

Patient Safety Technologies, Inc  
Form 10-K  
March 31, 2010

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, 2009

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.)

5 Caufield Place, Suite 102, Newtown, PA 18940  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 579-7789

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

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value \$0.33 per share	OTC Bulletin Board

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, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of

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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, 2009 was approximately \$18.0 million.

The number of outstanding shares of the registrant's common stock, par value \$0.33 per share, as of March 29, 2010 was 23,456,063.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant has incorporated by reference in Part III of this report on Form 10-K portions of its definitive Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year.

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PATIENT SAFETY TECHNOLOGIES, INC.

FORM 10-K FOR THE FISCAL YEAR  
ENDED DECEMBER 31, 2009

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this annual report on Form 10-K are forward-looking statements. You can sometimes identify forward-looking statements by our use of forward-looking words like “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “seeks,” “predicts,” “potential,” or “continue” or the negative of these terms and other similar expressions.

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. These factors include, but are not limited to, those described under the caption “Risk Factors” in this annual report on Form 10-K, including without limitation the following:

- our need for additional financing to support our business;
- the early stage of adoption of our Safety-Sponge® System and the need to expand adoption of our Safety-Sponge® System;
- any failure of our new management team to operate effectively;
- our reliance on third-party manufacturers, some of whom are sole-source suppliers, and on our exclusive distributor; and
- any inability to successfully protect our intellectual property portfolio

All written and oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements.

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 its 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 surgical sponges, our market share, the cumulative number of surgical sponges used and number of procedures are internal estimates only.

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



## PART I

### ITEM 1. BUSINESS

#### Overview

We focus on the development, marketing and sales of products and services in the medical patient safety markets. Our proprietary 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 eliminate the possibility of retained surgical sponges being unintentionally left inside of patients during surgical procedures by allowing faster and more accurate counting of surgical sponges. We sell our Safety-Sponge® System to hospitals through our direct sales force, but rely on an exclusive distributor for the ongoing supply of our proprietary surgical sponge products to hospitals that have adopted our system. Our business model consists of selling our unique surgical sponge products, which are manufactured for us by an exclusive supplier, on a recurring basis to those hospitals that have adopted our Safety-Sponge® System. One of the ways in which we differentiate our products from other competing products is by working closely with hospital personnel through education and implementation services. We currently sell our Safety-Sponge® System only in the United States and we had revenues of \$4,503,535 and \$2,779,871 in the years ended December 31, 2009 and 2008, respectively, and at December 31, 2009 we reached a milestone of having had a cumulative total of an estimated 25,000,000 sponges used in 1,000,000 procedures without a single sponge unintentionally left inside a surgical patient.

#### Organizational History

Patient Safety Technologies, Inc. is a Delaware corporation that currently conducts its operations through a wholly-owned subsidiary, SurgiCount Medical, Inc., a California corporation. 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 our 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. From July 2005 through August 2007, we also operated an express car wash business through a wholly-owned subsidiary, Automotive Services Group, Inc., a Delaware corporation, which held our investment in Automotive Services Group, LLC, or ASG. During 2007, all assets of Automotive Services Group, Inc., including our investment in ASG, were sold. Since the 2007 divestitures, we have focused solely on the medical patient safety market.

#### Patient Safety Industry

The U.S. medical patient safety market is a multi-billion dollar annual market, which includes a significant range of medical devices, technologies and other equipment, all geared towards addressing patient safety. We estimate that the current U.S. market for surgical sponges alone is \$400 million annually and that there is significant opportunity for us to expand our share of this specific market through expansion of adoption of our Safety-Sponge® System.

We believe that the healthcare system is highly receptive to cost-effective medical solutions that can help providers quickly lower costs, reduce potential liability and eliminate preventable errors. Increased litigation and a renewed focus on patient safety by regulators are also spurring demand for medical device solutions that address these issues, such as our Safety-Sponge® System. We believe that our Safety-Sponge® System is attractive to healthcare professionals because it has proven effective at both eliminating retained foreign object events, or RFO events, and reducing the costs associated with RFO events (such as the reoperative costs, insurance costs, litigation and arbitration expenses and settlement costs).



