Patient Safety Technologies, Inc
Form 10-K
March 18, 2013

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, 2012

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 and 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 $0.0001 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 x 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 BB on June 30, 2012 was approximately $36 million.

The number of outstanding shares of the registrant’s common stock, par value $0.0001 per share, as of March 15, 2013 was 37,374,262.

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 Annual Meeting of Stockholders to be held in 2013, 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, 2012

TABLE OF CONTENTS

## 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:

- our ability to successfully implement hospitals under contract but not yet implemented;
- 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 Forward Order (described herein) and 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;
- any inability to successfully protect our intellectual property portfolio; and
- the impact on our revenues and financial position from managing our growth, including the initial costs typically associated with hospital implementations.

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 SurgiCount360™ (formerly called 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. ("SurgiCount"). 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. As of the filing date of this Form 10-K document an estimated 150 million of our Safety-Sponges® have been successfully used in more than 7.1 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 performs the fulfillment of our products to our end-user hospitals by both delivering our products directly to our end-user hospitals and when appropriate to alternative distributors. As of December 31, 2012, we had approximately 278 facilities using the Safety-Sponge® System, all of which are located in the U.S. 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.

The Company generated revenues of $17.6 million and $9.5 million during the fiscal years ended December 31, 2012 and 2011, respectively. Our 2011 revenues of $9.5 million include approximately $1.1 million of revenues from the fulfillment of a $10.0 million stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health (the "Forward Order"). There were no revenues generated during 2012 related to the Forward Order. Under certain circumstances the Forward Order may negatively impact our future 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 performed annually in the U.S. in which our products can be used and that our average revenue per procedure opportunity is currently approximately $12 to $15 dollars, implying an immediate market opportunity in the U.S. for us of more than $450 million annually. 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 annually.

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 events.

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 items 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.

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 SurgiCount360™ software application is designed to provide hospitals with a documentation and compliance tool through the generation of an electronic report of each particular procedure. These procedure reports include 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 SurgiCount360™ 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 exclusive manufacturer, A Plus, manufactures our proprietary line of surgical sponges and towels for us. 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 pursuing 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 a commitment to purchase our Safety-Sponge® line of disposable sponges and towels. We continue to maintain title to the hardware while such hospital purchases our 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 that have adopted our Safety-Sponge® System with our sponge and towel products. 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 ("Supply and Distribution"). This new agreement had a five-year term expiring in 2014 and names Cardinal Heath as our exclusive distributor in the United States, Puerto Rico, and Canada of the current sponge and towel 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 only direct customers of Cardinal Health. Our products are available to every hospital that wishes to purchase them through their existing distribution relationships, whether with Cardinal Health or a competitor. In the event an end user hospital customer of ours does not have a distribution relationship with Cardinal Health, Cardinal Health then distributes our products directly to the alternative distributor that works with that hospital.

In connection with the execution of the new agreement in November 2009, Cardinal Health issued the Forward Order, which was a $10.0 million stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of that stocking inventory over a 12-month period. Cardinal Health initially 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 be used to pay for product that A Plus later invoiced us related to the Forward Order. Cardinal Health also agreed to maintain normal ordering patterns and volumes for purchasing our Safety-Sponge® products throughout 2010 and to not use any of the inventory delivered under the Forward Order to meet immediate hospital demand. In late 2010, Cardinal Health requested, and we agreed, to change the product mix of the Forward Order. However, because the products Cardinal Health requested were not immediately available, Cardinal Health 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 $10 million Forward Order, and we delivered the remaining $1.1 million of Forward Order inventory in the first half of 2011.

In March 2011, Cardinal Health and the Company signed its first amendment to the Supply and Distribution agreement. The Amended Supply and Distribution Agreement ("First Amendment") 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 the excess inventory of our products held by Cardinal Health. At that time Cardinal Health agreed to not sell any of the Forward Order inventory until calendar year 2012. We also agreed to a methodology for the amount of the Forward Order inventory Cardinal Health would be able to sell to our customers each month, establishing a more orderly inventory release process that would help to minimize the impact this inventory release would have on our sales during 2012.

