March 2011, management and Cardinal Health signed an amendment to the Cardinal Health Supply and Distribution agreement (the "Amended Supply and Distribution Agreement"). The Amended Supply and Distribution Agreement amended a number of terms and conditions of the previous agreement, including but not limited to extending the termination date of the agreement from November 19, 2014 to December 31, 2015 and adding certain terms and provisions regarding target inventory levels and excess inventory of our products held by Cardinal Health. Until December 31, 2011, Cardinal Health is required to maintain any inventory in excess of such target inventory levels, including inventory from the Forward Order. Additionally, we were granted the right to buy back any such excess inventory from Cardinal Health at any time. Cardinal Health has agreed to not sell any of the Forward Order inventory until calendar year 2012, and we have agreed to a methodology for how Cardinal Health will sell this inventory to our customers, so there is an orderly release throughout the 2012 year that more reasonably minimizes its impact to the Company's sales during 2012. The methodology sets a formula which limits the use of any excess inventory used in a particular month over a 12 month time period.

Should Cardinal Health have any excess inventory on January 1, 2012 and begins selling the excess inventory it holds to partially meet customer demand, our reported revenues and cash flows will be negatively affected. The magnitude this negative impact could have on our 2012 revenue will depend on a number of factors, including but not limited to how much excess inventory Cardinal Health actually has on hand in 2012, whether the Company chooses to purchase some or all of this excess inventory, and what our actual sales growth rates are during 2011 and 2012. Actual sales during 2011 and 2012 will depend on a number of factors including but not limited to actual end-user demand and Cardinal Health's estimates of what inventory levels it needs to meet that demand. Management has no immediate plans to repurchase Cardinal Health's excess inventory, however we will consider this option should an appropriate opportunity arise. While we have not provided any estimates of what we expect 2011 or 2012 sales growth to be, in order to prevent a significant negative impact to 2012 revenue and cash flow, (i) the Company would need to experience substantial growth in the number of hospitals using its products during 2011 and 2012, (ii) the Company would need to buyback any excess inventory from Cardinal Health or (iii) Cardinal Health would need to decide not to use its excess inventory to partially meet customer demand. If the Company were to buyback excess inventory from Cardinal, it could have a significant negative impact to earnings, financial position and our liquidity.

Revenues are subject to significant variation due to Cardinal Health's ordering patterns, and expectations of the size and timing of new customer hospital implementations.

Our exclusive distribution agreement with Cardinal Health results in all of our current revenues coming from orders placed by Cardinal Health. Cardinal Health has discretion in the timing and quantities with the orders they place, subject only to the limits contained in our agreements with them. As a result, our revenues may not necessarily correlate with the actual growth of our underlying customer base. In addition, our revenue can be materially impacted by the size of new customer hospital systems being implemented and the expected timing of those implementations by us and our distribution partners. Size of hospital systems connotes the number of actual hospitals that are a part of the hospital system and the number of surgical procedures that are performed at each hospital. Implementations with our large hospital system customers like the Mayo Clinic in Rochester or the Cleveland Clinic in 2009 had a material impact on our reported revenue and revenue growth for the year 2009. The timing of when these larger hospital system implementations are expected to occur also have a significant impact on our annual reported revenue, as both we and our distribution partners need to ensure adequate inventory on hand to accommodate them. The decision process that our distribution partner Cardinal Health uses in determining when to place orders is complex and subject to significant judgment. If those judgments prove incorrect, our revenues may be materially adversely impacted. For example, some of the factors that go into these judgments include, but are not limited to: (i) the size of some new pending and possible customers, (ii) the distribution agreements new pending and possible hospital customers have with their distribution partners, (iii) the multiple formats our products need to be available in (Single Sterile and Bulk Non Sterile), and (iv) the location of the manufacturing facilities of our China based manufacturing partner and the lead times needed in manufacturing our products. Although growth in the number of hospitals is a relevant general indicator of growth in our business and customer acceptance of our products, it is not necessarily proportional to revenue because of the factors that impact revenue growth, including the number of actual customers represented by the hospitals using our products, the number of procedures such hospitals actually perform, the timing of orders of our products and the other factors described in this annual report on Form 10-K.

Cost containment measures implemented by hospitals could adversely affect our ability to successfully market our Safety-Sponge® System, which would have a material adverse effect on our business.

The economic downturn in the U.S. during the last few has increased the focus of many of our current and potential customers on implementing cost containment measures. Cost containment measures instituted by healthcare providers could negatively affect our efforts to expand adoption of our Safety-Sponge® System, which would have a have a material adverse effect on our business, prospects, financial condition and results of operations.

Global financial conditions may negatively impact our business, results of operations, financial condition and or liquidity.

Continued or further deterioration or volatility in general economic and financial market conditions could materially adversely affect our business, financial condition and results of operations. Specifically, the impact of these volatile and negative conditions may include decreased demand for our products and services, decreased ability to accurately forecast future product trends and demand, a negative impact on our ability to timely collect receivables from our customers, a negative impact on our sole supplier's ability to provide us with product inventory, and a negative impact on our access to the capital markets.

The volatility of our stock price can have a material adverse effect on our reported profit or loss due to operation of applicable accounting rules.

At December 31, 2010, we had a warrant derivative liability recorded on our consolidated balance sheet with an estimated fair value of $992 thousand. Under applicable accounting rules, we are required to "mark to market" this liability each reporting period and record changes in the fair value associated with this liability in our consolidated statement of operations (see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies - Warrant Derivative Liability"). As such, when our stock price increases, the fair value of this liability increases, and we recognize an expense associated with this change in fair value. Similarly, when our stock price decreases, the fair value of this liability decreases, and we recognize a gain associated with this change in fair value. As such, though there is no cash flow impact to us caused by the volatility of our stock price (which ranged from a high of $1.90 to a low of $0.45 in the year ended December 31, 2010) applicable accounting rules have a direct impact on our reported profit or loss as per Generally Accepted Accounting Principles.