## Our Safety-Sponge® System

Our proprietary Safety-Sponge® System is designed to eliminate retained sponges and towels unintentionally left in patients during surgical procedures by allowing accurate tracking of surgical sponges and towels. Our proprietary Safety-Sponge® System is a patented system of bar-coded surgical sponges and towels, SurgiCounter™ scanners, and Citadel™, our proprietary file management system, integrated to form a comprehensive counting and documentation system. We sell our Safety-Sponge® System to hospitals through our direct sales force, but rely on an exclusive distributor for the ongoing supply of our proprietary surgical sponge and towel products to hospitals that have adopted our system. Our business model consists of selling our unique bar-coded surgical sponge and towel products on a recurring basis to those hospitals that have adopted our Safety-Sponge® System, and working closely with hospital personnel and distributors to differentiate our product from other competing products. We currently sell our Safety-Sponge® System only in the United States.

Our Safety-Sponge® System works much like a supermarket scanning checkout system: every surgical sponge and towel used during a surgical procedure must be “scanned in” prior to use and “scanned out” once the procedure is completed. Each of our Safety-Sponge® surgical sponge or towel products is affixed with a unique inseparable two-dimensional data matrix bar code. These individual bar coded Safety-Sponge® products are grouped together and banded into a pack. Each pack is then affixed with a unique code (Master Tag) that contains the data for the bar-coded products grouped in that pack. As the banded packs of our Safety-Sponge® products are opened for use during a surgical procedure, operating room staff use our SurgiCounter™ scanner to scan the tag on each pack of surgical sponge or towel products. This quick and simple process records the individual code of each product contained within the packs, thereby recording the beginning count. Similarly, at the end of a procedure, the SurgiCounter™ scanner is used to scan the bar code on each product at the final count. Our SurgiCounter™ scanner will not allow the same Safety-Sponge® sponge or towel to be counted more than one time. This prevents double-counting or missed counting and helps accurately track all surgical sponges and towels used in a procedure. When Safety-Sponge® sponge and towel counts are completed at the end of a surgical procedure; the Citadel™ software used in our Safety-Sponge® System stores an electronic record of the initial and final counts (including the unique bar codes of the sponges and towels used) and transfers the information to the hospital records system. The system has been designed with future applications in mind, and our goal is to apply the scanning and information management technology to other patient safety and workflow management areas within the operating room environment.

The software installed in the SurgiCounter™ scanners controls the individual sponge counts with easy-to-learn and easy-to-use touch screen. Our proprietary file management system, Citadel™, typically resides in a PC environment and is used to consolidate individual sponge reports from the SurgiCounter™ scanner software in a central database. This database can then be used to generate not only reports following a procedure, but also departmental statistics, documented outcome records and output to patient electronic records systems (such as electronic medical records (also called EMRs) or personal health records (also called PHRs)).

## Customers and Distribution

We currently target our sales efforts to hospitals in the United States that perform surgery in multiple operating rooms, OB/GYN departments and other surgical locations. Our sales process involves making contact with multiple stakeholders within a hospital. These include executives, surgeons, medical and nursing personnel, and risk management. We believe it is important that all of these stakeholders evaluate not only the economics, but also the effectiveness of our Safety-Sponge® System. As part of the sales process, we conduct a product evaluation event in which a subset of hospital clinicians are educated on the use of our system on a suitable number of cases in order to gain an understanding of the functionality and integration requirements of our Safety-Sponge® System.



Although sometimes customers will have entered into an agreement to adopt our Safety-Sponge® System prior to the evaluation event, we generally sign up new hospital customers following a successful evaluation event. Once a customer has agreed to adopt our Safety-Sponge® System by executing a purchase contract, we then provide the hardware used in our system to the hospital and make numerous visits to provide technical support for our hardware and systems integration, as well as clinical training of operating room staff on the proper use of our Safety-Sponge® System (see “Sales and Clinical Support” below). Following this intensive transition and clinical training process, use of our Safety-Sponge® System is implemented hospital-wide, and hospitals then begin placing purchase orders for products used in our Safety-Sponge® System. We estimate that the entire process ranges between five to eight months from initial presentation before implementation and use of our Safety-Sponge® System.

Cardinal Health – Exclusive U.S. Distributor

In November 2006, we began an exclusive distribution relationship with Cardinal Health for the supply to hospitals that had adopted our Safety-Sponge® System. 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 has a five-year term and names Cardinal Health as the exclusive distributor in the United States, Puerto Rico, and Canada of current products used in our proprietary Safety-Sponge® System.

