

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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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
(State or other jurisdiction of
incorporation or organization)

13-3419202
(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

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

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any,

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark, if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if smaller reporting company) Smaller Reporting Company

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

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

	Page
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	1
<u>HELPFUL INFORMATION</u>	1
PART I	
<u>ITEM 1. BUSINESS</u>	2
<u>ITEM 1A. RISK FACTORS</u>	9
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	20
<u>ITEM 2. PROPERTIES</u>	20
<u>ITEM 3. LEGAL PROCEEDINGS</u>	20
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	20
PART II	
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	20
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	21
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	21
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	29
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	30
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	31
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	31
<u>ITEM 9B. OTHER INFORMATION</u>	32
PART III	
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	32
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	33
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	33
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	33
<u>ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	33
PART IV	33
<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	
<u>SIGNATURES</u>	34
<u>EXHIBIT INDEX</u>	35

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,” “anticipates,” “believes,” “estimates,” “seeks,” “predicts,” “potential,” or “continue” or the negative of these terms and other similar expressions 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” mean 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 Health 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 hospital 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 expected 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 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 of 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.

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

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 Health 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 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 that 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, a 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.

Should Cardinal Health have any excess inventory on hand at December 31, 2013, and begins selling the excess inventory it holds to partially meet customer demand during 2014, our reported revenues and cash flows in 2014 could be negatively affected. The magnitude this negative impact could have on our 2014 revenue and cash flows will depend on a number of factors, including but not limited to how much excess inventory Cardinal Health actually has on hand at the end of the year 2013, whether the Company chooses to purchase some or all of this excess inventory, and what our actual sales growth rates are during 2013 and 2014. Actual sales during 2013 and 2014 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 2013 or 2014 sales growth to be, in order to prevent a significant negative impact to our 2014 revenue by Cardinal Health's release of Forward Order inventory, (i) the Company would need to experience substantial growth in the number of hospitals using its products during 2013 and 2014, (ii) the Company would need to buyback any excess inventory from Cardinal Health, or (iii) Cardinal Health would need to decide not to use its excess inventory to partially meet customer demand. If the Company were to buyback excess inventory from Cardinal Health, this also could have a significant negative impact to the Company's earnings, financial position and our liquidity.

Revenues Subject to Significant Variation Due to Cardinal Health's Ordering Patterns, and Expectations of the Size and Timing of New Customer Hospital Implementations.

Our exclusive distribution agreement with Cardinal Health results in all of our current revenues coming from orders placed by Cardinal Health. Cardinal Health has discretion in the timing and quantities with the orders they place, subject only to the limits contained in our agreements with them. As a result, our revenues may not necessarily correlate with the actual growth of our underlying customer base. In addition, our revenue can be materially impacted by the size of new customer hospital systems being implemented and the expected timing of those implementations by us and our distribution partners. Size of hospital systems connotes the number of actual hospitals that are a part of the hospital system and the number of surgical procedures that are performed at each hospital. Implementations with our large hospital system customers like the Mayo Clinic in Rochester and Cleveland Clinic both in 2009, or the large hospital group with 138 hospitals in 2012 had a material impact on our reported revenue and revenue growth for the years 2009 and 2012. The timing of when these larger hospital system implementations are expected to occur also have a significant impact on our annual reported revenue, as both the Company and our distribution partners need to ensure there is adequate inventory on hand to accommodate them. The decision process that our distribution partner Cardinal Health uses in determining when to place orders is complex and subject to significant judgment. If those judgments prove incorrect, or are 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. In addition, 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 future revenue. This is because revenue growth is impacted by a variety of factors, including the number of actual customers represented by the hospitals using our products, the number of procedures such hospitals actually perform, the timing of orders of our products and the other factors described in this Annual Report on Form 10-K.

Hardware Effect on Revenue and Cost of Revenue

We generally provide our SurgiCounter™ scanners and related software to all hospitals at no cost when they adopt our Safety-Sponge® System. We generally no longer engage in direct SurgiCounter™ scanner sales and anticipate only recognizing revenue associated with our SurgiCounter™ scanners in connection with reimbursement arrangements we have with Cardinal Health under our agreement with them. There has been a shift in product mix based on the growing number of scanners that we have given customers out in the field, which causes our gross margins to decline due to depreciation expense of these scanners being recorded in cost of revenue over the estimated useful life. However, we also anticipate that as we experience a significant increase in new customer surgical sponge revenue at current pricing levels, this revenue growth will eventually help offset the effects of a growing depreciation expense resulting from scanners being recorded as a cost of revenue.

Results of Operations

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenue

Total revenue for the year ended December 31, 2012 was \$17.6 million, which compared to total revenue for the year ended December 31, 2011 of \$9.5 million, representing year over year growth in reported revenue of 86%. For the year ended December 31, 2011, revenue of \$9.5 million included approximately \$1.1 million of revenue for filling a

\$10 million Forward Order to our exclusive distributor, Cardinal Health. The Forward Order was completed in the second quarter of 2011, so there was no revenue earned from the Forward Order during 2012. When excluding the effect of the Forward Order revenue on the reported year ended 2011 revenue, the year ended December 31, 2012 year-over-year revenue growth would have been 110%. The primary reason for the increased revenue growth is the larger number of new customer implementations we have had throughout 2012, having grown by 179 hospital facilities during the year ended December 31, 2012.

Cost of revenue

Costs of revenue of \$10.0 million increased by \$5.0 million or 96% for the year ended December 31, 2012 as compared to cost of revenue of \$5.1 million for the same period in 2011. This increase was primarily the result of a higher number of facilities purchasing our products. Our cost of revenue for the twelve months ended December 31, 2012 included a higher amount of non-cash depreciation expense from providing the scanner hardware at no cost to our new customer facilities (see “Factors effecting Past and Future Results — Reduction in Hardware Revenue”). Our cost of revenue as a percentage of revenue increased to 57% during the twelve months ended December 31, 2012 as compared to 54% during the same period in 2011. This increase was attributable mostly to higher non-cash depreciation expense that totaled \$1.7 million in our cost of revenue during the twelve months ended December 31, 2012, as compared to similar costs during the same period in 2011 of \$514 thousand. This 227% increase in depreciation expense reflected the large amounts of hardware purchased and implemented in order to support 179 new hospital customer implementations occurring in the twelve months ended December 31, 2012. Excluding non-cash depreciation expenses our adjusted costs of revenues for the year ended December 31, 2012 was \$8.4 million, an increase of \$3.8 million as compared to cost of revenue of \$4.6 excluding non-cash depreciation expenses for the year ended December 31, 2011.

Gross profit

Gross profit totaled \$7.6 million for the twelve months ended December 31, 2012, an increase of \$3.2 million, or 74%, compared to gross profit of \$4.3 million during the same period in 2011. Our gross profit for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011 was negatively impacted by higher amounts of non-cash depreciation expense (primarily associated with the relatively larger amount of scanning equipment we provided to support a higher number of new customers) offset by higher relative pricing on our products to new customers. Gross profit as a percent of revenue was 43% during the twelve months ended December 31, 2012 and 46% during the same period in 2011. Excluding the effect of non-cash depreciation expenses captured in our costs of revenues, our adjusted gross profit for the twelve months ended December 31, 2012 was \$9.2 million, an increase of \$4.4 million as compared to our adjusted gross profit excluding the effect of non-cash depreciation expenses captured in our costs of revenues for the twelve months ended December 31, 2011 of \$4.9 million. Excluding the effect of non-cash depreciation expenses adjusted gross profit as a percent of revenue was 52% for the twelve months ended December 31, 2012 and 51% for the twelve months ended December 31, 2011.

Operating expenses

Operating expenses totaled \$9.6 million for the twelve months ended December 31, 2012, an increase of \$2.6 million, or 37%, compared to \$7.0 million of operating expenses during the same period in 2011. The increase in operating expenses was primarily due to higher one-time costs associated with a significantly larger number of new customer implementations during the year of 2012 as compared to the same period of 2011. During the twelve months ended December 31, 2012 we successfully implemented 179 new customer facilities, the most new customer facilities we have ever implemented during a twelve month time period in our history. This compares to 30 new customer facilities implemented during the twelve months of 2011. Total one-time implementation costs in the twelve months ended December 31, 2012 were approximately \$2.0 million, as compared to approximately \$0.6 million during the twelve months ended December 31, 2011. One-time expenses associated with implementing new customer facilities included utilizing per diem clinical and IT personnel for upfront planning and staffing clinical and technical on-site support during the implementation process, associated travel and lodging expenses and other related implementation expenses. Additionally, during 2012, we continued the implemented a new large hospital system customer comprised of 138 hospital facilities, for which we originally initiated implementations in the first quarter of 2012 and completed by the fourth quarter 2012. The relatively fast pace with which we implemented these new facilities resulted in incurring higher implementation costs than we would otherwise would have.

Research and development expenses

Research and development expenses totaled \$580 thousand for the twelve months ended December 31, 2012, an increase of \$472 thousand, or 440%, compared to \$107 thousand during the same period in 2011. The year-over-year increase in research and development spending was primarily due to expanded investment in resources dedicated to improving and expanding our product offering.

Sales and marketing expenses

Sales and marketing expenses totaled \$4.9 million for the twelve months ended December 31, 2012, an increase of \$1.9 million, or 65%, compared to \$3.0 million during the same period in 2011. The increase in sales and marketing expenses during the twelve months of 2012 as compared to the same period in 2011 was due primarily to the significantly higher one-time implementation expenses to support new facility implementations during this period as described above in Operating expenses.

General and administrative expenses

General and administrative (“G&A”) expenses totaled \$4.1 million for the twelve months ended December 31, 2012, representing an increase of \$145 thousand, or 4%, compared to G&A expenses of \$3.9 million during the same period in 2011. The slight increase in G&A expenses during the twelve months ended December 31, 2012 as compared the same period in 2011 was due primarily to the addition of employees to support our growing customer base and expanded operations.

Total other income (expense)

We reported other expense of \$108 thousand for the twelve months ended December 31, 2012, a decrease of \$897 thousand of income compared to other income of \$788 thousand for the twelve months ended December 31, 2011. During the year we recorded interest expense of \$106 thousand related to our payables aging over standard payment terms. During the twelve months ended December 31, 2011, we had recognized a gain of \$221 thousand related to the reduction of a contingent tax liability, and also recognized a gain of \$568 thousand from recording a mark to market adjustment for changes in the fair value of a warrant derivative liability. The warrant derivative liability was extinguished in the fourth quarter of 2011, and as such, we have not had similar adjustments during 2012.

Net income (loss)

We had a net loss of \$2.7 million applicable to common stockholders for the twelve months ended December 31, 2012 compared to a net loss of \$2.4 million for the same period in 2011 based upon the reasons described above. Additionally, during the twelve months ended December 31, 2011 our net loss of \$2.4 million included the benefits of non-cash gains on the change in the fair value of a warrant derivative liability of \$0.2 million and \$0.6 million for a gain on the reduction of a contingent tax liability. There were no such non-cash gains during the twelve months ended December 31, 2012.