Although we do not manufacture the products for our Safety-Sponge® System, if one of our products proves to be defective or is misused by a health care practitioner, we may be subject to potential product liability risks, among others, which may not be covered by insurance, and could adversely affect our reputation, profitability and liquidity.

Although we do not manufacture the sponges, towels and scanner equipment used in our Safety-Sponge® System, a defect in the design or manufacture of our sponges, towels or scanner equipment could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Misuse of our products by a practitioner that results in an injury could subject us to liability. The nature of our business exposes us to potential product liability risks, which are inherent in the design, manufacture and distribution of medical products and systems, as well as the clinical use, manufacturing, marketing and use of our Safety-Sponge® System. Even though the Company carries what management believes to be adequate product liability insurance coverage, this insurance coverage may not be adequate to cover all risks and continuing insurance coverage may not continue to be available at an acceptable cost, if at all. In addition, we are exposed to the risks under our indemnification program, where if our Safety-Sponge® System is used properly but does not prevent the unintentional retention of one of our surgical sponges or towels. If we are required to indemnify customers for a significant number of events, our insurance may not cover the entire cost. Regardless of merit or eventual outcome, product liability claims or a high number of indemnifiable events could result in decreased demand for our products, injury to our reputation and loss of revenues. A substantial underinsured loss or product recall could have a material adverse effect on our financial condition, results of operations and cash flows. Furthermore, any impairment of our reputation could have a material adverse effect on our revenues and prospects for future business.

Our future reported financial results could be adversely impacted by impairments or other charges to our intangible assets.

As of December 31, 2010, we had goodwill of $1.8 million and other intangible assets of $2.8 million (or 18.8% and 28.6%, respectively of our total assets at year end). We are required to test goodwill and other intangible assets to determine whether there has been any impairment on an annual, or an interim basis if certain events occur or circumstances change that may result in reducing the carrying value of our goodwill or our intangible assets (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies" below). If circumstances change such that we are required to take an impairment charge, the amount of such annual or interim impairment charge could be significant and could have a material adverse effect on our financial condition and results of operations.

We have limited sales and marketing experience and in-house resources, and our failure to build and manage our sales efforts, or failure to market our products effectively would negatively affect our ability to grow our revenues and implement our growth strategy.

We currently have limited sales and marketing resources and experience in-house. We rely on a number of outside consultants and our distribution partners to complement our full-time employees who focus on these areas. If we do not select and work with our outside consultants effectively, or our distribution partners fail to provide adequate sales and marketing support, it could have a material adverse effect on our financial condition and results of operations. Additionally, no assurance can be given that we will be able hire additional sales or marketing personnel, or outside consultants, with the necessary skill and experience, or that we will be able to train such individuals properly, any of which could have a material adverse event on our growth, financial condition and results of operations.

As all sales personnel are employees at will, no assurance can be given that some or all of them will not seek employment on better terms for themselves elsewhere or, in such event, that we will be able to retain replacement sales personnel with appropriate skills and experience. Our failure to retain our current sales personnel could have a material adverse effect on our revenue, financial condition and results of operations.

If competitors become well capitalized, or we are not able to offer and/or supply our solution to customers, our market growth could be negatively impacted.

The market place in which we compete in has many smaller competitors that we do not consider to be a significant threat to our market growth because we believe that those companies are not well capitalized. Should one or more of these competitors become well capitalized or should our estimates of their capitalization prove incorrect, we could experience significant competition in our market place. We also believe that customers in our markets display a significant amount of loyalty to their hospital distributors, and to the extent we are not able to offer and/or supply our patented solution to eliminate retained surgical sponges and towels, customers may elect to buy the different solutions available from our competitors. These factors could cause our competitive position to suffer which could have a material adverse effect on our pricing, revenue, financial condition and results of operations.

The company has significant related party transactions with its exclusive manufacturer, A Plus. Wayne Lin, A Plus' founder and significant shareholder is also a significant shareholder and a member of the board of directors of the Company. There are risks that having significant related party transactions may result in not having terms that are arm's length or unfair to the company, even though we have company policy over related party transactions that requires the involvement of our executive team and board of directors to review and approve such related party transactions on an ongoing basis.

From time to time we have engaged into transactions with related parties, including the purchase from or sale to of products and services from related parties, where these related parties were paid in cash and or company stock. We have policies and procedures in place that require the pre-approval of related party transactions, including loans with any related parties. Notwithstanding these policies, we cannot assure that in every historical instance that the terms of the transactions with past related parties were on terms as fair as we might have received from or extended to third parties. Related party transactions in general have a higher potential for conflicts of interest than independent third-party transactions, and having related party transactions could result in potential significant losses to our company and could impair investor confidence, adversely affecting our business reputation and our stock price.

Any failure in our customer education and training efforts could negatively affect our efforts to expand adoption of our Safety-Sponge® System and our financial condition and results of operations.

It is important to the success of our sales efforts that our clinical support staff properly educates operating room nurses and staff in the techniques of using our Safety-Sponge® System. Such training and education is a key component of our sales process (see "Business—Sales and Clinical Support" above). Positive results using our Safety-Sponge® System are highly dependent upon proper training and education. If our Safety-Sponge® System is used sub-optimally or improperly, such use may contribute to unsatisfactory patient outcomes or failure to prevent one of our products from being unintentionally retained inside a patient. This could give rise to negative publicity or lawsuits against us, any of which could have a material adverse effect on our reputation as a medical device company, and on our revenue, financial condition and results of operations.

Our reliance on third parties for the supply and distribution of, and on proper training of hospital personnel in the use of, the surgical sponge and towel products used in our Safety-Sponge® System exposes us to risk of lack of quality control, which could harm our reputation and have a material adverse effect on our reputation as a medical device company, and on our financial condition and results of operations.