In connection with the execution of the new agreement, Cardinal Health issued a \$10,000,000 purchase order for products used in our Safety-Sponge® System that called for deliveries over the 12-month period ending November 2010. Cardinal Health paid us \$8,000,000 as partial pre-payment of the purchase order, and agreed to pay \$2,000,000 directly to A Plus International Inc., our exclusive supplier (see “—Manufacturing” below), when invoiced for delivery of product under the purchase order. Cardinal Health also agreed to place an additional \$5,000,000 purchase order prior to the end of the third quarter of 2010, if we have achieved a minimum target sales threshold for sales of our Safety-Sponge® products. Cardinal Health also agreed to maintain, for a period of time, its current ordering pattern and volume and that the Safety-Sponge® products delivered under the \$10,000,000 and \$5,000,000 purchase orders would be added to its customary inventory levels. For a discussion of the effects that this agreement is expected to have on our financial condition and results of operations, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Results—Cardinal Health Supply Agreement.”

In addition, we agreed to provide Cardinal Health a discount on pricing terms if we fail to meet delivery commitments, as well as minimum gross margins on the sale of our surgical sponge products. These guaranteed minimums vary depending on the product sold (Single Sterile or Bulk Non-Sterile) and how it is sold (directly by Cardinal Health, through sub-distributors or to convenience kit-packers). In addition, for Bulk Non-Sterile products included in Cardinal Health product kits, the guaranteed minimum gross margins are based on a formula that varies depending on sales performance criteria for specific time periods.

The new supply and distribution agreement terminates November 19, 2014 unless terminated earlier in accordance with its terms. Under the new supply and distribution agreement, either we or Cardinal Health may terminate upon written notice to the other (with a 30-day cure period) in the event of bankruptcy or insolvency, or material breach, or in the event either fails to maintain the agreed fill rates (with a 60-day cure period). In addition, Cardinal Health may terminate its obligation to distribute certain products if such products infringe upon third-party proprietary rights.

We also agreed to first negotiate with Cardinal Health if we intend to use a distributor to sell our products outside the territory for which Cardinal Health acts as our exclusive distributor. We also granted Cardinal Health a limited right of first negotiation in the event we decide to undertake certain fundamental corporate transactions (such as the sale of all our assets to a third party or a merger or other reorganization that would result in a change in control).

In connection with the new supply agreement described above, we entered into a Warrant Purchase 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. The warrants each have a term of five-years, but are subject to early expiration in certain circumstances, and grant the holder a right of first refusal for the initial year of the term with respect to certain issuances of common stock. We also granted Cardinal Health certain registration rights with respect to the shares of our common stock issuable upon exercise of the warrants pursuant to a Registration Rights Agreement dated November 19, 2009.

## Manufacturing

In 2005, we entered into an exclusive supply agreement for the manufacture of surgical products used in our Safety-Sponge® System with A Plus International Inc., or A Plus. Wenchen Lin, a member of our Board of Directors, is a founder and significant beneficial owner of A Plus (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Related Party Transactions” below).

In January 2007, we entered into a successor supply agreement and, in May 2008, we entered into our current exclusive supply agreement with A Plus. The current supply agreement grants A Plus the exclusive, world-wide license to manufacture and import the surgical 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 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 all related quality and regulatory compliance. A Plus has agreed not to manufacture, import or otherwise supply any bar coded surgical products for any other third party. Under the current supply agreement, we agreed to negotiate the pricing schedule annually to reflect manufacturing costs, taking into account changes in cotton prices and 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 successor supply agreement, we entered into a subscription agreement with A Plus, pursuant to which we sold A Plus 800,000 shares of our common stock and warrants to purchase 300,000 shares of our common stock at an exercise price of \$2.00 per share, which have a term of five years. We received gross proceeds of \$500,000 in cash and a \$500,000 deposit against future shipments (which has been fully utilized). A Plus was also granted the right to participate in future financings and was granted certain director designation rights, pursuant to which Wenchen Lin, currently a member of our board was proposed 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 such A Plus designated director's approval.