Financial Condition, Liquidity and Capital Resources

We had cash and cash equivalents of \$5.2 million at December 31, 2012 compared to \$3.7 million at December 31, 2011. As of December 31, 2012, we had total current assets of \$10.9 million and total current liabilities of \$6.3 million resulting in a positive working capital of \$4.6 million, which is compared to \$4.3 million in positive working capital as of December 31, 2011. Current liabilities as of December 31, 2012 include deferred revenue of \$0.8 million relating to hardware reimbursement payments from Cardinal Health, which is a non-cash liability. Excluding this non-cash liability, our current liabilities would have been \$5.5 million as of December 31, 2012, giving us an adjusted positive working capital of \$5.4 million.

We believe our sources of liquidity are sufficient to satisfy our anticipated cash requirements through at least the next 12 months as we expect the business to generate improved cash flow from operations as result of our growing installed base of customer facilities. We may seek financing to fund future growth for periods beyond the next 12 months, through future offerings of equity or debt, or through agreements with strategic partners to help fund our growth and the development of future products and technologies. However, we can offer no assurances that we will be able to obtain additional financing or agreements with strategic partners on acceptable terms, if at all. Management continually evaluates our liquidity needs and whether to increase capital resources. See Item 1A "Risk Factors" located elsewhere in this Report for additional information on factors that could impact our future liquidity and capital resources.

Operating activities

We had positive net cash flow from operating activities of \$2.6 million during the twelve months ended December 31, 2012. Our net loss of \$2.7 million for the twelve months ended December 31, 2012 included non-cash charges in the form of stock-based compensation, amortization of intangible assets and depreciation totaling \$2.9 million during the twelve months ended December 31, 2012.

Cash provided by working capital components during the year ended December 31, 2012 was \$1.9 million. Working capital consists primarily of accounts receivable, inventory, other assets, net of deferred revenue and other current liabilities. Accounts receivable increased by \$108 thousand or 8% as of December 31, 2011 mostly reflecting the timing of our yearend sales orders with Cardinal Health. Inventory increased by \$1.2 million or 43% as of December 31, 2012 due to our business growth and building up safety stock levels needed for scheduled implementations at new hospitals during 2012. Accounts payable increased by \$1.7 million or 60%, reflecting inventory we took in for both filing fourth quarter 2012 sales as well as first quarter 2013 safety stock needed for scheduled implementations at new hospitals during 2013.

Deferred revenue of \$1.8 million as of December 31, 2012 represents a significant component of our working capital, having increased by \$1.3 million or 233% during the twelve months ended December 31, 2012, as compared to fiscal year end 2011. This increase in deferred revenue was a result of the large increase in implementations particularly during the first three quarters of 2012 and Cardinal Health's agreement in certain situations to reimburse half of our hardware costs that are typically provided to our customers for use at no cost while they purchase our disposable sponges and towels.

Cash used in working capital during the year ended December 31, 2011 was \$2.9 million. Working capital consists primarily of accounts receivable, inventory, other assets, net of deferred revenue and other current liabilities. Accounts receivable increased by \$535 thousand or 69% as of December 31, 2011 reflecting timing of sales and our growth in non-Forward Order revenue during the year 2011. Inventory increased by \$1.67 million or 149% as of December 31, 2011 due to our business growth and building up safety stock levels needed for scheduled implementations at new hospitals during early 2012. Accounts payable increased by \$203 thousand or 7%, as we took delivery of much of the

increased inventory late in Q4 2011. Deferred revenue decreased by \$1.0 million or 63% during the year ended December 31, 2011 due to the Company completing all shipments to Cardinal Health in fulfilling the Forward Order. In 2011, we also reclassified restricted cash transfers from being reported as financing activities to operating activities within our consolidated statements of cash flows.

Investing activities

We used \$4.9 million of net cash in investing activities during the twelve months ended December 31, 2012, almost entirely for the purchase of scanners and related hardware used for implementing our Safety-Sponge® System at new customer facilities. This compares to using \$1.3 million of net cash in investing activities during the twelve months ended December 31, 2011, which were also primarily for the purchase of scanners and related hardware for implementing our Safety Sponge® System at new customers.

Financing activities

During the twelve months ended December 31, 2012, we generated \$3.8 million of net cash from financing activities primarily from the net proceeds from closing a \$3.5 million private placement in May 2012, along with \$470 thousand of proceeds received from the exercise of employee stock options, offset by the payment of preferred stock dividends and other stock issuance costs.

We generated \$7.0 million of net cash from financing activities in the twelve months ended December 31, 2011, primarily from the net proceeds of our \$7.1 million private placement and exercise of employee stock options, offset by the payment of preferred stock dividends and other stock issuance costs.

Sources of Revenues and Expenses

Revenues

We generate revenue primarily from the sale of surgical sponges and towels used in our Safety-Sponge® System to our exclusive distributor, Cardinal Health, who then sells directly and through alternative distributors to hospitals that have adopted our Safety-Sponge® System. Revenue related to surgical products is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, when collectability is reasonably assured and when risk of loss transfers, usually when products are shipped. Advanced payments are classified as deferred revenue and recognized as product is shipped to the customer. When the Company receives any reimbursement related to hardware implementations, hardware revenue is recognized on a straight-line basis over the life of the customer contract, while the cost of the hardware equipment is carried in hardware equipment within property, plant and equipment and depreciated over its estimated useful life. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts or rebates given to the buyer.

Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. The Company records shipping and handling costs charged to customers as revenue and shipping and handling costs to cost of revenue as incurred. Revenue is reduced for any discounts, trade in allowances and rebates given to the buyer.

Cost of revenue

Our cost of revenues consists primarily of our direct product costs for surgical sponges and towels from our exclusive third-party manufacturer, A Plus. We also include a reserve expense for obsolete and slow moving inventory in the cost of revenues. In addition, when we provide scanners and other related hardware to hospitals for their use at no cost (rather than sell these), we include only the depreciation expense of the related hardware in cost of revenues over the three year estimated useful life of the scanners. In rare cases where we sell the scanners to hospitals, our cost of revenue includes the full related hardware cost when shipped.

Research and development expenses

Our research and development expenses consist of costs associated with the design, development, testing and enhancement of our products. These expenses are mostly consultant related expenses for fees paid to external service providers supporting our product development programs and salary and related employee benefit costs for a full time employee.

Sales and marketing expenses

Our sales and marketing expenses consist primarily of salaries and related employee benefits, sales commissions and support costs for our sales employees, along with travel, education, trade show, professional service fees for use of outside consultants and various marketing costs, including the use of nurse and technical consultants to support our new customer implementations and client training.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and related employee benefits for corporate and support employees, professional service fees, expenses related to being a public entity, and depreciation and amortization expense.

Total other income (expense)

Our total other income (expense) primarily reflects changes in the fair value of warrants classified as derivative liabilities. Under applicable accounting rules (discussed below under “—Critical Accounting Policies—Warrant Derivative Liability”), we are required to make estimates of the fair value of our warrants each reporting period, and to record the change in fair value each period in our statement of operations. As a result, changes in our stock price from period to period result in other income (when our stock price decreases) or other expense (when our stock price increases) in our income statement.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and other financial information. We base these estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and these estimates form the basis for our judgments concerning the carrying values of assets and liabilities that are not readily apparent from other sources. We periodically evaluate our estimates and judgments based on available information and experience. Actual results could differ from our estimates under different assumptions and conditions. If actual results significantly differ from our estimates, our financial condition and results of operations could be materially impacted.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that could have been used, or changes in the accounting estimate that are reasonably likely to occur periodically, could materially impact our consolidated financial statements. See Note 3 of our Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K for a description of our significant accounting policies and method used in preparation of our consolidated financial statements.

Revenue Recognition

Revenue related to surgical products is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, when collectability is reasonably assured and when risk of loss transfers, usually when products are shipped. Reimbursements related to scanners and related equipment provided to hospitals are initially recognized as deferred revenue when cash is received and recognized as revenue on a straight-line basis over the expected term life of the related customer contract, while the cost of the scanners and related equipment is carried in hardware equipment within property, plant and equipment and depreciated as a component of cost of revenue over its estimated useful life. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. The Company records shipping and handling costs charged to customers as revenue and shipping and handling costs to cost of revenue as incurred. Revenue is recorded net of any discounts or rebates given to the buyer.

Goodwill

Our goodwill represents the excess of the purchase price over the estimated fair values of the net tangible and intangible assets of SurgiCount Medical, Inc., which we acquired in February 2005. We review our goodwill for impairment at least annually in the fourth quarter, as well as whenever events or changes in circumstances indicate that its carrying value may be impaired. We first assess qualitative factors to determine if it is necessary to perform the two-step quantitative goodwill impairment test. Under ASU No. 2011-08, companies should assess qualitative factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying value, including goodwill. In the event we determine that it is more likely than not that our sole reporting unit's fair value is less than its carrying amount, quantitative testing would be performed comparing recorded values to estimated fair values. As part of our goodwill qualitative testing process, we evaluate various factors to determine whether it is reasonably likely that management's assessment would indicate a material impact on the fair value of our reporting unit. Factors assessed in the qualitative approach are cash flow forecasts of our reporting unit, the strength of our balance sheet, changes in strategic outlook or organizational structure, industry and market changes and macroeconomic indicators.

Inventories

Inventory consists of finished goods and scanner hardware. Finished goods include sponge and towel product products ready for customer use or distribution. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and record allowances for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected demand based upon projected product sales.

Stock-Based Compensation

We recognize compensation expense in an amount equal to the estimated grant date fair value of each option grant, or stock award over the estimated period of service and vesting. This estimation of the fair value of each stock-based grant or issuance on the date of grant involves numerous assumptions by management. Although we calculate the fair value under the Black Scholes Merton option pricing model, which is a standard option pricing model, the model still requires the use of numerous assumptions, including, among other things, the expected life (turnover), volatility of the underlying equity security, a risk free interest rate and expected dividends. The model and assumptions used also attempt to account for changing employee behavior when the stock price changes, and capture the observed pattern of increasing rates of exercise as the stock price increases. The use of different values by management in connection with assumptions used in the Black Scholes option pricing model could produce substantially different results.

Impairment of Long-Lived Assets

Our management reviews our long-lived assets with finite useful lives for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We recognize an impairment loss when the sum of the future undiscounted net cash flows expected to be realized from the asset is less than its carrying amount. If an asset is considered to be impaired, the impairment charge to be recognized is measured by the amount of difference between the recorded carrying value of the asset versus its fair value. Considerable judgment is

necessary to estimate the fair value of the assets and accordingly, actual results can vary significantly from such estimates. Our most significant estimate and judgment used when measuring whether there is an impairment to our long-lived assets includes the timing and amount of projected future cash flows.

Accounting for Income Taxes

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement basis and tax basis of assets and liabilities using enacted tax rates. Future tax benefits are subject to a valuation allowance when management is unable to conclude that our deferred tax assets will more-likely-than-not be realized in future results of operations. Our estimate for the valuation allowance for deferred tax assets requires management to make significant estimates and judgments about projected future operating results. If actual results differ from these projections or if management's expectations of future results change, it may be necessary to adjust the valuation allowance.