Our Safety-Sponge® System is dependent on proper technique, including the proper handling and use of the scanner device, surgical sponges and towel products used therein. There are a number of third parties that handle such products in our supply and distribution chain, as well as at the hospitals who have adopted our system, over which and whom we have no control. Although we have put in place contractual arrangements to ensure quality control in the supply and distribution chain, and although we engage in extensive training and provide clinical support to ensure proper technique and use or our products by our hospital customers, we cannot guarantee that such third parties will not mishandle or misuse the scanner, surgical sponges and towel products used in our Safety-Sponge® System. Because we are not directly involved in the supply and distribution of our products (see "Business– Customers and Distribution – Cardinal Health – Exclusive U.S. Distributor"), we may not be aware of quality control issues that arise with our customers. Moreover, we might not be aware of improper handling techniques at our hospital customers. If such quality control issues arise and we are not able to promptly remedy them, it could harm our reputation and have a material adverse effect on our revenue, financial condition or results of operations.

We rely on a sole supplier for manufacture of the surgical sponges and towels used in our Safety-Sponge® System.

We have an exclusive supply arrangement with A Plus for the manufacture of the surgical sponge and towel products used in our Safety-Sponge® System (see "Business - Manufacturing" above). While we believe our relationship with A Plus is on good terms, we cannot assure you that we will be able to maintain our relationship with A Plus or that A Plus will be able to continue manufacturing adequate supplies of our products in the future. In addition, A Plus is considered to be a related party of the Company, as described above. While we believe that we could find alternative suppliers, in the event that A Plus fails to meet our needs, a change in suppliers or any significant delay in our ability to supply products for resale would have a material adverse effect on our delivery schedules, which could have a material adverse effect on our reputation, revenue, financial condition and results of operations.

A primary component of our disposable sponges and towels is cotton and those products are currently manufactured for us primarily in China. Accordingly, we are exposed to risks associated to the supply of cotton, the price of cotton and the Yuan/US Dollar currency exchange rates.

Our exclusive supply agreement with A Plus for the manufacture of our surgical sponge and towel products allow for annual cost increases if there are significant increases in a certain cotton index, or significant changes in the Yuan/Dollar exchange rate. Cotton prices have increased significantly this last twelve months, and we have received a reasonable cost increase in 2011 as a result. However if there continues to be significant price increases for cotton, and or significant changes in the Yuan exchange rates, this could have a material impact on our product cost, causing potentially a negative impact on our revenue should we raise prices accordingly, and or a negative impact on our results of operations from lower profitability. Additionally with A plus operating out of the People's Republic of China we cannot assure that the Chinese government will not alter its policies to further restrict foreign participation in businesses operating in China, further there is no assurance that the Chinese government will continue to pursue the current economic reform policies, or that it will not significantly alter these policies from time to time without notice and the future direction of these economic reforms is uncertain.

We rely on a number of third parties in the execution of our business plan. If such third parties do not perform as agreed, or relations with such third parties are not good, it could harm our reputation and disrupt our business, which could have a material and adverse effect on our revenue, financial condition and results of operations.

We rely on a number of third parties in the execution of our business plan. Examples include contracting for nurses to support clinical trials and new customer implementations, technology experts to assist the software maintenance and development of our software applications, and various consultants to support our marketing, accounting and other functions. We also have an exclusive manufacturing arrangement with A Plus (see above) and have an exclusive distribution arrangement with Cardinal Health for the distribution of disposable sponge and towel products used in our Safety-Sponge® System (see "Business - Customers and Distribution - Cardinal Health - Exclusive U.S. Distributor" above). Although we believe that our relationships with all of the third-parties we work with are good, if such third parties fail to honor their contract obligations or the relationships deteriorate, it could lead to disruptions in our business while we negotiate replacement agreements and find other suppliers or distributors for our products. In addition, there is no guarantee that we would be able to negotiate a distribution agreement with a contract party comparable to Cardinal Health, or be able to obtain comparable contract provisions in terms of pricing and quality control. These disruptions, or inability to effectively distribute our products, could harm our reputation and customer relationships, which could have a material adverse effect on our financial condition and results of operations.

We intend to pursue opportunities for further expansion of our business through strategic alliances, joint ventures and or acquisitions. Future strategic alliances, joint ventures and or acquisitions may require significant resources and could result in significant unanticipated costs or liabilities to us.

Over the next few years we intend to pursue opportunities for further expansion of our business through strategic alliances, joint ventures and or acquisitions. Any future strategic alliances, joint ventures and or acquisitions will depend on our ability to identify suitable partners or acquisition candidates, negotiate acceptable terms for such transactions and obtain financing if necessary. We also could face competition for suitable acquisition candidates

which may increase our costs. Acquisitions or other investments require significant management attention, which may be diverted from our other operations. Any future acquisitions could also expose us to unanticipated liabilities. If we engage in strategic acquisitions, we may experience significant costs and difficult assimilating operations or personnel, which could impact our future growth.

If we make any acquisitions, we could have difficulty assimilating operations, technologies and products, or integrating and retaining personnel of acquired companies. In addition, acquisitions may involve entering markets in which we have no or limited prior experience. The occurrence of any one or more of these factors could disrupt our ongoing business, distract our management and employees and increase our expenses. In addition, pursuing acquisition opportunities could divert our management's attention from our ongoing business operations and result in decreased operating performance. Moreover, our profitability may suffer because of acquisition related costs or amortization of intangible assets. Furthermore, we may have to incur debt or issue equity securities in future acquisitions, with the issuance of equity securities diluting our existing stockholders.

We depend on our executive officers and key personnel to implement our business strategy and could be harmed by the loss of their services. In addition, competition for qualified personnel is intense.