We do not engage in any manufacture of the hardware used in our Safety-Sponge® System (such as our SurgiCounter™ scanners) but purchase these items from third-party vendors on a purchase order basis. We also utilize third party developers to create, document and test our proprietary software that operates in our SurgiCounter™ scanners and interfaces with our proprietary Citadel™ file management system.

#### Sales and Clinical Support

As of December 31, 2009, our sales organization consisted of seven full-time sales personnel and one full-time administrative employee. Our sales organization provides consultation and assistance to our customers on the effective use of our Safety-Sponge® System, both prior to implementation and after adoption. We believe that maintaining this consultative effort allows us to develop a long-term relationship with our customers.

The time between identifying a customer for our Safety-Sponge® System and such customer adopting and implementing our system can vary substantially from customer to customer, particularly given the validation and training we provide (see "Customers and Distribution" above). Our sales organization works closely with each customer throughout this process.

In addition to our sales organization, we have a team of clinical support specialists, which included one full-time employee and 20 outside nursing consultants at December 31, 2009. Our clinical support specialists all have nursing backgrounds and not only train our customers in the utilization of our Safety-Sponge® System and products, but also provide clinical consultation regarding safety and clinical protocols.

#### 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. Under the program, we indemnify customers who properly use our Safety-Sponge® System in conjunction with our proprietary file management system, Citadel™, up to \$1

million per RFO event. We maintain insurance to cover the potential liability we may have under this program. We implemented this indemnification program to provide an additional level of security for our customers, not only because we believe that it has the potential to increase interest in, and accelerate adoption of, our Safety-Sponge® System, but also because we are confident in the overall effectiveness and reliability of our Safety-Sponge® System.

## Research and Development

Research and development activities are a critical component of our business. We use contract firms with suitable expertise for much of the research and development activities related to maintaining or improving our Safety-Sponge® System and products used therein. We incurred costs of \$321,116, and \$270,858, respectively, during the fiscal years ended December 31, 2009 and 2008 for research and development activities.

In 2005, we entered into a clinical trial agreement with Brigham and Women's Hospital, the teaching affiliate of Harvard Medical School, relating to our Safety-Sponge® System. Under terms of the agreement, Brigham and Women's Hospital collected data on how our Safety-Sponge® System saves time, reduces costs and increases patient safety in the operating room. The clinical study also was intended to provide clear guidance and instruction to hospitals on techniques to easily integrate our Safety-Sponge® System into operating room protocols. In connection with the study, which included a research grant, we provided Brigham and Women's Hospital a non-exclusive license to use our Safety-Sponge® System, and we retained rights to all technical innovations and other intellectual properties derived from the study.

Researchers at Brigham and Women's Hospital found that using bar-code technology to augment the physical counting of surgical sponges during surgery enhances the detection rate of miscounted and/or misplaced sponges. Previous studies have shown that counts are falsely reported as correct in the majority of cases of retained sponges, resulting in the surgical team believing that all the sponges are accounted for. In this study, researchers compared the traditional counting protocol with and without augmentation by the bar-code technology in 300 general surgery operations. The researchers found that our technology can reduce the incidence of retained surgical sponges at a materially lower cost than the combined legal and medical costs of an RFO event.

## 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 technology, inventions and improvements to inventions that are commercially important to the development of our business, in particular, as pertains to the technology used in our proprietary Safety-Sponge® System, including our SurgiCounter™ scanners and Citadel™ file management system. We also rely on trademark registrations, trade secrets, employee and third-party nondisclosure agreements and other protective measures to protect our intellectual property rights pertaining to our products and technology.

We currently hold patents in the United States and Europe related to our Safety-Sponge® System, which will expire in August 2019 and March 2017, respectively. We also own a number of registered and unregistered trademarks, including Safety-Sponge®, SurgiCounter™ and Citadel™.

## Competition

We face competition in a number of ways. Our Safety-Sponge® System faces competition from other products in the marketplace for adoption as a solution by hospitals to lower costs and reduce medical errors. RF Surgical Systems, Inc. and ClearCount Medical Solutions, Inc. provide products using radio frequency identification technology to identify surgical sponges with embedded chips. In addition, as a growing business, we continue to face competition for financial resources, technology and personnel.