On September 28, 2011, we announced an agreement to implement the Safety-Sponge® System with a large hospital group with approximately 138 hospitals. The implementations started in the beginning of 2012 and were completed at the end of the fourth quarter of the fiscal year ended 2012 with 138 hospitals implemented. The magnitude of this large implementation compelled us to prioritize our resources in order to scale up for costs associated with the large implementation, including the need to buy more sponge and towel inventory and scanners, as well as hiring and training more staff to support the implementations. As a result of this and other factors, management approached Cardinal Health in late 2011 to discuss the timing of when Cardinal Health would begin to release the Forward Order inventory. At the time, Cardinal Health agreed to delay the release of Forward Order inventory until April 1, 2012, to allow both sides additional time to negotiate a possible revision to the previously agreed upon terms, including the

release of the Forward Inventory. Due to a number of other items effecting both the Company and Cardinal Health during 2012, final agreement with Cardinal Health on changing the previously agreed upon terms, including setting a date for Cardinal Health to begin releasing the Forward Order inventory was not reached until January 2013.

In January 2013, Cardinal Health and the Company signed the second amendment to the Supply and Distribution agreement or the "Second Amendment". The Second Amendment changed a number of terms under the Supply and Distribution Agreement and the First Amendment including but not limited to adding certain provisions regarding target inventory levels of the Company's products held by Cardinal Health, and extending the termination date of the Supply and Distribution Agreement from December 31, 2015 to December 31, 2016. Under the terms of the Second Amendment, Cardinal Health is required to maintain any inventory in excess of set target inventory levels up through to December 31, 2013, and the Company agrees to pay a monthly fee to Cardinal Health throughout 2013 based on the amount of any excess inventory held each month by Cardinal Health. The Company will continue to have the right to buy back any such excess inventory from Cardinal Health at any time. Beginning January 1, 2014, Cardinal Health may use any remaining excess inventory to partially meet customer demand according to a formula set forth in the First Amendment which limits their use of any excess inventory over a 12 month time period. Should there be any excess inventory during 2014, the Company will continue to pay Cardinal Health a monthly fee on the excess inventory up through to December 31, 2014, and if there is any excess inventory held by Cardinal Health after December 31, 2014, Cardinal Health will have the right to use that excess inventory to meet customer demand of the Company's products. Management currently estimates that any fees paid to Cardinal Health under the Second Amendment will not have a material impact on the Company's financial results (currently estimated to range from 1% to 3% of reported revenue for the Company during the years 2013 and 2014), and that any additional growth the Company experiences during 2013 and 2014 will minimize the impact of any fees paid. Additionally, the Second Amendment provides that the Supply and Distribution Agreement is terminable by Cardinal Health upon a change of control of the Company.

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 trays the guaranteed minimum gross margins are based on a formula that varies depending on certain sales performance results during specific time periods.

Should Cardinal Health have any excess inventory on the date that, in accordance with the arrangements described immediately above, Cardinal Health can start releasing Forward Order inventory, and should Cardinal Health begin selling the excess inventory it holds to partially meet customer demand, our reported revenues and cash flows will be negatively affected. The magnitude of this negative impact on our 2014 revenue and cash flows will depend on a number of factors, including but not limited to the amount of excess inventory Cardinal Health actually has on hand at the end of 2013, whether the Company chooses to purchase some or all of this excess inventory, and our actual and expected sales growth rates in 2013 and 2014. Actual future sales 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 future sales growth to be, in order to prevent a significant negative impact to our future revenue by Cardinal Health's release of Forward Order inventory, (i) we would need to experience substantial growth in the number of hospitals using our products, (ii) we 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 we were to buyback excess inventory from Cardinal Health, this also could have a significant negative impact on our earnings, financial position and our liquidity.

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. The required registration statement became effective on August 12, 2011 and the Company has agreed to use commercially reasonable efforts to maintain effectiveness for three years after the registration statement became effective, or through to August 11, 2014.

Manufacturing

All of our sponge and towel products are currently manufactured for us by our exclusive manufacturing partner, A Plus International Inc. 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. 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 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 had a term of five years. A Plus was also granted certain rights 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.

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 internal resources and 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 and customer support 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 consists primarily of specialists with extensive nursing backgrounds. Our clinical team plays an essential role in our sales, education, implementation and on-going customer 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 Safety-Sponge® disposable surgical sponge and towel products, using our SurgiCount360™ (formerly called 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 rely on a combination of patent, trade secret, copyright and trademark laws and contractual restrictions, such as confidentiality agreements and licenses, to establish and protect our rights in our products, services, know-how and information.

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 SurgiCount360™ (formerly called 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 other 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, Inc. 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, our reduced 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. The FDA monitors compliance with applicable regulatory requirements through periodic site inspections. 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.