We believe that our growth and future success will depend in large part upon the knowledge, skills experience of our executive team. In particular, our success depends in part upon the continued service and performance of: Brian E. Stewart, our President and Chief Executive Officer, and David C. Dreyer, our Chief Financial Officer and Secretary. Although we have employment agreements with Mr. Stewart and Mr. Dreyer, the loss of the services of one or both of these executive officers would adversely affect our ability to implement our business and growth strategy.

We cannot assure investors that we will be able to retain our existing key personnel or to attract additional qualified personnel. In addition, we do not have key-person life insurance on any of our employees. The loss of our key personnel or an inability to continue to attract, retain and motivate key personnel could adversely affect our business.

We have experienced historical turnover in our chief executive officer position and board of directors, and if we continue to have frequent executive turnover, we may have difficulty implementing our business plan and growth strategy.

From January 2007 to the present, we have had six different Chief Executive Officers, and in June 2010, five of our directors resigned (see Item 1 “13D and Subsequent Restructuring”). Our history of management and director turnover, combined with the large losses reported by us under the leadership of our previous executives, may raise concern as to the stability of management and Board of Directors. Such instability has made it difficult to implement our business plan and strategy in the past, and any continued instability will affect our ability to implement our business plan and growth strategy in the future.

Risks Related to Our Industry

Our success is dependent on intellectual property rights held by us, and our business will be adversely affected if we are unable to protect these rights.

Our success depends, in part, on our ability to maintain and defend our patents protecting the technology in our proprietary Safety-Sponge® System. However, we cannot guarantee that the technologies and processes covered by our patents will not be found to be obvious or substantially similar to prior work, which could render these patents unenforceable. If we are not able to successfully protect and defend our intellectual property, it could have a material adverse effect on our business, revenue, financial condition and results of operations.

Defending against intellectual property infringement claims could be time-consuming and expensive, and if we are not successful, could cause substantial expenses and disrupt our business.

We cannot be sure that the products and technologies used in our business do not or will not infringe valid patents, trademarks, copyrights or other intellectual property rights held by third parties. We may be subject in the ordinary course of our business to legal proceedings and claims relating to the intellectual property or derivative rights of others. Any legal action against us claiming damages or seeking to enjoin commercial activities relating to the affected products or our methods or processes could:

- require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected products, methods or processes, and such a license may not be available on commercially reasonable terms, if at all;
-

prevent us from making, using or selling the subject matter claimed in patents held by others and subject us to potential liability for damages;

- consume a substantial portion of our managerial and financial resources; or

- result in litigation or administrative proceedings that may be costly or not covered by our insurance policies, whether we win or lose.

If any of the foregoing were to occur, it could have a material adverse effect on our financial condition and results of operations.

We may not be able to protect our intellectual property rights outside the United States.

Intellectual property laws outside the United States are uncertain and in many countries are currently undergoing review and revision. While we do not sell our products outside the U.S. currently, it is a part of our growth strategy to expand into foreign markets. The laws of some countries do not protect our intellectual property rights to the same extent as laws in the United States. The intellectual property rights we enjoy in one country or jurisdiction may be rejected in other countries or jurisdictions, or, if recognized there, the rights may be significantly diluted. It may be necessary or useful for us to participate in proceedings to determine the validity of our foreign intellectual property rights, or those of our competitors, which could result in substantial cost and divert our resources, efforts and attention from other aspects of our business. If we are unable to defend our intellectual property rights internationally, it could limit our ability to execute a growth strategy to expand into foreign markets which could materially and adversely affect our revenue, financial condition and results of operations.

Our business is subject to extensive regulation and we need FDA clearances and approval to distribute and market our products.

Our Safety-Sponge® System is considered a medical device and is subject to extensive regulation. Although we believe that we are in compliance with all material applicable regulations, current regulations depend heavily on administrative interpretation. We are also subject to periodic inspections by the FDA and other third party regulatory groups, as is our exclusive manufacturer, A Plus. Future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, could vary from current interpretations and may adversely affect our business.

Laws and regulations regarding the design, development, manufacture, labeling, distribution and sale of medical devices are subject to future changes, as are administrative interpretations of regulatory requirements. Failure to comply with applicable laws or regulations would subject us to enforcement actions, including, but not limited to, product seizures, injunctions, recalls, possible withdrawal of product clearances, civil penalties and criminal prosecutions, all of which could have a material adverse effect on our revenue, financial condition and results of operations.

If we fail to comply with applicable healthcare regulations that include the potential for substantial penalties, our business, operations and financial condition could be adversely affected as a result.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patient's rights may be applicable to our business and may have a negative impact on our business beyond our control, including subjecting us to burdensome compliance obligations. The laws that may affect our operations include:

- The federal healthcare program Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving or providing remuneration, directly or indirectly, to induce (i) the referral of an individual, for an item or service, or (ii) the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPPA, which prohibits executing a scheme to defraud any healthcare benefit program or make false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- State law equivalents of each of the above federal laws, such as anti-kickback and false claim laws that may apply to items or services reimbursed by any third party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ in significant ways from state to state and often are not preempted by HIPPA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethic codes, and spending limits, and other states, such as Vermont, Maine, Minnesota, requiring reporting to state government of gifts, compensation and other remuneration to physicians. Federal legislation, the Physician Payments Sunshine Act of 2009, has been proposed and is moving forward in Congress. This legislation would require disclosure to the federal government o payments to physicians. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with difference compliance and reporting requirements, increases the possibility that a company may unintentionally run afoul of one or more laws.

If operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Recently adopted healthcare reform legislation may adversely affect our business.