## 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. Our Safety-Sponge® System is in Class I.

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). Class I and II devices also have subsets of "exempt devices" that are exempt from the PMA requirement subject to certain limitations. Our Safety-Sponge® System is within a defined device group that is specifically denoted as "exempt" from the PMA process. As such, on our Safety-Sponge® System received FDA clearance through the 510(k) notification process.

The FDA's quality system regulations also require companies to adhere to current good manufacturing practices requirements, which include testing, quality control, storage, and documentation procedures. Compliance with applicable regulatory requirements is monitored through periodic site inspections by the FDA. Our exclusive manufacturer, A Plus manufactures our products in FDA approved 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, which imposes certain reporting requirements on distributors in the event of an incident involving serious illness, injury or death caused by a medical device.

Given the state of the new healthcare legislation it's far too early to evaluate its impact on our business and on our customers. Changes in regulations and healthcare policy occur frequently and may impact our results, growth potential and the profitability of products we sell. There can be no assurance that changes to governmental reimbursement programs will not have a material adverse effect on our business, results of operations or financial condition.

#### Investments

Because of our legacy business as an investment company, we have an investment portfolio of non-core assets. As of the date of this annual report on Form 10-K, our investment portfolio is comprised solely of our continued ownership of shares of Series F Convertible Preferred Stock of Alacra Corporation, which we acquired in April, 2000. The Series F Convertible Preferred Stock gives us the right, subject to Alacra having the available cash from operations, to have it redeemed by Alacra over a period of three years for face value plus accrued dividends beginning on December 31, 2006, if any. We notified Alacra of our exercise of this right in December 2006 and Alacra completed the redemption of one-third of our preferred stock in December 2007. Since that time, Alacra has not redeemed any more of our Series F Convertible Preferred Stock. Based on discussions with Alacra management, we currently anticipate redemption and subsequent receipt of funds for all of our remaining shares of Alacra Series F Convertible Preferred Stock (50% in each of the fourth quarters of 2010 and 2011, respectively). Following the eventual redemption of this stock by Alacra, we do not anticipate undertaking any investments in non-core assets. For more information, see Note 8 to our Consolidated Financial Statements, appearing elsewhere in this annual report on Form 10-K

#### Employees

As of December 31, 2009, we had 16 full-time employees, which consisted of two executive officers, three senior managers, six sales managers, one clinical support employee, one customer-field engineer, one quality assurance employee, one finance employee and one sales administrative staff member. We also regularly use the services of



outside consultants on an as needed basis for sales, finance and clinical support staff. We intend to hire additional personnel as the development of our business makes such action appropriate. Our employees are not represented by a labor union nor covered by a collective bargaining agreement. We believe that our relations with our employees are good.

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Executive Officers

The following is a list of our executive officers as of the date of this annual report on Form 10-K:

Name	Age	Position	Served as an Officer Since
Steven H. Kane	57	President and Chief Executive Officer	2009
Marc L. Rose	44	Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary	2009

Steven H. Kane, age 57, has served as our President and Chief Executive Officer since May 2009, and has served as a Director since November 26, 2007 (and acted as Chairman from February 7, 2008 through January 26, 2010). Mr. Kane has over 30 years experience in the health care industry. Before joining our company, from 2002 to 2009 he was the President, Chief Executive Officer and Director of Protalex, Inc. (OTCBB: PRTX). From April 1997 to August 2000, Mr. Kane served as Vice President of North American Sales & Field Operations for Aspect Medical. While at Aspect, he helped guide the company to a successful initial public offering in January 2000. Prior to Aspect, Mr. Kane was Eastern Area Vice President for Pyxis Corporation, where he was instrumental in positioning the company for its successful initial public offering in 1992. Pyxis later was acquired by Cardinal Health for \$1 billion. Prior to that, Mr. Kane worked in sales management with Eli-Lilly and Becton Dickinson.

Marc L. Rose, age 44, has served as our Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary since November 2009. From November 2004 to November 2009, Mr. Rose served as the Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary of Protalex, Inc. (OTCBB: PRTX). From March 2001 to November 2004, Mr. Rose served as Vice President and Chief Financial Officer of the DentalEZ Group, a privately held manufacturer of dental equipment and dental handpieces located in Malvern, PA. From January 1998 to March 2001, Mr. Rose was Practice Manager of Oracle Consulting Services for Oracle Corporation responsible for designing and implementing Oracle financial and project applications. From September 1990 to January 1998, Mr. Rose held several positions with the controllership organization of Waste Management, Inc and from June 1988 to September 1990, was an auditor with Ernst & Young in Philadelphia. Mr. Rose is a Certified Public Accountant in the Commonwealth of Pennsylvania and received his BA in Accounting/Finance from Drexel University.