Employees

As of December 31, 2012, we had approximately 25 total and full-time employees. 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 have not experienced any work stoppages. We believe that relations with our employees are good.

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 (“SEC”).

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 for the year ended December 31, 2012 and 2011, our accumulated deficit was $61.7 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, 2012 and 2011, we had revenues of $17.6 million and $9.5 million respectively. During 2011 our reported revenues included $1.1 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") there was no revenue earned from the Forward Order during 2012. The $1.1 million of Forward Order revenue during 2011 represented the final sales under the Forward Order arrangement with Cardinal Health. 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 initially achieved for the fiscal years ended 2011 and 2012, suggest 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 sources of liquidity, which included $7.1 million of proceeds at the closing of a private placement on March 29 and 30, 2011 and $3.5 million of proceeds at the closing of a private placement on May 18, 2012 (see Note 9 to our consolidated financial statements appearing elsewhere in this Report), along with our actual cash flows from operations during 2012 and excepted cash flows from operations during 2013, 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 fund growth of 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 2 years, 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 cannot guarantee we will be able to successfully integrate these 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 2014 could have a material negative impact to our revenues and cash flows.

In January 2013, Cardinal Health and the Company signed the second amendment to the Supply and Distribution agreement or the "Second Amendment". The Second Amendment changed a number of terms under the Supply and Distribution Agreement and the First Amendment including but not limited to adding certain provisions regarding target inventory levels of the Company's products held by Cardinal Health, and extending the termination date of the Supply and Distribution Agreement from December 31, 2015 to December 31, 2016. Under the terms of the Second Amendment, Cardinal Health is required to maintain any inventory in excess of set target inventory levels up through to December 31, 2013, and the Company agrees to pay a monthly fee to Cardinal Health throughout 2013 based on the amount of any excess inventory held each month by Cardinal Health. The Company will continue to have the right to buy back any such excess inventory from Cardinal Health at any time. Beginning January 1, 2014, Cardinal Health may use any remaining excess inventory to partially meet customer demand according to a formula set forth in the First Amendment which limits their use of any excess inventory over a 12 month time period. Should there be any excess inventory during 2014, the Company will continue to pay Cardinal Health a monthly fee on the excess inventory up through to December 31, 2014, and if there is any excess inventory held by Cardinal Health after December 31, 2014, Cardinal Health will have the right to use that excess inventory to meet customer demand of the Company's products. Management currently estimates that any fees paid to Cardinal Health under the Second Amendment will not have a material impact on the Company's financial results (currently estimated to range from 1% to 3% of reported revenue for the Company during the years 2013 and 2014), and that any additional growth the Company experiences during 2013 and 2014 will minimize the impact of any fees paid. Additionally, the Second Amendment provides that the Supply and Distribution Agreement is terminable by Cardinal Health upon a change of control of the Company.

Should Cardinal Health have any excess inventory on the date that, in accordance with the arrangement described immediately above, Cardinal Health can start releasing Forward Order inventory, and should Cardinal Health begin selling the excess inventory it holds to partially meet customer demand, our reported revenues and cash flows could be negatively affected. The magnitude of this negative impact on our 2014 revenue and cash flows will depend on a number of factors, including but not limited to the amount of excess inventory Cardinal Health actually has on hand in 2013, whether the Company chooses to purchase some or all of this excess inventory, and our actual sales growth rates. Actual future sales 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 future sales growth to be, in order to prevent a significant negative impact to our future revenue by Cardinal Health's release of Forward Order inventory, (i) we would need to experience substantial growth in the number of hospitals using our products, (ii) we 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 we were to buyback excess inventory from Cardinal Health, this also could have a significant negative impact on our 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. In addition, the actual end user hospital market revenue for our products in the U.S., Canada and Puerto Rico is approximately 25% higher than our related reported revenues, because we pay Cardinal Health commissions averaging approximately 20%. 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 our distribution partners and us. 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. 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, or inconsistent with our business needs or expectations, 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 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 years 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.

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 also 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, 2012, we had goodwill of $1.8 million and other intangible assets of $2.1 million (or 9% and 11%, 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 “Item 7 - 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 could 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, founder and significant shareholder of A Plus 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. See "Related Party Transactions" in Note 12 in our financial statements for a discussion of our relationship with A Plus.