The U.S. healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. On March 23, 2010, healthcare reform legislation (the "Healthcare Legislation") was approved by Congress and has been signed into law that seeks to, among other things, increase access to healthcare for the

uninsured and control the escalation of healthcare expenditures within the economy. This legislation has only recently been enacted and requires the adoption of implementing regulations, which may impact our business. Given the state of the new healthcare legislation, it's far too early to evaluate its impact on our business and on our customers. Changes in regulations and healthcare policy occur frequently and may impact our results, growth potential and the profitability of products we sell. The Healthcare Legislation could result in changes to governmental reimbursement programs and possibly result in consolidating healthcare providers potentially reducing the number of available customers, both of which could have negative effects on our efforts to expand adoption of our Safety-Sponge® System, hurting our business, financial condition and results of operations.

Our failure to respond to rapid changes in technology and its applications and intense competition in the medical devices industry could make our system obsolete.

The medical devices industry is subject to rapid and substantial technological development and product innovations. To be successful, we must respond to new developments in technology and new applications of our existing technology. Our limited resources may limit our ability to innovate and respond to such developments. In addition, we compete against several companies offering alternative systems, some of which have, or could obtain greater financial, marketing and technical resources than us. If our products fail to compete favorably against competing products, or if we fail to be responsive on a timely and effective basis to competitors' new devices, applications, or price strategies, it could have a material adverse effect on our revenue, financial condition and results of operations.

Risks Related to Our Common Stock

Our common stock is only minimally traded and could remain so for some time. Our stock price has been and is expected to continue to be volatile, and the market price of our common stock could drop significantly.

In the year ended December 31, 2010, our stock price ranged from a high of $1.90 to a low of $0.45 per share. Stock markets in general have experienced substantial volatility in recent years that has often been unrelated to the operating performance of individual companies. Our stock price volatility is attributable, in part, to our very low average daily trading volumes. Broad market fluctuations may also adversely affect the trading price of our common stock.

Future sales of our common stock could adversely affect its price and our future capital-raising activities, and could involve the issuance of additional equity securities, which would dilute current shareholder investments in our common stock and could result in lowering the trading price of our common stock.

We may sell securities in the public or private equity markets if and when conditions are favorable. Sales of substantial amounts of common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our common stock and our ability to raise capital. We may issue additional common stock in future financing transactions or as incentive compensation for our management team and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. The market price for our common stock could decrease as the market takes into account the dilutive effect of any of these issuances. Furthermore, we may enter into financing transactions and issue securities with rights and preferences senior to the rights and preferences of our common stock, and we may issue securities at prices that represent a substantial discount to the market price of our common stock. A negative reaction by investors and securities analysts to any discounted sale of our equity securities could result in a decline in the trading price of our common stock.

We have a significant number of outstanding warrants and options, and future sales of these shares could adversely affect the market price of our common stock.

As of April 1, 2011, we had outstanding warrants for an aggregate of 7.3 million shares of common stock at a weighted average exercise price of $1.53 per share and options exercisable for an aggregate of 8.0 million shares of common stock at a weighted average exercise price of $0.88 per share. The holders may sell these shares in the public markets from time to time, without limitations on the timing, amount or method of sale. As our stock price rises, more outstanding warrants and options will be in-the-money and the holders may exercise their warrants and options and sell a large number of shares. This could cause the market price of our common stock to decline.

Our common stock is quoted on the OTC QB market place, which may have an unfavorable impact on our stock price and liquidity.

Our common stock is currently quoted under the symbol “PSTX” on the OTC QB market operated by OTC Markets Group, Inc. Prior to February 2007, our stock was listed on the American Stock Exchange, now known as the NYSE Amex, under the symbol “PST.” Prior to March 1, 2011, our stock was quoted on the OTC Bulletin Board under the symbol “PSTX.” The OTC Bulletin Board and the OTC QB market are not “national securities exchanges”, nor do they have any listing standards to which we are bound, and in general are significantly more limited markets than the New York Stock Exchange, NASDAQ system, or our former trading market, now known as the NYSE Amex. The quotation of our shares on the OTC QB could result in a less liquid market being available for existing and potential stockholders to trade shares of our common stock, which could depress the trading price of our common stock and have long-term adverse impact on our ability to raise capital in the future. Because of the limited trading market for our common stock, and because of the significant price volatility, investors may not be able to sell their shares of common stock when they want to do so. In the year ended December 31, 2010, our stock price ranged from a high of $1.90 to a low of $0.45 per share. The inability to sell shares in a rapidly declining market may substantially increase the risk of loss as a result of such illiquidity, because the price for our common stock may suffer significant declines due to price volatility.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never paid cash dividends on our common stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility, and the terms of our Series A Preferred Stock and Series B Preferred Stock, may preclude us from paying dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be the sole source of potential gain in the foreseeable future. Investors seeking cash dividends should not invest in our common stock. We do pay cash and stock dividends on our Series A and Series B Preferred stock in accordance with their terms. Starting in January 1, 2012, we will be required to pay cash dividends on our Series B preferred stock in the amount of approximately $110 thousand per quarter.

Common stockholders may not be able to elect a majority of our Board of Directors.

The terms of our Series A Preferred Stock provide that if at any time dividends on the Series A Preferred Stock shall be unpaid in an amount equal to two full years' of dividends (eight quarters), until such time as all dividends in arrears have been paid, the holders of the Series A Preferred Stock shall have the right to elect a majority of our Board of Directors. If the company was not able to obtain financing, and not able continue to pay dividends on our Series A Preferred Stock, holders of our common stock would lose their ability to control our Board of Directors, as the holders of the Series A Preferred Stock would have the right to elect a majority of our Board of Directors. We are currently in arrears on six quarters to the Series A Preferred Stock. We do not intend to go into arrears beyond six quarters, and eventually intend to become current with our Series A Preferred Stock. Our Series B Preferred does not have voting rights except (i) as provided by Delaware law; (ii) upon the occurrence of the fifth anniversary of the issue date; or (iii) upon our failure to pay dividends for two consecutive quarters or three non-consecutive quarters. Upon the occurrence of either event described in (ii) or (iii), the holders of the Series B Preferred are entitled to elect two additional directors to our board of directors and, within two business days, we must create a special committee of our board of directors consisting of up to three directors, of which two must be the two newly-elected additional directors, and promptly grant such special committee sole and exclusive authority and power to investigate, negotiate and consummate a sale of the Company or strategic alternative thereto.