Since January 1, 2007, we have measured and recorded uncertain tax positions in accordance with accounting guidance as codified in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 740-10, Income Taxes (formerly FIN 48) that took effect on such date that prescribe a threshold for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Accordingly, we now only recognize (and continue to recognize) tax positions meeting the more-likely-than-not recognition threshold (or that met such a threshold on the effective date). Accounting for uncertainties in income tax positions involves significant judgments by management. If actual results differ from management’s estimates, we may need to adjust the provision for income taxes in both the current and prior periods.

Non-GAAP Financial Measures

To supplement our consolidated financial statements presented in accordance with GAAP, we disclose and discuss non-Forward Order revenues, a non-GAAP measure derived from results based on GAAP. The presentation of this additional information is not meant to be considered superior to, in isolation of or as a substitute for results prepared in accordance with GAAP. Non-Forward Order revenues should not be considered as an alternative to revenue (determined in accordance with GAAP) or as an indication of our performance, but we believe non-Forward Order revenues is important because it provides information about the current hospital customer demand for our product and the performance of our current operations by excluding the impact of the Forward Order revenue recognized. See discussion above in “Results of Operations”.

Adjusted cost of revenue and gross profit are not measures calculated in accordance with U.S. GAAP. Adjusted cost of revenue and gross profit should not be considered as an alternative to gross profit or, income (loss) from operations or any other measure of financial performance calculated and presented in accordance with U.S. GAAP. We prepare adjusted cost of revenue and gross profit to eliminate the impact of items that we do not consider indicative of our core operating performance and we use this as a measure of operating performance. We encourage you to evaluate these adjustments and the reasons we consider them appropriate, as well as the material limitations of non-GAAP measures and the manner in which we compensate for those limitations.

Adjusted working capital is a non-GAAP financial measure that management uses to assess the Company’s performance. Management believes adjusted working capital provides investors with an additional view of the Company’s liquidity and ability to repay current obligations. We calculate adjusted working capital as working capital (i.e., current assets less current liabilities, each as determined under GAAP) less deferred revenue, as deferred revenue relates to hardware reimbursement payments from Cardinal Health that are a non-cash liability. The presentation of this additional information is not meant to be considered superior to, in isolation of or as a substitute for results prepared in accordance with GAAP. This calculation of adjusted working capital should not be considered as an alternative (determined in accordance with GAAP) or as an indication of our performance. Our calculation of adjusted working capital, not including deferred revenue, may not be comparable to similarly titled measures reported by other companies. See discussion above in “Financial Condition, Liquidity and Capital Resources”.

Off-Balance Sheet Arrangements

As of December 31, 2012 and 2011, we had no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PATIENT SAFETY TECHNOLOGIES, INC.
INDEX TO FINANCIAL STATEMENTS

<u>Report of Squar, Milner, Peterson, Miranda & Williamson, LLP</u>	F-1
<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	F-2
<u>Consolidated Statements of Operations for the years ended December 31, 2012 and 2011</u>	F-3
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012 and 2011</u>	F-4
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Patient Safety Technologies, Inc.

We have audited the accompanying consolidated balance sheets of Patient Safety Technologies, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that were appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Patient Safety Technologies, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ SQUAR, MILNER, PETERSON, MIRANDA & WILLIAMSON, LLP

Newport Beach, California
March 18, 2013

F-1

PATIENT SAFETY TECHNOLOGIES, INC.

Consolidated Balance Sheets

	December 31,	
	2012	2011
Assets		
Current assets		
Cash and cash equivalents	\$ 5,177,082	\$ 3,668,524
Accounts receivable	1,415,634	1,307,510
Inventories, net	3,968,436	2,772,117
Prepaid expenses	308,285	180,802
Total current assets	10,869,437	7,928,953
Property and equipment, net	4,833,754	1,691,961
Goodwill	1,832,027	1,832,027
Patents, net	2,139,202	2,464,142
Other assets	37,462	40,463
Total assets	\$ 19,711,882	\$ 13,957,546
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 4,499,002	\$ 2,808,524
Accrued liabilities	960,062	574,917
Deferred revenue – current portion	846,395	278,002
Total current liabilities	6,305,459	3,661,443
Deferred revenue	969,395	267,025
Total liabilities	\$ 7,274,854	\$ 3,928,468
Commitments and contingencies (Note 15)		
Stockholders' equity		
Preferred stock, \$1.00 par value, 1,000,000 shares authorized:		
Series A preferred stock, \$1.00 par value, cumulative 7% dividend: 500,000 shares designated; 10,950 issued and outstanding at December 31, 2012 and December 31, 2011; (Liquidation preference of \$1.1 million at December 31, 2012 and December 31, 2011)	10,950	10,950
Series B convertible preferred stock, \$1.00 par value, cumulative 7% dividend: 150,000 shares designated; 70,425 issued and outstanding at December 31, 2012 and 65,864 issued and outstanding at December 31, 2011; (Liquidation preference of \$7.0 million at December 31, 2012 and \$6.6 million at December 31, 2011)	70,425	65,864
Common stock, \$0.0001 par value: 100,000,000 shares authorized; 37,041,170 shares issued and outstanding at December 31, 2012 and 34,020,255 shares issued and outstanding at December 31, 2011	3,705	3,402
Additional paid-in capital	74,094,855	68,957,072
Accumulated deficit	(61,742,907)	(59,008,210)
Total stockholders' equity	12,437,028	10,029,078

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

Total liabilities and stockholders' equity	\$ 19,711,882	\$ 13,957,546
--	---------------	---------------

The accompanying notes are an integral part of these consolidated financial statements.

F-2

PATIENT SAFETY TECHNOLOGIES, INC.

Consolidated Statements of Operations

	For the Years Ended December 31,	
	2012	2011
Revenues	\$ 17,589,391	\$ 9,463,479
Cost of revenue	10,038,046	5,115,946
Gross profit	7,551,345	4,347,533
Operating expenses		
Research and development	580,254	107,397
Sales and marketing	4,912,508	2,971,525
General and administrative	4,076,532	3,931,049
Total operating expenses	9,569,294	7,009,971
Operating loss	(2,017,949)	(2,662,438)
Other income (expense)		
Gain on change in fair value of warrant derivative liability	—	567,573
Interest expense to related party	(106,182)	—
Other income (expense), net	(2,095)	221,201
Total other income (expense)	(108,277)	788,774
Loss before income taxes	(2,126,226)	(1,873,664)
Income tax provision	(75,304)	(25,887)
Net Loss	(2,201,530)	(1,899,551)
Preferred dividends	(533,167)	(503,632)
Net loss applicable to common stockholders	\$ (2,734,697)	\$ (2,403,183)
Loss per common share		
Basic and Diluted	\$ (0.08)	\$ (0.08)
Weighted average common shares outstanding:		
Basic and Diluted	35,862,020	31,510,716

The accompanying notes are an integral part of these consolidated financial statements.

PATIENT SAFETY TECHNOLOGIES, INC.
Consolidated Statements of Stockholders Equity

	Series A		Series B		Common Stock		Additional Paid-in Capital *	Accumulated Deficit	Total Stockholders Equity
	Preferred Stock Shares	Amount	Convertible Preferred Stock Shares	Amount	Shares	Amount			
BALANCES, December 31, 2010	10,950	\$ 10,950	61,589	\$ 61,589	23,956,063	\$ 2,395	\$ 60,260,036	\$ (56,605,027)	\$ 3,729,943
Series A Preferred Stock Dividends	-	-	-	-	-	-	-	\$ (76,650)	\$ (76,650)
Series B Convertible Preferred Stock Dividends	-	-	4,275	\$ 4,275	-	-	\$ 421,686	\$ (426,982)	\$ (1,021)
Issuance of Common Stock net of transaction costs	-	-	-	-	9,489,192	\$ 949	\$ 6,786,310	-	\$ 6,787,259
Issuance of restricted stock	-	-	-	-	75,000	\$ 8	\$ (8)	-	\$ -
Warrants reclassified from derivative liability to equity	-	-	-	-	-	-	\$ 424,109	-	\$ 424,109
Stock-based compensation	-	-	-	-	-	-	\$ 743,507	-	\$ 743,507
Exercise of stock options	-	-	-	-	500,000	\$ 50	\$ 374,950	-	\$ 375,000
Repurchase of warrants	-	-	-	-	-	-	\$ (53,518)	-	\$ (53,518)
Net loss	-	-	-	-	-	-	-	\$ (1,899,551)	\$ (1,899,551)
BALANCES, December 31, 2011	10,950	\$ 10,950	65,864	\$ 65,864	34,020,255	\$ 3,402	\$ 68,957,072	\$ (59,008,210)	\$ 10,029,078
Series A Preferred Stock Dividends	-	-	-	-	-	-	-	\$ (76,650)	\$ (76,650)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

Series B Convertible Preferred Stock										
Dividends	-	-	4,561	\$ 4,561	-	-	\$ 451,539	\$ (456,517)	\$ (417)	
Issuance of Common Stock net of transaction costs	-	-	-	-	2,499,998	\$ 251	\$ 3,434,507	-	\$ 3,434,758	
Issuance of restricted stock	-	-	-	-	3,000	\$ 1	\$ (1)	-	\$ -	
Stock-based compensation	-	-	-	-	-	-	\$ 781,789	-	\$ 781,789	
Exercise of stock options	-	-	-	-	450,000	\$ 45	\$ 469,955	-	\$ 470,000	
Cashless exercise of warrants	-	-	-	-	67,917	6	\$ (6)	-	\$ -	
Net loss	-	-	-	-	-	-	-	\$ (2,201,530)	\$ (2,201,530)	
BALANCES, December 31, 2012	10,950	\$ 10,950	70,425	\$ 70,425	37,041,170	\$ 3,705	\$ 74,094,855	\$ (61,742,907)	\$ 12,437,028	

* The par value of common stock has been retroactively adjusted for a change in par value from \$0.33 to \$0.0001 in 2012.

The accompanying notes are an integral part of these consolidated financial statements.