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 "Item 1- "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 Safety-Sponge® 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 "Item 1 - Business– Customers and Distribution – Cardinal Health – Exclusive U.S. Distributor"), we may not be aware of quality control issues that arise with by our hospital 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, the cost of labor in China 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 increased significantly during 2010, and the labor costs in the area of China where the manufacturing plant of our sponges and towels is located increased significantly in both 2010 and 2011. Because of this, we have received reasonable cost increases by A Plus in both 2011 and 2012. However if there continues to be significant price increases for cotton, local labor and or significant changes in the Yuan exchange rates, these 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 if we don't raise our prices. 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, there is also no assurance that the Chinese government will continue to pursue its current economic reform policies, or that it will not significantly alter these policies from time to time without notice, making 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 revenue, 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 that 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. 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 our 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 that 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.

Components of our Safety-Sponge® System are considered to be medical devices and are 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 of 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 differences in 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 is 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 the 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 device 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, 2012, our stock price ranged from a high of $1.98 to a low of $1.05 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 convertible securities, warrants and options, and future sales of these shares could adversely affect the market price of our common stock.

As of December 31, 2012, we had outstanding warrants for an aggregate of 4.3 million shares of common stock at a weighted average exercise price of $1.87 per share and options exercisable for an aggregate of 5.6 million shares of common stock at a weighted average exercise price of $1.17 per share. In addition, as of December 31, 2012, we had outstanding 70,425 shares of Series B Preferred Stock, which are convertible into 9.4 million shares of common stock. As a result, as of December 31, 2012, we have an aggregate of 56.3 million in common stock equivalents either issued and outstanding or convertible under our Series B Preferred Stock or exercisable under other warrants and options to acquire our common stock at various prices. The holders may sell these shares in the public markets from time to time, without limitations on the timing, amount or method of sale, except for certain timing restriction in the Series B Preferred Stock related to 5% and 10% ownership levels. In addition, 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 FINRA OTC Bulletin Board and the OTC QB market places, which may have an unfavorable impact on our stock price and liquidity.

Our common stock is currently quoted under the symbol “PSTX.OB” on the FINRA OTC Bulletin Board market (“OTC Bulletin Board”) operated by FINRA (Financial Industry Regulatory Authority), and it is also quoted on the OTC QB market place (“OTC QB”), 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.” From February 2007 to February 2011, our stock was quoted on the OTC Bulletin Board under the symbol “PSTX.” Starting March 1, 2011 due to

actions by broker dealers generally and impacting many issuers, and to the best of our knowledge, unrelated to us specifically, our stock ceased to be quoted on the OTC Bulletin Board but continued to be quoted on the OTC QB. Beginning August 9, 2011 we rejoined the OTC Bulletin Board market, and are currently dual quoted on both the OTC Bulletin Board and OTC QB. 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 Bulletin Board and 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 addition, an event such as the one that occurred in March 2011 could recur, resulting in our not being quoted on the OTC Bulletin Board. In the year ended December 31, 2012, our stock price ranged from a high of $1.98 to a low of $1.05 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. Between January 1, 2012 and December 31, 2012, we had consent by the holders of our Series B Preferred Stock to pay either cash dividends or pay dividends with paid in kind shares. Starting on January 1, 2013 we pay cash dividends on our Series B Preferred Stock in accordance with the terms thereof. The dividends on our Series B Preferred Stock during the year averaged approximately $114 thousand per quarter and Series A are $19 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. At December 31, 2012 we were in arrears on six quarters to the Series A Preferred Stock. In the first quarter of 2013 we paid all such arrears dividends. Our Series B Preferred Stock 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 Stock 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.

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

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 DGCL, in general, prohibits any business combination with a beneficial owner of 15% or more of our common stock for three years unless our Board of Directors approved the holder's acquisition of our stock in advance. 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

Our operating leases are principally for our corporate headquarters and warehousing facilities. We currently lease approximately 9,600 square feet of space at our headquarters and warehouse facilities both located in Irvine, California. In connection with the closure of our Newtown, Pennsylvania corporate location where previous management temporarily located in 2010, we accrued the fair value of future payments under the lease. In November 2010, we entered into a sub-lease for the Newtown facility, which provides for sub-lease payments to us through the term of the lease, or April 2013. Beginning January 1, 2012 we entered into a lease for combined office/warehouse space in Irvine California, approximately 5 miles from our corporate offices. The total square footage is approximately 3,790, with approximately 2,000 square feet of warehouse space, and 1,790 square feet of office space. The additional space was needed primarily to support the significant increase in new customer implementations we have experiences, for storing and preparing our SurgiCounters™ for new customers and supplying sponge product for implementation training.