We are subject to penny stock regulations and restrictions, which could make it difficult for stockholders to sell their shares of our stock.

SEC regulations generally define "penny stocks" as equity securities that have a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exemptions. As of April 1, 2011, the last sale price for our common stock was $0.85 per share. For transactions in securities that are not exempt from the "penny stock" definition, the SEC has adopted rules and regulations that impose additional sales practice requirements on broker-dealers prior to selling penny stocks, which may make it burdensome to conduct transactions in our shares. Because our shares are subject to these rules, it may be difficult to sell shares of our stock, and because it may be difficult to find quotations for shares of our stock, it may be very difficult to accurately price an investment in our shares. In addition, the SEC has the authority to restrict any person from participating in a distribution of a penny stock if the SEC determines that such a restriction would be in the public interest.

The Financial Industry Regulatory Authority, or FINRA, sales practice requirements may also limit a stockholder's ability to buy and sell our stock.

In addition to the penny stock rules described above, the FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional

customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, the FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and applicable Delaware law may prevent or discourage third parties or our stockholders from attempting to replace our management or influencing significant decisions.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change in control of our company or our management, even if doing so would be beneficial to our stockholders. These provisions include:

- authorizing our Board of Directors to issue preferred stock without stockholder approval;
- limiting the persons who may call special meetings of stockholders;
- prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 % stockholder approval; and
- requiring advance notice for raising business matters or nominating directors at stockholders' meetings.

As a Delaware corporation, we are also subject to section 203 of the Delaware General Corporation Law ("DGCL"), which among other things, and subject to various exceptions, restricts against certain business transactions between a corporation and a stockholder owning 15% or more of the corporation's outstanding voting stock ("an interested stockholder") for a period of three years from the date the stockholder becomes an interested stockholder. The Delaware corporate law, in general, prohibits any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real estate or other physical properties materially important to our operations. In November 2010, we relocated our corporate headquarters to 2 Venture Plaza, Suite #350, Irvine, CA 92618, where we rent approximately 5,000 square feet of office space. In January 2010, previous management temporarily relocated our headquarters to 5 Caufield Place, Suite 102, Newtown, PA 18940 (the CEO and CFO at the time were based in Pennsylvania), where they entered into a sublease on December 31, 2009 for 5,670 square feet of office space. Effective in June 2010, we took a charge of $371 thousand for the present value of the remaining lease payments of the Newtown property and at the time assumed there would be no sub-sublease income to offset this cost, given the soft local commercial real estate rental market. However, in November 2010, we entered into a sub-sublease with Centrak, to take over the space in Newtown, PA, where they agreed to sub-sublease the space through the remaining term of our sublease or through to April 30, 2013, paying $8,225 per month starting in January 2011 for each month during months one (1) through twelve (12), (ii) $8,697 per month for months thirteen (13) through twenty four (24), and (iii) $9,170 per month for months twenty five (25) through the expiration of the Sub-Sublease. The base rent paid by Centrak includes landlord operating expenses, taxes and utilities that a reasonable tenant making comparable use of the subleased premises to that being made by the Sub-Subtenant would typically incur. The Sub-Subtenant will be responsible for any additional utility costs that are not our responsibility. As a result of this sub-sublease arrangement, the Company adjusted its charge taken in the second quarter of 2010 by reducing it $219 thousand for the present value of expected sub-subrental income to be received through to the end of this sublease.

We also vacated our approximate 4,000 square feet of office space at our former headquarters located at 43460 Ridge Park Drive, Suite 140, Temecula, CA 92590 on December 31, 2010, which was the termination date in our lease. During 2010, we paid $11,576 per month in rent for our temporary Pennsylvania headquarters through to June 2010, paid $9,757 per month in rent for our former Temecula office space through to the termination of the lease at Dec. 31, 2010, and paid $0 cash for rent of our Irvine, CA corporate headquarter space. The Irvine, CA corporate headquarters lease had “free rent” for the first two months in 2010, with the first cash rent payment due in January 2011. As a result, we amortized this free rent over the term of the lease, resulting in recording $15 thousand of rent expense for this property in 2010. We also did not receive any sub sublease rental income from Centrak, our sub-sublease tenant in Newtown, PA until January 2011, in accordance with our sub-sublease agreement with them.

ITEM 3. LEGAL PROCEEDINGS

Leve Matter

On October 15, 2001, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. filed a lawsuit against our company, Sunshine Wireless, LLC, and four other defendants affiliated with Winstar Communications, Inc. This lawsuit alleged that the Winstar defendants conspired to commit fraud and breached their fiduciary duty to the plaintiffs in connection with the acquisition of the plaintiff's radio production and distribution business. The complaint further alleged that our company and Sunshine joined the alleged conspiracy. On February 25, 2003, the case against our company and Sunshine was dismissed. However, on October 19, 2004, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. exercised their right to appeal. On June 1, 2005, the United States Court of Appeals for the Second Circuit affirmed the February 25, 2003 judgment of the district court dismissing the claims against us.

On July 28, 2005, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. filed another lawsuit against our company, Sunshine and four other defendants affiliated with Winstar. That lawsuit attempted to collect a federal default judgment of $5 million entered against two entities, Winstar Radio Networks, LLC and Winstar Global Media, Inc., by attempting to enforce the judgment against our company and others under the doctrine of de facto merger. The action was tried before a Los Angeles County Superior Court judge, without a jury, in 2008. On August 5, 2009, the Superior Court issued a statement of decision in our favor, and on October 8, 2009, the Superior Court entered judgment in our favor, and judged plaintiffs' responsible for our court costs. On November 6, 2009, the plaintiffs filed a notice of appeal in the Superior Court of the State of California, County of Los Angeles Central District. We have engaged appellate counsel, and believe the plaintiff's case is without merit and intend to continue to defend the case vigorously.