PATIENT SAFETY TECHNOLOGIES, INC.
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2012	2011
Operating activities:		
Net loss	\$ (2,201,530)	\$ (1,899,551)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,793,911	582,799
Amortization of patents	324,941	324,941
Gain on contingent tax liability	—	(223,523)
Stock-based and warrant compensation	781,789	743,507
Gain on change in fair value of warrant derivative liability	—	(567,573)
Changes in operating assets and liabilities:		
Restricted cash	—	223,630
Accounts receivable	(108,124)	(535,129)
Inventories	(1,196,319)	(1,661,285)
Prepaid expenses	(127,483)	(76,174)
Other assets	3,001	(1,425)
Accounts payable	1,690,478	202,855
Accrued liabilities	385,145	(144,032)
Deferred revenue	1,270,763	(932,693)
Net cash provided by (used) in operating activities	2,616,572	(3,963,653)
Investing activities:		
Purchase of property and equipment	(4,935,704)	(1,294,927)
Net cash used in investing activities	(4,935,704)	(1,294,927)
Financing activities:		
Proceeds from issuance of common stock	3,499,997	7,112,501
Proceeds from exercise of stock options	470,000	375,000
Payments for common stock issuance costs	(65,240)	(325,242)
Repurchase of warrants	—	(53,518)
Payments of convertible preferred stock series B dividends	(417)	(1,021)
Payments of preferred stock series A dividends	(76,650)	(76,650)
Net cash provided by financing activities	3,827,690	7,031,070
Net increase in cash and cash equivalents	1,508,558	1,772,490
Cash and cash equivalents at beginning of year	3,668,524	1,896,034
Cash and cash equivalents at end of year	\$ 5,177,082	\$ 3,668,524
Supplemental disclosures of cash flow information:		
Cash paid during the period for taxes	\$ 4,258	\$ 25,887
Non cash investing and financing activities:		
Payment of Series B preferred dividends in shares	\$ 456,100	\$ 425,961
Issuance of common stock previously earned	\$ 7	\$ 8
Warrant reclassified from derivative liability to equity	\$ —	\$ 424,109

The accompanying notes are an integral part of these consolidated financial statements.

F-5

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Patient Safety Technologies, Inc. (the "Company") is a Delaware corporation. The Company's operations are conducted through its wholly-owned operating subsidiary, SurgiCount Medical, Inc. ("SurgiCount"), a California corporation.

The Company's operating focus is the development, marketing and sales of products and services focused in the medical patient safety markets. The SurgiCount Safety-Sponge® System is a patented system of bar-coded surgical sponges, SurgiCounter™ scanners, and software applications integrated to form a comprehensive counting and documentation system. This system is designed to reduce the number of retained surgical sponges unintentionally left inside of patients during surgical procedures by allowing faster and more accurate counting of surgical sponges.

2. LIQUIDITY

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. At December 31, 2012, the Company has an accumulated deficit of approximately \$62 million and positive working capital of approximately \$4.6 million and cash and cash equivalents of approximately \$5.2 million. For the year ended December 31, 2012, the Company had a net operating loss of approximately \$2.0 million and generated positive cash flow from operating activities of approximately \$2.6 million.

Management believes the Company's cash and cash equivalents on hand as of December 31, 2012, are sufficient to fund the Company's currently projected cash requirements, including funding planned sales growth and other identified needs for at least the next 12 months.

3. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements for 2012 and 2011 include the accounts of the Company and its wholly owned subsidiary SurgiCount Medical, Inc. All significant intercompany balances and transactions have been eliminated in consolidation.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Use of Estimates

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. These estimates and assumptions include, but are not limited to, assessing the following: the valuation of accounts receivable and inventory, valuation of investments, estimated useful lives of long lived assets, impairment of goodwill and other intangible assets, stock-based compensation, fair value of derivative liabilities, valuation allowance related to deferred tax assets, warranty obligations, provisions for returns and allowances and the determination of assurance of the collection of revenue arrangements.

Reclassifications

Certain prior year amounts have been reclassified to conform to the 2012 presentation. These reclassifications had no effect on previously reported results of operations or accumulated deficit.

Revenue Recognition

Revenue related to surgical products is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, when collectability is reasonably assured and when risk of loss transfers, usually when products are shipped. Reimbursements related to scanners and related equipment provided to hospitals are initially recognized as deferred revenue when cash is received and recognized as revenue on a straight-line basis over the expected term of the related customer contract, while the cost of the scanners and related equipment is carried in hardware equipment within property, plant and equipment and depreciated as a component of cost of sales over its estimated useful life. Generally, the expected term of the customer contracts and the estimated useful life of the scanners are both three years. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any rebates or discounts given to the buyer.

The Company records shipping and handling costs charged to customers as revenue and shipping and handling costs to cost of revenue as incurred.

Financial Instruments

The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, accounts receivable and accounts payable approximate their fair values because of the short-term nature of these financial instruments.

Fair Value Measurements

The Company adopted the fair value measurement and disclosure requirements of FASB guidance as codified in ASC 820 Fair Value Measurements and Disclosures (“ASC 820”) effective January 1, 2008 for financial assets and liabilities measured on a recurring basis. ASC 820 defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. This standard applies in situations where other accounting pronouncements either permit or require fair value measurements. ASC 820 does not require any new fair

value measurements.

Fair value is defined in ASC 820 as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are to be considered from the perspective of a market participant that holds the assets or owes the liability. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The standard describes three levels of inputs that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical or similar assets and liabilities.

Level 2: Quoted prices for identical or similar assets and liabilities in markets that are not active or observable inputs other than quoted prices in active markets for identical or similar assets and liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company did not have any recurring or nonrecurring fair value measurements as of December 31, 2012 and 2011.

Cash and Cash Equivalents

Cash equivalents are short-term, highly liquid investments with original maturities of three months or less when purchased.

F-7

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Concentration of Credit Risk and Limited Suppliers

The financial instruments that potentially subject the Company to concentrations of credit risk are cash and cash equivalents and accounts receivable. From time to time, the Company maintains its cash balances in accounts at a financial institution that exceed the Federal Deposit Insurance Corporation coverage. The Company has not experienced any losses in such accounts.

The Company sells its products primarily to Cardinal Health based on its exclusive distribution agreement with Cardinal Health. Cardinal Health in turn resells the products to alternative distributors or hospitals that have contracts with the Company. Substantially all of the Company's accounts receivable and revenues were to Cardinal Health. The loss of the Cardinal Health contract and disruption of the distribution channel would adversely affect the Company's operating results.

The Company relies primarily on a third-party supplier, A Plus International ("A Plus"), to supply all the surgical sponges and towels used in its Safety-Sponge® System. The Company also relies on a number of third parties to manufacture certain other components of its Safety-Sponge® System. If A Plus or any of the Company's other third-party manufacturers cannot, or will not, manufacture its products in the required volumes, on a cost-effective basis, in a timely manner, or at all, the Company will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on the Company's business and operating results.

Furthermore, all products obtained from A Plus are manufactured in China. As such, the supply of product from A Plus is subject to various political, economic, and other risks and uncertainties inherent in importing products from this country, including among other risks, export/import duties, quotas and embargoes; domestic and international customs and tariffs; changing taxation policies; foreign exchange restrictions; and political conditions and governmental regulations.

Accounts Receivable

Accounts receivable are recorded at the invoice amount and do not bear interest. Historically, the Company has incurred minimal credit losses on extended credits. An allowance for bad debts has not been recorded and is not considered necessary due to the nature of the Company's customer base and the lack of historical write offs. If customer payment timeframes were to deteriorate, allowances for doubtful accounts would be required.

Inventories

Inventories are stated at the lower of cost or market on the first-in, first-out (FIFO) basis. The FIFO cost for all inventories approximates replacement cost.

The Company maintains reserves for excess and obsolete inventory resulting from the potential inability to sell its products at prices in excess of current carrying costs. The markets in which the Company operates are highly competitive, and new products and surgical procedures are introduced on an ongoing basis. Such marketplace changes may cause the Company's products to become obsolete. The Company makes estimates regarding the future recoverability of the costs of these products and records a provision for excess and obsolete inventories based on historical experience and expected future trends.

Property and Equipment

Property and equipment is stated at cost. Depreciation is amortized straight-line over the estimated useful lives of three to seven years. Upon retirement or disposition of equipment, the related cost and accumulated depreciation or amortization is removed and a gain or loss is recorded, as applicable.

Impairment of Long Lived Assets and Intangible Assets with Finite Lives

Property and equipment and intangible assets with finite lives are amortized using the straight line method over their estimated useful lives. These assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Conditions that would indicate impairment and trigger an assessment include, but are not limited to, a significant adverse change in the legal factors or business climate that could affect the value of an asset, an adverse action or assessment by a regulator or a current expectation that, more likely than not, a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. If, upon assessment, the carrying amount of an asset exceeds its estimated fair value, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds its estimated fair value of the asset. As of December 31, 2012 and 2011 there was no impairment recorded.

Impairment of Goodwill

The Company applies Financial Accounting Standards Board's ("FASB") Accounting Standards Update No. 2011-08 ("ASU No. 2011-08"), which allows a company to first assess qualitative factors to determine if it is necessary to perform the two-step quantitative goodwill impairment test. The Company assesses qualitative factors to determine if its sole reporting unit's fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit's fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. Quantitative testing compares the fair value of the reporting unit to its book value, including goodwill. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded. There was no impairment of goodwill for the years ended December 31, 2012 and 2011.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Research and Development

Our research and development expenses consist of costs associated with the design, development, testing and enhancement of the Company's products.

Advertising

Advertising costs, which include promotional expenses, are expensed in the period incurred and reported under sales and marketing expenses. The Company recorded \$15 thousand and \$39 thousand in advertising costs during the years ended December 31, 2012 and 2011, respectively.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. To the extent that available evidence about future taxable earnings indicates that it is more likely than not that the tax benefit associated with the deferred tax assets will not be realized, a valuation allowance is established.

Stock-Based Compensation

The Company measures compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes-Merton option-pricing model. Compensation expense is recognized on a straight-line basis over the service period for awards expected to vest. The risk-free interest rate for periods within the expected life of options granted is based on the U.S. Treasury yield curve in effect at the time of grant. Expected stock price volatility is based on historical volatility of the Company's stock. The expected option life, representing the period of time that options granted are expected to be outstanding, is based on historical option exercise and employee termination data.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Net Loss per Common Share

Income (loss) per common share is determined by dividing the income (loss) applicable to common shareholders by the weighted average number of common shares outstanding. The Company complies with FASB ASC 260-10 Earnings Per Share, which requires dual presentation of basic and diluted earnings per share on the face of the consolidated statements of operations. Basic income (loss) per common share excludes dilution and is computed by dividing loss attributable to common stockholders by the weighted-average common shares outstanding for the period. Diluted income (loss) per common share reflects the potential dilution that could occur if convertible preferred stock or debentures, options and warrants were to be exercised or converted or otherwise resulted in the issuance of common stock that then shared in the earnings of the entity.

The following table sets forth the computation of basic and diluted loss per share:

	Years Ended December 31,	
	2012	2011
Basic and Diluted		
Loss available to common stockholders	\$ (2,734,697)	\$ (2,403,183)
Weighted average common shares outstanding	35,862,020	31,510,716
Loss per common share	\$ (0.08)	\$ (0.08)
Potentially dilutive securities outstanding at period end excluded from diluted computation as they were anti-dilutive	16,812,007	17,056,797

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

4. INVENTORIES, net

Inventories, net, consist of the following:

	December 31, 2012	December 31, 2011
Surgical sponges and towels	\$ 3,722,211	\$ 1,150,253
Scanners and related hardware	363,409	1,790,861
Reserve of obsolescence	(117,184)	(168,997)
Total inventories, net	\$ 3,968,436	\$ 2,772,117

5. PROPERTY AND EQUIPMENT, net

Property and equipment consists of the following:

	December 31, 2012	December 31, 2011
Computer software and equipment	\$ 1,718,247	\$ 1,504,971
Furniture and equipment	88,626	70,571
Hardware equipment for customer use	6,992,994	2,288,621
Property and equipment, gross	8,799,867	3,864,163
Less: accumulated depreciation	(3,966,113)	(2,172,202)
Property and equipment, net	\$ 4,833,754	\$ 1,691,961

Depreciation expense for the years ended December 31, 2012 and 2011 was \$1.8 million and \$583 thousand, of which \$1.7 million and \$514 thousand was recorded as cost of revenue, respectively.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

6. GOODWILL AND PATENTS

The Company recorded goodwill in the amount of \$1.8 million in connection with its acquisition of SurgiCount Medical, Inc. In addition, in connection with the SurgiCount acquisition, the Company recorded patents acquired that were valued at \$4.7 million.