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities.

ITEM 3. LEGAL PROCEEDINGS

On June 12, 2012, the Company filed a complaint in the United States District Court for the Central District of California (Case No. SACV12-00937 DOC) alleging infringement of United States Patent No. 5,931,824 entitled "Identification and Accountability System for Surgical Sponges" by ClearCount Medical Solutions, Inc. (the "Complaint"). The Complaint seeks damages and injunctive relief relating to ClearCount's allegedly infringing sales of its SmartSponge System and SmartSponge Flex Products. On December 12, 2012, the Company agreed to dismiss the Complaint, without prejudice, subject to rights to re-file the Complaint under certain circumstances, with tolling of applicable statutes of limitations.

The Company may at times be involved in litigation in the ordinary course of business. There are no other pending material legal proceedings to which the Company is a party or to which any of its property is subject.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

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 Bulletin Board operated by FINRA, however from March 1, 2011 through August 9, 2011 our common stock was quoted only on the OTC QB market operated by OTC Markets Group, Inc.

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 (except for March 1, 2011 through August 9, 2011, where the information below was reported by the OTC QB). 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, 2012 | | |
| First Quarter | $ 1.70 | $ 1.05 |
| Second Quarter | 1.89 | 1.30 |
| Third Quarter | 1.98 | 1.45 |
| Fourth Quarter | 1.86 | 1.51 |
| | | |
| Year Ended December 31, 2011 | | |
| First Quarter | $ 0.97 | $ 0.69 |
| Second Quarter | 1.50 | 0.85 |
| Third Quarter | 1.50 | 0.82 |
| Fourth Quarter | 1.45 | 0.97 |

Stockholders

As of March 14, 2013, there were 602 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 Preferred Stock and Series B Preferred Stock limit our ability to pay any such dividends on our common stock.

Recent Sales of Unregistered Securities

None.

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 safety 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. As of the filing date of this Form 10-K document an estimated 150 million of our Safety-Sponges® have been successfully used in more than 7.1 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, a leading, China-based manufacturer of disposable medical and surgical supplies. 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. As of December 31, 2012, we had approximately 278 facilities using the Safety-Sponge® System, all of which are located in the U.S. During 2012 the number of hospitals using our Safety-Sponge® System increased by 179 hospitals or 181% compared to December 31, 2011. 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.

We generated revenues of $17.6 million and $9.5 million during the fiscal years ended December 31, 2012 and 2011, respectively. Our 2011 revenues of $9.5 million include approximately $1.1 million of revenues from the fulfillment of a $10.0 million stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health (the "Forward Order"). There were no revenues generated during 2012 related to the Forward Order. Under certain circumstances the Forward Order may negatively impact our future 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".

Factors Affecting Future Results

Cardinal Health Supply Agreement

In November 2006, we began an exclusive distribution relationship with Cardinal Health to supply hospitals that have adopted our Safety-Sponge® System with our sponge and towel products. 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. This new agreement had a five-year term expiring in 2014 and names Cardinal Heath as the exclusive distributor in the United States, Puerto Rico, and Canada of the current sponge and towel 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 only direct customers of Cardinal Health. Our products are available to every hospital that wishes to purchase them through their existing distribution relationships, whether that is with Cardinal Health or a competitor. In the event an end user hospital customer of ours does not have a distribution relationship with Cardinal Health, Cardinal Health then distributes our products directly to the alternative distributor that works with that hospital.

In connection with the execution of the new agreement in November 2009, Cardinal Health issued the Forward Order, which was a $10.0 million stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of that stocking inventory over a 12-month period. Cardinal Health initially paid us $8.0 million as partial pre-payment of the Forward Order, and agreed to pay $2.0 million directly to A Plus, that was used to pay for product that A Plus later invoiced the Company related to the Forward 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, however because the products Cardinal Health requested were not immediately available, Cardinal Health 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 $10 million Forward Order and delivered 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 during 2010, and ended up recognizing $1.1 million of Forward Order revenue during 2011, thereby fully satisfying the Forward Order. There will be no additional Forward Order revenue in the future with Cardinal Health unless we enter a new stock order, which we have no plans to do.

In March 2011, Cardinal Health and the Company signed its first amendment to the Supply and Distribution agreement. The Amended Supply and Distribution Agreement or “First Amendment” revised a number of terms and conditions of the previous agreement, including but not limited to extending the termin