Ault Glazer Matter

On December 30, 2010, the Company entered into a Settlement Agreement, dated as of December 27, 2010 (the "Agreement"), with the parties to the Agreement other than the Company being Ault Glazer Capital Partners, LLC ("AGCP"), Zealous Asset Management, LLC ("ZAM") and certain of its affiliates, Milton "Todd" Ault III and a creditor (and such creditor's affiliate) to AGCP, who also is a shareholder of the Company (the "AGCP Creditor"). The former relationship of Mr. Ault and AGCP to the Company has been previously disclosed in the Company's public filings. The Agreement related to (i) our previously disclosed Amendment and Early Conversion agreement, dated September 5, 2008 (the "Note Agreement"), between the Company and AGCP and the related and previously disclosed Secured Convertible Promissory Note dated on or about August 10, 2008 (the "Note") and a related and previously disclosed Advancement Agreement between the same parties dated September 12, 2008 (together with the Note and Note Agreement, the "Note Documents"); under the Note Documents, there was an original principal balance of $2,530,558.40 and Note Documents provided, subject to certain conditions, that the entire principal balance owing under the Note would be converted into 1,300,000 shares of our common stock and other consideration; all but 500,000 of which shares of our common stock (such 500,000 shares, the "Shares"), were previously delivered to AGCP, (ii) a judgment obtained against AGCP by AGCP Creditor in a separate lawsuit, which lawsuit is completely unrelated to the Company, with respect to which, as the Company previously disclosed, AGCP Creditor procured a Writ of Execution from the United States District Court, Central District of California, (the "Writ") and a Notice of Levy (the "Levy") to levy upon the Company against all stock of the Company that the Company owed to AGCP; and (iii) a previously disclosed case currently pending before the Superior Court of California, County of Orange, Central Justice Center, entitled "Zealous Asset Management, LLC v. Patient Safety Technologies, et. al", Case No. 00424948 (the "Action") concerning, among other things, the Note Documents, as well as 2,600 shares of our Series A Preferred Stock (the "Series A Preferred") and certain dividends thereon.

In broad terms the Agreement provided that the Company delivers to AGCP Creditor the Shares that, as the Company has previously disclosed, it conditionally owed to AGCP, and AGCP dismissed the Action against the Company upon receiving the Shares, AGCP Creditor terminated the Writ and Levy and agreed that its judgment against AGCP was satisfied. In addition, the Note Documents and the liabilities thereunder were deemed satisfied and extinguished. The Company was carrying a liability on its books in connection with the Note Documents of approximately $1.42 million and the fair value of the (500 thousand common) Shares issued was less than the carrying value of such liability, the Company recorded a non-cash gain on the extinguishment of debt totaling $893 thousand in the fourth quarter of 2010. Generally, the material terms of the Agreement became effective after the Company delivered the Shares to the AGCP Creditor, and made a cash payment of $16 thousand to AGCP's counsel on Dec. 31, 2010. Shortly after Dec. 28, 2010, AGCP dismissed the causes of action in the Action related to the Note Documents, and granted certain releases and covenants not to sue the Company. In addition, there were causes of action in the Action relating to the Series A Preferred shares owned by AGCP that were dismissed after the Company interpleaded a total of $22.8 thousand of dividends owed on these Series A Preferred shares in January 2011 ($9.1 thousand) and March 2011 ($13.7 thousand). The Agreement also contained a provision pertaining to the interpleading of future dividends on these Series A Preferred shares, which the Company plans to follow when such dividends become payable. Accordingly, the terms of the Agreement have become fully effective.

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ITEM 4. (REMOVED AND RESERVED)

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently quoted under the symbol "PSTX" on the OTC QB market operated by OTC Markets Group, Inc. Prior to February 2007, our stock was listed on the American Stock Exchange, now NYSE Amex, under the symbol "PST." Prior to March 1, 2011, our stock was quoted on the OTC Bulletin Board under the symbol "PSTX."

The following table sets forth the high and low bid quotations for our common stock for the periods indicated below, as reported by the OTC Bulletin Board. Such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission and may not necessarily represent actual transactions in our common stock.

	High	Low
Year Ended December 31, 2010		
First Quarter	$ 1.90	$ 0.85
Second Quarter	1.20	0.55
Third Quarter	0.90	0.45
Fourth Quarter	0.99	0.65
Year Ended December 31, 2009		
First Quarter	$ 1.20	$ 0.47
Second Quarter	1.10	0.60
Third Quarter	1.40	0.70
Fourth Quarter	2.25	1.06

Stockholders

As of April 1, 2011, there were 690 holders of record of our common stock.

Dividends

We have not paid any dividends on our common stock in the last two fiscal years and currently have no intention of paying dividends on our common stock. Terms of our Series A Convertible Preferred Stock and Series B Preferred limit our ability to pay any such dividends on our common stock.

Recent Sales of Unregistered Securities

In February 2011, in connection with a consulting agreement with Kenneth Taub, we issued Mr. Taub 75,000 restricted shares of our common stock. These shares are restricted under Rule 144 of the Securities Act.

In addition, we issued 60,500 shares of $1 par value, $100 stated value Series B Preferred Convertible Shares on June 24, 2010 raising $6.1 million (of which 500 were issued on December 6, 2010). See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Condition, Liquidity and Capital Resources". See also the Subsequent Event discussion regarding our March 2011 offering.