Patents, net, consist of the following:

	December 31, 2012	December 31, 2011
Patents	\$ 4,684,576	\$ 4,684,576
Accumulated amortization	(2,545,374)	(2,220,434)
	\$ 2,139,202	\$ 2,464,142

The patents are subject to amortization over their original estimated useful life of 14.4 years. Amortization expense was \$325 thousand for the years ended December 31, 2012 and 2011. The following table presents estimated amortization expense for each of the succeeding five calendar years and thereafter:

2013	\$ 324,941
2014	324,941
2015	324,941
2016	324,941
2017	324,941
Thereafter	514,497
Total	\$ 2,139,202

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

7. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31, 2012	December 31, 2011
Accrued lease liability	\$ 24,113	\$ 78,057
Accrued dividends on Series A Preferred Stock	114,976	114,976
Compensation related accruals	576,973	210,291
Other	244,000	171,593
Total accrued liabilities	\$ 960,062	\$ 574,917

8. DEFERRED REVENUE

The Company generally provides its SurgiCounter™ scanners and related software to most hospitals at no cost when they adopt its Safety-Sponge® System. Under the Company's existing distribution agreement with Cardinal Health, Inc. ("Cardinal Health"), Cardinal Health has agreed to reimburse the Company for a percentage of the scanner costs supplied to certain hospitals. Payments received from Cardinal Health relating to scanner cost reimbursements are deferred, and recognized as revenue on a pro-rata basis over the life of the scanner (which approximates the term of the hospital purchase commitment as they are refundable in the event a hospital contract is cancelled). Revenue recognized related to these reimbursements for the year ended December 31, 2012 and 2011 was \$707 thousand and \$191 thousand.

9. EQUITY TRANSACTIONS

Change in Par value

On July 18, 2012 the Company amended its Amended and Restated Certificate of Incorporation to change the par value of its common stock from \$0.33 to \$0.0001. All common stock per share information in the accompanying condensed consolidated financial statements and notes thereto have been adjusted to reflect retrospective application of the change in par value.

Series A Preferred Stock

The Series A Preferred Stock has a cumulative 7% per annum quarterly dividend and is convertible into the number of shares of common stock by dividing the purchase price for the convertible preferred stock by conversion price in effect, currently \$4.44. The convertible preferred stock has anti-dilution provisions, which can change the conversion price in certain circumstances. Upon liquidation, dissolution or winding up of the Company, the stockholders of the convertible preferred stock are entitled to receive \$100 per share plus any accrued and unpaid dividends before distributions to any holder of the Company's common stock. The Company may redeem the convertible preferred stock at a redemption price in cash equal to the liquidation preference per share plus any accrued and unpaid dividends thereon through the date of such redemption. The Series A Stock votes on all matters submitted to our stockholders for a vote, voting together with the holders of our common stock as a single class, with each share of Series A Stock entitled to one vote per share.

The Company recorded \$77 thousand in Series A Preferred Stock dividend for the years ended December 31, 2012 and 2011. The Company had Series A Preferred Stock accrued dividends of \$115 as of December 31, 2012 and 2011.

Series B Preferred Stock

In June 2010, the Company issued 60,500 shares of \$1 par value, \$100 stated value Series B preferred convertible shares ("Series B Preferred"). The buyers of the Series B Preferred shares were accredited investors under Rule 501(a) of Regulation D of the Securities Act of 1933, and included A Plus, JMR Capital Ltd., and Catalysis Partners, LLC. Wayne Lin, a member of our Board of Directors ("Board") is founder and significant beneficial owner of A Plus. John Francis, a member of our Board, has voting and investment control over securities held by Francis Capital Management, LLC, which acts as the investment manager for Catalysis Partners, LLC.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Holders of the Series B Preferred are entitled to receive quarterly cumulative dividends at a rate of 7% per annum. All dividends due on or prior to December 31, 2011 (since amended to December 31, 2012) are payable in kind in the form of additional shares of Series B Preferred, and all dividends payable after December 31, 2011 (since amended to December 31, 2012) are payable solely in cash. For the years ended December 31, 2012 and 2011, the Company issued 4,561 and 4,275 shares, respectively, of additional shares of Series B Preferred Stock for dividends payable.

As long as shares of Series B Preferred are outstanding, we are restricted from making certain payments in respect of any of our junior and pari passu securities, except that we may pay dividends due and paid in the ordinary course on our Series A Preferred Stock when we are otherwise in compliance with our payment obligations to the holders of the Series B Preferred.

The Series B Preferred does not have voting rights except (i) as provided by Delaware law; (ii) upon the occurrence of the fifth anniversary of the issue date; or (iii) upon our failure to pay dividends for two consecutive quarters or three non-consecutive quarters. Upon the occurrence of either event described in (ii) or (iii), the holders of the Series B Preferred are entitled to elect two additional directors to our board of directors and, within two business days, we must create a special committee of our board of directors consisting of up to three directors, of which two must be the two newly-elected additional directors, and promptly grant such special committee sole and exclusive authority and power to investigate, negotiate and consummate a sale of the Company or strategic alternative thereto. The Series B Preferred are entitled to receive, prior and in preference to all other shares of our capital stock (with an exception noted below), upon liquidation, dissolution or winding up of the Company an amount per share equal to the greater of (i) the stated value of the Series B Preferred, plus accrued but unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series B Preferred Stock been converted into our common stock immediately prior to such liquidation. Notwithstanding the foregoing, the first \$1,095,000 of distributable amounts in liquidation shall first be paid to the holders of our Series A Preferred Stock. Mergers, sales of substantially all assets and similar transactions are deemed to be liquidations for purposes of the liquidation preference.

The Series B Preferred is convertible at any time at the option of the holder into shares of our common stock at \$0.75 per share, subject to conventional adjustments for stock splits, stock combinations and the like. The Series B Preferred is not redeemable either by the Company or by the holders. However, shares of the Company's Series B Preferred automatically convert into shares of our common stock at the \$0.75 conversion price if both of the following conditions are satisfied: (a) the daily volume weighted average price of our common stock is equal to or in excess of \$1.50 per share for all trading days during any 6-month period and (b) the number of shares traded during such period averages at least 50,000 shares of common stock per trading day. Also, the Series B Preferred automatically convert into shares of our common stock at the applicable conversion price if our operating income is positive for at least four consecutive fiscal quarters and our cumulative operating income during such four fiscal quarters is at least \$5,000,000.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Common Stock

In February 2011 the Company issued 75,000 shares of restricted stock to a consultant for services previously rendered in 2010, contracted for by prior management.

On March 29 and March 30, 2011, the Company closed on a private placement financing raising \$7.1 million through the issuance of 9.489 million shares of the Company's common stock at a selling price of \$0.75 per share ("Common"). The buyers of the common shares were accredited investors under Rule 501(a) of Regulation D of the Securities Act of 1933., and included Kinderhook Partners, L.P. ("Kinderhook") and A Plus and certain members of management (collectively referred to as the "Buyers"). Wayne Lin, a member of our Board of Directors is founder and significant beneficial owner of A Plus. Kinderhook is an investment fund based in Fort Lee, NJ.

On May 18, 2012 the Company closed a financing transaction (the "Financing") pursuant to a Common Stock Purchase Agreement (the "Purchase Agreement") dated May 15, 2012 with certain accredited investors (the "Buyers"), most of whom are previous purchasers of the Company's securities and all of whom are accredited investors, including Wenchen ("Wayne") Lin, a member of the Company's Board of Directors, as defined under Rule 501(a) of Regulation D of the Securities Act of 1933, as amended.

Pursuant to the Purchase Agreement, the Company issued to the Buyers an aggregate of 2,499,998 shares of our Common Stock at a purchase price of \$1.40 per share (or \$3,499,997 in gross proceeds), payable in cash.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

10. WARRANTS

The following table summarizes warrants to purchase common stock activity for the years ended December 31, 2012 and 2011:

	# of Warrants	Range of Exercise Price
Warrants outstanding December 31, 2010	7,486,586	\$ 0.75 - 4.50
Issued	51,177	\$ 0.75
Exercised	(170,032)	\$ 0.75 - 1.25
Cancelled/Expired	(2,213,419)	\$ 0.75 - 6.05
Warrants outstanding December 31, 2011	5,154,312	\$ 0.75 - 4.00
Issued		—\$ —
Exercised	(188,377)	\$ 0.75 - 1.40
Cancelled/Expired	(718,000)	\$ 2.00
Warrants outstanding December 31, 2012	4,247,935	\$ 0.75 - 4.50

At December 31, 2012, warrants to purchase common stock will expire as follows:

	# of Warrants	Range of Exercise Price
2013	1,661,060	\$ 0.75 - 1.40
2014	1,890,000	\$ 1.82 - 4.00
2015	696,875	\$ 1.25 - 0.75 -
Total	4,247,935	\$ 4.00

The weighted-average remaining contractual life of the warrants outstanding at December 31, 2012 is 1.3 years.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Warrants and Warrant Derivative Liability

On October 14, 2011 the Company's Board of Directors approved exchanging certain warrant contracts involving 511,767 shares that had terms that created certain anti-dilutive features under ASC 815-40. As part of compensation for eliminating these anti-dilutive accounting features from these respective warrants, the warrant holders received an additional 51,177 warrants at the original terms. The exchange was accounted for as a modification. Based on the change in fair value the company recorded a non-cash stock compensation expense of \$42 thousand for the year ended December 31, 2011.

At December 31, 2012 and 2011 the Company did not have a warrant derivative liability in the accompanying consolidated balance sheet as a result of the October 14, 2011 exchange. The Company did record a non-cash gain of \$568 thousand for the year ended December 31, 2011 in other income (expense) for the extinguishment of the warrant derivative liability.

11. STOCK OPTION PLANS

In November 2005, the Company approved the Amended and Restated 2005 Stock Option and Restricted Stock Plan (the "2005 SOP"). The 2005 SOP reserves 2,000,000 shares of common stock for grants of incentive stock options, nonqualified stock options, warrants and restricted stock awards to employees, non-employee directors and consultants performing services for the Company. Options granted under the 2005 SOP have an exercise price equal to or greater than the fair market value of the underlying common stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options generally expire 10 years from the date of grant. Restricted stock awards granted under the 2005 SOP are subject to a vesting period determined at the date of grant. As of December 31, 2012 1,257,132 shares remain available under this plan.

In August 2009, the Company approved the 2009 Stock Option Plan (the "2009 SOP"). The 2009 SOP reserves 3.0 million shares of common stock for grants of incentive stock options, nonqualified stock options, warrants and restricted stock awards to employees, non-employee directors and consultants performing services for the Company. The Company's shareholders amended the 2009 Stock Option Plan to increase the number of shares issuable under the plan from 3,000,000 to 4,500,000 and clarify the non-discretionary nature of the annual share limit, whereby no more than 500,000 shares may be granted under options to any person in a calendar year. Options granted under the 2009 SOP have an exercise price equal to or greater than the fair market value of the underlying common stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options generally expire 10 years from the date of grant. Restricted stock awards granted under the 2009 SOP are subject to a vesting period determined at the date of grant. As of December 31, 2012, 1,501,099 shares remain outstanding under this plan.

All options that the Company granted during the years ended December 31, 2012 and 2011 were granted at the per share fair market value on the grant date. Vesting of options differs based on the terms of each option. The Company utilized the Black-Scholes option pricing model and the assumptions used for each period are as follows:

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

	Year Ended December 31,	
	2012	2011
Weighted average risk free interest rate	1.01%	1.63%
Weighted average expected life (in years)	6.09	6.07
Weighted average volatility	89%	91%
Expected dividend yield	0%	0%
Weighted average grant-date fair value per share of options granted	\$ 0.98	\$ 0.76

The dividend yield of zero is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends on its common stock. Expected volatility is based on the historical weekly volatility of the Company's common stock. The risk-free interest rate is based on rates published by the Federal Reserve Board. The expected life is based on observed and expected time to post-vesting exercise. The expected forfeiture rate is based on past experience and employee retention data. Forfeitures are estimated at the time of the grant and revised in subsequent periods if actual forfeitures differ from those estimates or if the Company updates its estimated forfeiture rate. Such amounts will be recorded as a cumulative adjustment in the period in which the estimate is changed.

A summary of stock option activity for the years ended December 31, 2012 and 2011 are presented below:

	Outstanding Options			
Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (1)
Balance at December 31, 2010	7,971,949	\$ 1.11	7.35	\$ —
Granted	437,000	\$ 1.02	9.57	—
Exercised	(500,000)	\$ 0.75	—	—
Forfeited/Cancelled	(1,729,572)	\$ 0.92	—	—
Balance at December 31, 2011	6,179,377	\$ 1.19	7.52	—
Granted (2)	513,400	\$ 1.33	9.19	—
Exercised	(450,000)	\$ 1.04	—	—
Forfeited/Cancelled	(645,542)	\$ 1.63	—	—
Balance at December 31, 2012	5,597,235	\$ 1.17	7.45	\$ 3,613,649
Vested and exercisable as of December 31, 2012	3,641,544	\$ 1.27	7.01	\$ 2,300,545
Unvested and expected to vest as of December 31, 2012	1,857,971	\$ 0.98	8.27	\$ 1,247,489

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$1.65 of the Company's common stock at December 31, 2012.

(2)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

Includes 230,000 non-qualified options and 40,000 incentive stock options that were issued outside the 2005 and 2009 stock option plans which are all outstanding as of December 31, 2012.

The total grant date fair value of stock options granted during the years ended December 31, 2012 and 2011 was \$502 thousand and \$333 thousand, respectively. During the fiscal years ended December 31, 2012 and 2011, the Company recognized stock-based compensation expense relating to stock options of \$779 thousand and \$701 thousand, respectively.

As of December 31, 2012, there was approximately \$1.3 million of unrecognized compensation costs related to outstanding employee stock options. This amount is expected to be recognized over a weighted average period of 2.16 years. To the extent the forfeiture rate is different from what the Company anticipated; stock-based compensation related to these awards will be different from the Company's expectations.

F-18

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

12. RELATED PARTY TRANSACTIONS

For the years ended December 31, 2012 and 2011, the Company purchased from A Plus approximately \$10.5 million and \$4.3 million, respectively, in connection with the manufacture of surgical products used in the Safety-Sponge® System by A Plus. Wayne Lin, a Director and significant beneficial owner of the Company is a founder and significant owner of A Plus. The vast majority of these amounts were recognized in cost of revenues. At December 31, 2012 and 2011, the Company's accounts payable included \$4.0 million and \$1.2 million respectively, owed to A Plus in connection with the manufacture and supply of surgical products used in the Safety-Sponge® System. In addition the Company recognized for the year ended December 31, 2012 and 2011 \$106 thousand and \$0 in interest expense related to the Company incurring interest charges for payables aging outside of contractual terms, respectively. Such interest was classified as a financing cost in the accompanying consolidated financial statements.

During the years ended December 31, 2012 and 2011 the Company issued to A Plus Series B preferred shares as paid in kind dividends of 746 and 701, respectively.

13. INCOME TAXES

For financial reporting purposes, loss before income taxes includes the following components for the years ended December 31, 2012 and 2011:

	2012	2011
United States	\$(2,126,226)	\$(1,873,664)
International	—	—
	\$(2,126,226)	\$(1,873,664)

The provision for income taxes for the years ended December 31, 2012 and 2011 are as follows:

	2012	2011
Current:		
Federal	\$ —	\$ —
State	75,304	25,887
Total current tax expense	75,304	25,887
Deferred:		
Federal	—	(9,366)
State	—	9,366
Total deferred taxes	—	—
Total income tax provision	\$ 75,304	\$ 25,887

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

For the years ended December 31, 2012 and 2011, a reconciliation of the federal statutory tax rate to the Company's effective tax rate is as follows:

	2012	2011
Statutory rate	34.00%	34.00%
State rate	4.29%	6.45%
Uncertain tax position adjustments	(2.25)%	—
Warrant derivative liability	(0.04)%	9.23%
Incentive stock option	(6.25)%	(8.32)%
Other	(3.65)%	(0.80)%
Change in valuation allowance	(29.64)%	(41.94)%
Total effective tax rate	(3.54)%	(1.38)%

Deferred income taxes reflect the net tax effects of (a) temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses. Significant components of the Company's deferred tax assets as of December 31, 2012 and 2011 are as follows:

	2012	2011
Deferred Tax Assets:		
Compensation related accruals	\$ 348,317	\$ 320,587
Inventory	46,680	67,319
Investments	265,563	265,563
Net operating loss carryovers	4,000,949	3,265,439
Deferred revenue	460,771	17,121
Other	33,275	—
Total deferred tax assets	5,155,555	3,936,029
Deferred Tax Liabilities:		
Book and tax basis differences arising from purchased patents	(852,138)	(981,576)
Fixed assets	(820,159)	(101,505)
Total deferred tax liability	(1,672,297)	(1,083,081)
Net deferred tax asset before valuation allowance	3,483,258	2,852,948
Less: valuation allowance	(3,483,258)	(2,852,948)
Net deferred tax asset	\$ —	\$ —

The Company reduced its deferred tax asset related to share-based compensation expense as of December 31, 2011 to \$321 thousand to reflect the reversal of amounts attributable to stock-based awards forfeited by individuals that are no longer employed with the Company. The adjustment resulted in a corresponding reduction of the valuation allowance.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets depends upon the generation of future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2012, the Company has provided a valuation allowance of \$3.5 million. The valuation

allowance increased by \$630 thousand during 2012.

F-20

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

At December 31, 2012 the Company had federal and state net operating losses of \$10 million and \$8 million, respectively. These net operating losses expire in varying amounts through 2032. Utilization of our net operating loss may be subject to annual limitation due to ownership change limitations that may have occurred or that could occur the future, as required by Section 382 of the Internal Revenue Service Code of 1986, as amended (the "Code") as well as similar state provisions. These ownership changes may limit the amount of NOL carryovers that can be utilized annually to offset future taxable income and tax respectively. During 2010, the Company performed a limited scope analysis of the potential impact of a limitation of the usage of its net operating carryovers under Internal Revenue Code Section 382. Based upon the analysis, management concluded that it was appropriate to include a portion of the federal and state net operating loss carryovers in the determination of its net deferred tax asset or liability as it did not appear that an annual limitation under Code Section 382 would cause all of the net operating loss carryovers to expire unutilized.

On January 1, 2007 the Company adopted the provisions of ASC 740-10, Income Taxes, relating to accounting for uncertain tax positions. ASC 740-10 addresses the determination of how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company must recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution. The Company did not recognize any additional liabilities for uncertain tax positions as a result of the implementation of ASC 740-10.

As of December 31, 2012 and 2011, the Company had unrecognized tax benefits of \$113 thousand and \$54 thousand, respectively, all of which, if subsequently recognized, would impact the Company's tax rate. A reconciliation of the beginning and ending amount of recognized tax benefits is as follows:

	2012	2011
Gross unrecognized tax benefits at January 1,	\$ 53,958	\$ 53,958
Changes to unrecognized tax positions from a prior period	—	—
Increases for tax positions in current year	59,379	—
Gross unrecognized tax benefits at December 31,	\$ 113,337	\$ 53,958

The Company files income tax returns in the U.S. federal and various state jurisdictions. In general, the Company is no longer subject to U.S. federal and state income tax examinations for years prior to 2007 (except for the use of tax losses generated prior to 2007 that may be used to offset taxable income in subsequent years). The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months.

The Company accrues interest and penalties on any unrecognized tax benefits, as applicable, on unrecognized tax benefits as a component of income tax expense. The Company accrued \$9 thousand and \$0 of interest and penalties associated with unrecognized tax benefits in the years ended December 31, 2012 and 2011, respectively.

14. MAJOR CUSTOMERS, SUPPLIERS, SEGMENT AND RELATED INFORMATION

Major Customers

During the years ended December 31, 2012 and 2011, due to its exclusive distribution agreement with Cardinal Health See –“Factors affecting Future Results” described elsewhere in this Report, the Company had one customer that represented in excess of 99% of revenues and accounts receivables.

Suppliers

The Company relies primarily on a third-party supplier, A Plus, to supply all the surgical sponges and towels used in its Safety-Sponge® System. The Company also relies on a number of third parties to manufacture certain other components of its Safety-Sponge® System. If A Plus or any of the Company’s other third-party manufacturers cannot, or will not, manufacture its products in the required volumes, on a cost-effective basis, in a timely manner, or at all, the Company will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on the Company’s business and operating results.

F-21

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Segment and Related Information

The Company presents its business as one reportable segment due to the similarity in nature of products marketed, financial performance measures, and methods of distribution and customer markets. The Company's chief operating decision making officer reviews financial information on the Company's patient safety products on a consolidated basis.

The following table summarizes revenues by geographic region. Revenues are attributed to countries based on customer location:

Years Ended December 31,	2012	2011
Revenues:		
United States	\$ 17,589,391	\$ 9,463,479
Other	—	—
Total revenues	\$ 17,589,391	\$ 9,463,479

The following table summarizes revenues by product line:

Years Ended December 31,	2012	2011
Revenues:		
Surgical sponges and towels	\$ 16,792,455	\$ 9,163,149
Scanners and related products	796,936	300,330
Total revenues	\$ 17,589,391	\$ 9,463,479

15. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company does not own any real estate or other physical properties materially important to our operations. In November 2010, the Company relocated corporate headquarters to Irvine, California, where the Company rents approximately 5,800 square feet of office space with initial monthly installments of \$8,800 with annual adjustments over the lease term. The Company also rents approximately 3,800 square feet of warehouse space in Irvine California with initial monthly installments of \$4,600 with annual adjustments over the lease term.