The Series B Convertible Preferred does not have voting rights except (a) as provided by Delaware law; (b) upon the occurrence of the fifth anniversary of the issue date; or (c) upon our failure to pay dividends for two consecutive quarters or three non-consecutive quarters. Upon the occurrence of either event described in (b) or (c), the holders of the Series B Convertible Preferred are entitled to elect two additional directors to our Board of Directors and, within two business days, we must create a special committee of our Board of Directors consisting of up to three directors, of which two must be the two newly-elected additional directors, and promptly grant such special committee sole and exclusive authority and power to investigate, negotiate and consummate a sale of our company or strategic alternative thereto. The Series B Convertible Preferred are entitled to receive, prior and in preference to all other shares of our capital stock (with an exception noted below), upon liquidation, dissolution or winding up of our company an amount per share equal to the greater of (i) the stated value of the Series B Convertible Preferred, plus accrued but unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series B Convertible Preferred been converted into our common stock immediately prior to such liquidation. Notwithstanding the foregoing, the first $1.1 of distributable amounts in liquidation must first be paid to the holders of our Series A Convertible Preferred Stock. Mergers, sales of substantially all assets and similar transactions are deemed to be liquidations for purposes of the liquidation preference.

The Series B Convertible Preferred is convertible at any time at the option of the holder into shares of our common stock at $0.75 per share, subject to conventional adjustments for stock splits, stock combinations and the like. We are subject to certain liquidated damages if we fail to timely honor our conversion obligations as set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. The Series B Convertible Preferred is not redeemable either by us or by the holders. However, shares of our Series B Convertible Preferred automatically convert into shares of our common stock at the $0.75 conversion price if both of the following conditions are satisfied: (a) the daily volume weighted average price of our common stock is equal to or in excess of $1.50 per share for all trading days during any 6-month period and (b) the number of shares traded during such period averages at least 50,000 shares of common stock per trading day. Also, the Series B Convertible Preferred automatically convert into shares of our common stock at the applicable conversion price if our operating income is positive for at least four consecutive fiscal quarters and our cumulative operating income during such four fiscal quarters is at least $5.0 million.

We relied on the exemption from the registration requirements of the Securities Act, provided by Section 4(2) thereof and the rules and regulations promulgated thereunder, including Regulation D, in connection with the issuance of the warrants. The offer, sale and issuance of the warrants were made without general solicitation or advertising. The warrants were offered and issued only to "accredited investors" as such term is defined in Rule 501 under the Securities Act.

Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

As a Smaller Reporting Company as defined by Rule 12b-2 of the Exchange Act and in item 10(f)(1) of Regulation S-K, we are electing scaled reporting obligations and therefore are not required to provide the information requested by this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes thereto and the description of our business appearing elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Known and unknown risks, uncertainties and other factors could cause our actual results to differ materially from those projected in any forward-looking statements. In evaluating these statements, you should specifically consider various factors, including, but not limited to, those set forth under the caption "Risk Factors" in Item 1.A of this annual report on Form 10-K.

Overview

We focus on the development, marketing and sale of products designed to improve patient outcomes and reduce costs in the healthcare industry. We conduct our business through our wholly owned subsidiary, SurgiCount Medical, Inc. Our proprietary Safety-Sponge® System is a patented solution designed to eliminate one of the most common errors in surgery, retained surgical sponges, and the human and economic costs associated with this surgical mistake. The Safety-Sponge® System is comprised of a line of uniquely identified surgical sponges and towels and a turnkey hardware and software offering integrated to form a comprehensive accounting and documentation system. Over an estimated 45.4 million of our Safety-Sponges® have been successfully used in more than 2.1 million surgical procedures. We sell our Safety-Sponge® System to hospitals through our direct sales force and by leveraging the sales and marketing capabilities of our distribution partners. Our proprietary line of surgical sponges and towels are manufactured for us by our exclusive manufacturer, A Plus International Inc. ("A Plus"), a leading, China-based manufacturer of disposable medical and surgical supplies. Our sponge and towel products are distributed through Cardinal Health, Inc. ("Cardinal Health"), who provides us sales, marketing and logistics support and the fulfillment of our products to our end user hospitals by both delivering our products directly to our end user hospitals and where appropriate through alternative distributors. We currently have over 60 hospitals using the Safety-Sponge® System, all of which are located in the U.S. During 2010 the number of hospitals using our Safety-Sponge® System more than doubled and we lost no customers. Although not necessarily proportionally related to future revenue, growth in the number of hospitals using our products is a good indicator of our underlying business. Once implemented, the vast majority of our user hospitals use the Safety-Sponge® System across all of their relevant surgical and OB/GYN procedures.

Subsequent to the resignation of our previous President and Chief Executive Officer and four other board members, during the third quarter of 2010 newly appointed management implemented a comprehensive restructuring program focused on a number of initiatives, including the reduction of operating expenses and aggressively managing the Company to achieve positive operating income and operating cash flow. Restructuring activities included the elimination of certain job positions, lowering executive and employee cash compensation levels, refining and enforcing expense and travel policies and initiating spend measurement systems and accountability across various functional areas. As a result of a number of factors, primarily the continued growth of the Company's revenues from both delivery of Cardinal Health's stocking inventory (as discussed in "Cardinal Health – Exclusive U.S. Distributor" above and "—Cardinal Health Supply Agreement" below) and increased number of hospitals using the Company's products, and the impact on operating expenses from the restructuring initiative, the Company reported positive operating income of $925 thousand during the quarter ended September 30, 2010, the first period of positive reported

operating income in the history of the Company's ownership of SurgiCount since 2005 and the first reporting period under newly appointed management.

We generated revenues of $14.8 million and $4.5 million during the fiscal years ended December 31, 2010 and 2009, respectively. Our 2010 revenues of $14.8 million include approximately $8.9 million of revenues from the partial fulfillment of a $10 million stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health (the "Forward Order"). Also during 2010 we generated an additional approximately $5.9 million of revenue, separate from the Forward Order, from the delivery of products to Cardinal Health to meet immediate demand from end-user hospitals. Under certain circu