During the years ended December 31, 2012 and 2011, the Company recorded total rent expense of \$146 thousand and \$104 thousand, respectively.

The following table summarizes operating obligations, net of sublease commitments, as of December 31, 2012:

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

Years ending December 31,	Operating lease payments	Sub-lease income	Net lease Payments
2013	\$ 185,311	(36,680)	148,631
2014	—	—	—
2015	—	—	—
2016	—	—	—
Total minimum lease payments	\$ 185,311	(36,680)	148,631

Contingent Tax Liability

In the process of preparing the Company's federal tax returns for prior years, the Company's management found there had been errors in reporting income to the recipients and the respective taxing authorities, related to stock grants made to those certain employees and consultant recipients. In addition, the Company determined that required tax withholding relating to these stock grants had not been made, reported or remitted, as required in fiscal years 2006 and 2007. Due to the Company's failure to properly report this income and withhold/remit required amounts, the Company may be held liable for the amounts that should have been withheld plus related penalties and interest. The Company had estimated its contingent liability based on the estimated required federal and state withholding amounts, the employee and employer portion of social security taxes as well as the possible penalties and interest associated with the error.

During the quarter ended June 30, 2011, the Company reduced the tax contingent liability by \$223 thousand as the Company determined that it is improbable that it could be held liable for this amount owed related to the 2006 and 2007 tax years, which resulted in a \$223 thousand gain recorded as other income. The Company had also previously agreed to set aside restricted cash in an escrow account for satisfying any potential liability.

Legal Proceedings

The Company is involved in various proceedings, legal actions and claims arising in the normal course of business. The outcomes of these matters will generally not be known for prolonged periods of time. In certain of the legal proceedings, the claimants seek damages, as well as other compensatory relief, which could result in the payment of significant claims and settlements. In legal matters for which management determines both that a loss is probable and has sufficient information to reasonably estimate the Company's future obligations, a liability representing management's best estimate of the probable cost, or the minimum of the range of probable losses when a best estimate within the range is not known, for the resolution of these legal matters is recorded. The estimates are based on consultation with legal counsel, previous settlement experience and settlement strategies.

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.

Patient Safety Technologies, Inc.
Notes to Consolidated Financial Statements

16. SUBSEQUENT EVENTS

Management has evaluated events through the date these consolidated financial statements were filed with the Securities and Exchange Commission.

In January 2013, Cardinal Health and the Company signed the second amendment to the Supply and Distribution agreement. The Second Amendment amends a number of terms under the Supply 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 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 the 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 Agreement is terminable by Cardinal Health upon a change of control of the Company.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Limitations on the Effectiveness of Controls

We seek to improve and strengthen our control processes to ensure that all of our controls and procedures are adequate and effective. We believe that a control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. No evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company will be detected.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2012.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Changes in Internal Control over Financial Reporting

During the most recent fiscal quarter 2012 (the fourth fiscal quarter of 2012) there were no significant changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information appearing under the headings “Board of Directors and Corporate Governance, “ Executive Officers” and Election of Directors” in our 2013 Proxy Statement or in a future amendment to the Annual Report on Form 10-K, in either case, is incorporated in this Section by reference.

Code of Business Conduct and Ethics

Each of our executive officers and directors, as well as all of our employees (including our Chief Executive Officer, principal financial officer, principal accounting officer, controller and persons performing similar functions) are subject to our Code of Business Conduct and Ethics, which was adopted by our Board of Directors on November 11, 2004 and is incorporated by reference as an Exhibit to this Annual Report on Form 10-K.

Printed copies of our Code of Business Conduct and Ethics; the Charters of each of our Audit Committee, Compensation Committee, and Nominating and Governance Committees, are also available upon written request to the Chief Financial Officer, Patient Safety Technologies, Inc., c/o Chief Financial Officer, 2 Venture Plaza, Suite 350, Irvine, CA 92618.

ITEM 11. EXECUTIVE COMPENSATION

The information appearing under the headings “Director Compensation” and “Executive Compensation” in our 2013 Proxy Statement or in a future amendment to this Annual Report on Form 10-K, in either case, is incorporated section by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information appearing under the headings “Security Ownership of Certain Beneficial Owners and Management and “Equity Compensation Plan Information” in our 2013 Proxy Statement or in a future amendment to this Annual Report on Form 10-K, in either case, is incorporated in this section by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information appearing under the headings “Certain Relationships and Related Party Transactions,” and “Board of Directors and Corporate Governance - Independence of the Board of Directors” in our 2013 Proxy Statement or in a future amendment to this Annual Report on Form 10-K, in either case, is incorporated in this section by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information appearing under the headings “Ratification of Selection of Independent Public Accountants – Principal Accountant Fees and Services” Fees” and “Ratification of Selection of Independent Public Accountants – Policies and Procedures Relating to Approval of Services by Auditor” in our 2013 Proxy Statement or in a future amendment to this Annual Report on Form 10-K, in either case is incorporated in this section by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Item 15(a)

(1) Financial Statements:

(i) The following financial statements are included in Item 8 of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets at December 31, 2012 and 2011
Consolidated Statements of Operations for the years ended December 31, 2012 and 2011
Consolidated Statements of Stockholders’ Equity (Deficit) for the years ended December 31, 2012 and 2011
Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

Schedules have been omitted because they are inapplicable, not required, or the information is included elsewhere in the financial statements or notes thereto.

(3) Exhibits

The exhibits listed on the accompanying Exhibit Index are incorporated in this Annual Report on Form 10-K by this reference and filed as part of this report. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K is indicated by a “***” on the accompanying Exhibit Index. See “Exhibit Index” for important information regarding our exhibits.

- (b) See Item 15(a)(3) above.
- (c) See Item 15(a)1 and 15(a)2 above

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 18th day March, 2013.

PATIENT SAFETY
TECHNOLOGIES,
INC.

By: /s/ Brian E.
Stewart
Name: Brian E.
Stewart
Title: President
and Chief
Executive
Officer

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian Stewart and David Dreyer, each of whom may act without joinder of the other, as their true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Brian E. Stewart Brian E. Stewart	Director, President and Chief Executive Officer (Principal Executive Officer)	March 18, 2013
/s/ David Dreyer David Dreyer	Executive Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), Secretary	March 18, 2013
/s/ John P. Francis John P. Francis	Director	March 18, 2013
/s/ Louis Glazer	Director	

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

Louis Glazer, M.D., Ph.G.		March 18, 2013
/s/ Lynne Silverstein Lynne Silverstein	Director	March 18, 2013
/s/ Wenchen Lin Wenchen Lin	Director	March 18, 2013

EXHIBIT INDEX

Agreements included as exhibits to this annual report on Form 10-K are included to provide information regarding their terms and are not intended to provide any other factual or disclosure information about our company (including its consolidated subsidiary) or the other parties to the agreements. Where an agreement contains representations and warranties by any party, those representations and warranties have been made solely for the benefit of the other parties to the agreement or express third-party beneficiaries as explicitly set forth in the agreement. Any such representations and warranties:

should not be treated as categorical statements of fact, but rather as an allocation of risk;

may have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;

may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and

were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and may be subject to more recent developments.

Accordingly, any such representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time.

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of February 3, 2005, by and among Franklin Capital Corporation (n/k/a Patient Safety Technologies, Inc.), SurgiCount Acquisition Corp., SurgiCount Medical, Inc., Brian Stewart and Dr. William Stewart (incorporated by reference to our current report on Form 8-K filed with the SEC on February 9, 2005)
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Appendix A to the our definitive proxy statement on Schedule 14A filed with the SEC on July 13, 2009)
3.2	By-laws (incorporated by reference to the company's Form N-2 filed with the SEC on July 31, 1992)
4.1	Certificate of Designation of Series A Convertible Preferred Stock (included in Exhibit 3.1 hereto)
4.2	Certificate of Designation of Series B Convertible Preferred Stock (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
10.1****	Supply and Distribution Agreement dated effective November 19, 2009, by and between Patient Safety Technologies, Inc. and Cardinal Health 200, LLC (incorporated by reference to our current report on Form 8-K filed with the SEC on November 24, 2009)
10.2	Warrant Purchase Agreement dated effective as of November 19, 2009 by and between Patient Safety Technologies, Inc. and Cardinal Health, Inc. (incorporated by reference to our current report on Form 8-K filed with the SEC on November 24, 2009)
10.3	Registration Rights Agreement dated effective as of November 19, 2009, by and between Patient Safety Technologies, Inc. and Cardinal Health, Inc. (incorporated by reference to our current report on Form 8-K filed with the SEC on November 24, 2009)
10.4	Warrant dated November 19, 2009 issued to Cardinal Health, Inc. to purchase up to 1,250,000 shares of our common stock at \$2.00 per share, expiring November 19, 2014 (incorporated by reference to our current report on Form 8-K filed with the SEC on November 24, 2009)
10.5	Warrant dated November 19, 2009 issued to Cardinal Health, Inc. to purchase up to 625,000 shares of our common stock at \$4.00 per share, expiring November 19, 2014 (incorporated by reference to our current report on Form 8-K filed with the SEC on November 24, 2009)
10.6	Exclusive License and Supply Agreement dated May 15, 2008, by and among SurgiCount Medical, Inc. and A Plus International, Inc. (incorporated by reference to our annual report on Form 10-K filed with the SEC on March 31, 2010)
10.7	Subscription Agreement dated January 26, 2007 between Patient Safety Technologies, Inc. and A Plus International, Inc. (incorporated by reference to our current report on Form 8-K filed with the SEC on February 2, 2007)
10.8	Form of Exchange Agreement dated July 29, 2009 between Patient Safety Technologies, Inc. and certain investors (incorporated by reference to our current report on Form 8-K filed with the SEC on August 3, 2009)

- 10.9 Form of Purchase Agreement dated July 29, 2009 between Patient Safety Technologies, Inc. and certain investors (incorporated by reference to our current report on Form 8-K filed with the SEC on August 3, 2009)
- 10.10 Form of Senior Secured Note and Warrant Purchase Agreement dated January 29, 2009 (incorporated by reference to our current report on Form 8-K filed with the SEC on February 3, 2009)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

- 10.11 Form of Security Agreement dated January 29, 2009 (incorporated by reference to our current report on Form 8-K filed with the SEC on February 3, 2009)
- 10.12 Form of Senior Secured Note dated January 29, 2009 (incorporated by reference to our current report on Form 8-K filed with the SEC on February 3, 2009)
- 10.13 Form of Warrant dated January 29, 2009 to purchase shares of our common stock at \$1.00 per share, expiring January 29, 2014 (incorporated by reference to our current report on Form 8-K filed with the SEC on February 3, 2009)
- 10.14 Form of Securities Purchase Agreement dated August 1, 2008 (incorporated by reference to our current report on Form 8-K filed with the SEC on August 14, 2008)
- 10.15 Registration Rights Agreement dated August 1, 2008 (incorporated by reference to our current report on Form 8-K filed with the SEC on August 14, 2008)
- 10.16 Form of Warrant dated August 1, 2008 to purchase shares of our common stock at \$1.40 per share, expiring August 1, 2013 (incorporated by reference to our current report on Form 8-K filed with the SEC on August 14, 2008)
- 10.17 Form of Securities Purchase Agreement dated May 20, 2008 (incorporated by reference to our current report on Form 8-K filed with the SEC on June 2, 2008)
- 10.18 Registration Rights Agreement dated May 20, 2008 (incorporated by reference to our current report on Form 8-K filed with the SEC on June 2, 2008)
- 10.19 Form of Warrant dated May 27, 2008 to purchase shares of our common stock at \$1.40 per share, expiring May 27, 2013 (incorporated by reference to our current report on Form 8-K filed with the SEC on June 2, 2008)
- 10.20 Securities Purchase Agreement dated as of October 17, 2007 between Patient Safety Technologies and Francis Capital Management, LLC (incorporated by reference to our current report on Form 8-K filed with the SEC on October 22, 2007)
- 10.21 Registration Rights Agreement dated as of October 17, 2007 between Patient Safety Technologies and Francis Capital Management, LLC (incorporated by reference to our current report on Form 8-K filed with the SEC on October 22, 2007)
- 10.22 Secured Convertible Promissory Note issued August 10, 2007 with an effective date of June 1, 2007 to Ault Glazer Capital Partners, LLC in the amount of \$2,530,558.40 (incorporated by reference to our current report on Form 8-K filed with the SEC on August 16, 2007)
- 10.23 Amendment and Early Conversion of Secured Promissory Note dated as of September 5, 2008 between Ault Glazer Capital Partners, LLC (incorporated by reference to our annual report on Form 10-K filed with the SEC on April 16, 2009)
- 10.24 Security Agreement dated August 10, 2007 in favor of Ault Glazer Capital Partners, LLC (incorporated by reference to our current report on Form 8-K filed with the SEC on August 16, 2007)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

- 10.25 Guaranty of Payment by SurgiCount Medical, Inc. in favor of Ault Glazer Capital Partners, Inc. in connection with the \$2,530,558.40 Promissory Note issued August 10, 2007 (incorporated by reference to our current report on Form 8-K filed with the SEC on August 16, 2007)
- 10.26 Form of Subscription Agreement entered into between March 7, 2007 to April 5, 2007 (incorporated by reference to our annual report on Form 10-K filed with the SEC on May 16, 2007)
- 10.28 Subscription Agreement dated January 29, 2007 between Patient Safety Technologies, Inc. and David Wilstein and Susan Wilstein, as Trustees of the Century Trust (incorporated by reference to our current report on Form 8-K filed with the SEC on February 2, 2007)
- 10.29 Form of Warrant dated January 29, 2007 issued to Century Trust to purchase 12,000 shares of our common stock at \$2.00 per share, expiring January 29, 2012 (incorporated by reference to Exhibit C to Exhibit 10.4 to our current report on Form 8-K filed with the SEC on February 2, 2007)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

10.30	Form of Warrant dated September 8, 2006 issued to Steven J. Caspi to purchase up to \$312,500 of shares of our common stock (consisting of 250,000 shares of our common stock at \$1.25 per share, or a combination of shares of our common stock and shares of common stock of our subsidiary, SurgiCount Medical, Inc.), expiring September 8, 2011 (incorporated by reference to our amended current report on Form 8-K/A filed with the SEC on March 1, 2007)
10.31	Form of SurgiCount Medical, Inc. Warrant dated September 8, 2006 issued to Steven J. Caspi to purchase up to \$312,500 in shares of common stock of SurgiCount Medical, Inc. (or 250,000 shares of our common stock at \$1.25 per share), expiring September 8, 2011 (incorporated by reference to our amended current report on Form 8-K/A filed with the SEC on March 1, 2007)
10.32	Form of Warrant dated November 3, 2006 issued to Charles J. Kalina III to purchase 100,000 shares of our common stock at \$1.25 per share, expiring November 3, 2011 (incorporated by reference to our annual report on Form 10-K filed with the SEC on May 16, 2007)
10.33	Form of Warrant dated July 12, 2006 issued to Charles J. Kalina III to purchase 85,000 shares of our common stock at \$2.69 per share, expiring July 11, 2011 (incorporated by reference to our current report on Form 8-K filed with the SEC on July 14, 2006)
10.34	Warrant dated June 6, 2006 issued to Alan E. Morelli to purchase 401,460 shares of our common stock at \$3.04 per share, expiring June 6, 2011 (incorporated by reference to our current report on Form 8-K filed with the SEC on June 9, 2006)
10.35	Form of non-callable Warrant dated April 22, 2005 issued to James Colen to purchase 10,000 shares of our common stock at \$6.05 per share, expiring April 22, 2010 (incorporated by reference to our current report on Form 8-K filed with the SEC on April 26, 2005)
10.36	Form of callable Warrant dated April 22, 2005 issued to James Colen to purchase 10,000 shares of our common stock at \$6.05 per share, expiring April 22, 2010 (incorporated by reference to our current report on Form 8-K filed with the SEC on April 26, 2005)
10.37	Lease for 43460 Ridge Park Drive, Temecula, California (incorporated by reference to our annual report on Form 10-K filed with the SEC on March 31, 2010)
10.38	Sublease for 5 Caufield Place, Suite 102, Newtown, Pennsylvania (incorporated by reference to our current report on Form 8-K filed with the SEC on January 7, 2010)
10.39**	2005 Stock Option Plan (incorporated by reference to Appendix A to our definitive proxy statement on Schedule 14A filed with the SEC on March 2, 2005)
10.40**	2009 Stock Option Plan (incorporated by reference to Appendix B to our definitive proxy statement on Schedule 14A filed with the SEC on July 13, 2009)
10.41**	Form of Stock Option Agreement (incorporated by reference to our registration statement on Form S-8 filed with the SEC on February 16, 2010)
10.42**	Employment Agreement dated May 7, 2009 between Patient Safety Technologies Inc. and Steven H. Kane (incorporated by reference to our quarterly report on Form 10-Q filed with the SEC on May 20, 2009)

- 10.43** Employment Agreement dated effective as of November 24, 2009 between Patient Safety Technologies Inc. and Marc L. Rose (incorporated by reference to our current report on Form 8-K filed with the SEC on December 1, 2009)
- 10.44** Employment Agreement dated January 5, 2009 between Patient Safety Technologies, Inc. and David I. Bruce (incorporated by reference to our annual report on Form 10-K filed with the SEC on April 16, 2009)
- 10.45** Separation Agreement and General Release dated May 6, 2009 between Patient Safety Technologies, Inc. and David Bruce (incorporated by reference to our quarterly report on Form 10-Q filed with the SEC on May 20, 2009)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

- 10.46** Executive Services Agreement dated July 11, 2008 between Patient Safety Technologies, Inc. and Tatum, LLC for the services of Mary A. Lay (incorporated by reference to our annual report on Form 10-K filed with the SEC on April 16, 2009)
- 10.47** Employment Agreement dated January 5, 2009 between Patient Safety Technologies, Inc. and Brian Stewart (incorporated by reference to our amended annual report on Form 10-K/A filed with the SEC on July 13, 2009)
- 10.48** Form of Indemnification Agreement with Directors and Executive Officers dated effective June 1, 2010 (with then current directors and executive officers) and dated effective June 24, 2010 and October 22, 2010 with each of Messrs. Stewart and Dreyer (incorporated by reference to our current report on Form 8-K filed with the SEC on June 6, 2010)
- 10.49 Convertible Preferred Stock Purchase Agreement (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
- 10.50 Registration Rights Agreement (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
- 10.51 Separation and Release Agreement with Messrs. Chase, McFarland, Hitchcock and Bauer (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
- 10.52 Separation and Release Agreement with Steven H. Kane (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
- 10.53 Amendment to Employment Agreement with Marc L. Rose (incorporated by reference to our current report on Form 8-K filed with the SEC on June 29, 2010)
- 10.54 Employment Agreement with John A. Hamilton (incorporated by reference to our current report on Form 8-K filed with the SEC on August 9, 2010)
- 10.55 Tax Escrow Agreement (incorporated by reference to our current report on Quarterly Report on Form 10-Q filed with the SEC on August 16, 2010)
- 10.56 Employment Agreement with David Dreyer (incorporated by reference to our current report on Form 8-K filed with the SEC on October 28, 2010)
- 10.56 Employment Agreement with Brian E. Stewart (incorporated by reference to our current report on Form 8-K filed with the SEC on November 18, 2010)
- 10.57 Office Building Lease dated September 15, 2010 (incorporated by reference to our current report on Form 8-K filed with the SEC on September 20, 2010)
- 10.58 Sub-Lease Agreement dated as of November 18, 2010 (incorporated by reference to our current report on Form 8-K filed with the SEC on November 30, 2010)
- 10.59 Settlement Agreement (incorporated by reference to our current report on Form 8-K filed with the SEC on January 3, 2011)

Edgar Filing: Patient Safety Technologies, Inc - Form 10-K

10.60**	2009 Stock Option Plan Stock Option Agreement, grant date November 15, 2010 — Brian Stewart
10.61**	Non Plan Stock Option Agreement, grant date November 15, 2010 — Brian Stewart
10.62**	2009 Stock Option Plan Stock Option Agreement, grant date October 22, 2010 — David Dreyer
10.63**	Non Plan Stock Option Agreement, grant date October 22, 2010 — David Dreyer
10.64	Office building lease dated January 27, 2011(incorporated by reference to our annual report on Form 10-K filed with the SEC on March 26, 2012)
10.65	Office building lease dated December 5, 2011 (incorporated by reference to our current report on Form 10-K filed with the SEC on March 26, 2012)
10.66	First Amendment to the Supply and Distribution Agreement, dated November 19, 2009 between Cardinal Health 200, LLC and Patient Safety Technologies, Inc. (incorporated by reference to our current report on Form 8-K filed with the SEC on March 28, 2011)****
10.67*	Second Amendment to the Supply and Distribution Agreement, dated January 31, 2013 between Cardinal Health 200, LLC and Patient Safety Technologies, Inc.***
14.1	Code of Business Conduct and Ethics (incorporated by reference to our amended annual report on Form 10-K/A filed with the SEC on July 13, 2009)

21.1	Subsidiary of the company (incorporated by reference to our annual report on Form 10-K filed with the SEC on March 31, 2010)
23.1*	Consent of Squar, Milner, Peterson, Miranda & Williamson, LLP
31.1*	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a)*
31.2*	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a)*
32.1*	Certification of Chief Executive Officer and Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code*
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Management or compensatory plan or arrangement.

*** Confidential treatment requested for certain confidential portions of this exhibit. These confidential portions have been omitted from this exhibit and filed separately with the Commission.

**** Confidential treatment requested and received as to certain portions.