Code of Business Conduct and Ethics

Each of our executive officers and directors, as well as all of our employees, 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. Our Code of Business Conduct and Ethics encompasses our “code of ethics” applicable to our Chief Executive Officer, principal financial officer, and principal accounting officer and controller and persons performing similar functions. We intend to make any required disclosures regarding any amendments of our Code of Business Conduct and Ethics or waivers granted to any of our directors or executive officers under our Code of Business Conduct and Ethics on Form 8-K.

Printed copies of our Code of Business Conduct and Ethics; the Charters of each of the Audit, Compensation, and Nominating and Governance Committees of the Board of Directors materials are also available upon written request to the Corporate Secretary, Patient Safety Technologies, Inc., c/o Corporate Secretary, 5 Caufield Place, Suite 102, Newtown, Pennsylvania 18940.

Available Information

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

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

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## Other Information

Our principal executive offices are located at 5 Caufield Place, Suite 102, Newtown, Pennsylvania 18940 and our telephone number is (215) 579-7789. Our website is [www.surgicountmedical.com](http://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 become profitable and generate sufficient cash from operations.

Historically, we have incurred significant losses and have had negative cash flows from our operations. To date, we have dedicated most of our financial resources to selling, general and administrative expenses. As of December 31, 2009, our accumulated deficit was \$58,418,330. Our future success depends significantly upon continued expansion of adoption of our Safety-Sponge® System and our ability to obtain financing. Although the sale of products used in our Safety-Sponge® System generates revenues, those revenues are presently insufficient to generate consistent, positive cash flows from our operations. 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”) we expect that our cash needs will increase before we begin to generate cash from such efforts. During the years ended December 31, 2009 and 2008, we had revenues of \$4,503,535 and \$2,779,871, respectively. If we are not successful in generating sufficient revenues from sales of products used in our Safety-Sponge® System and we are unable to obtain sufficient capital to fund our efforts to 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, you might lose all or part of your investment in our company.

Our auditors’ opinion includes a going concern explanatory paragraph, which could have a negative effect on the price of our common stock and our ability to obtain financing.

The report of our independent registered public accounting firm dated March 31, 2010 for the years ended December 31, 2009 and 2008 includes a going concern explanatory paragraph, which states that our significant operating losses and working capital deficit cause substantial doubt about our ability to continue as a going concern. This may have a negative effect on the trading price of our common stock and adversely impact our ability to obtain financing. If we are not able to continue as a going concern, you might lose all or part of your investment.

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

Because revenues from sales of products used in our Safety-Sponge® System are presently insufficient to generate consistent, positive cash flows from our operations, we have historically financed our activities through additional

cash proceeds from the private placement of debt and equity securities. We believe that our existing working capital and expected future cash flows from operating activities will only be sufficient to meet our operating and capital requirements into the second quarter of 2010. Accordingly, we will need to raise additional capital.

If additional debt financing is raised in the future, we may be required to grant lenders a security interest in all or a portion of our assets and issue warrants to acquire our equity securities, resulting in dilution to our stockholders. In addition, any such debt financing may 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 will dilute your current investment 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, you might lose all or part of your 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, any growth in our operations will place a significant strain on our existing resources and increase demands on our management, our operational and administrative systems and controls. In addition, because of how our sales cycle works (see “Business—Customers and Distribution”), any growth in our customer base will require the investment of a significant amount of 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 operations in the future or that we will be able to successfully implement appropriate measures consistent with our growth strategy. We need to implement new operational and financial systems, procedures and controls to expand, train and manage our employee base. We will also need to continue to attract, retain and integrate additional personnel in all aspects of our operations. We cannot guarantee that we will be able to do so, or that if we are able to do so, we will be able to effectively integrate them into our existing organization. Failure to manage our growth effectively could have a material adverse effect on our financial condition and results of operations.

We may incur significant costs to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to document and test the effectiveness of our internal control over financial reporting in accordance with an established internal control framework and to report on our management’s conclusion as to the effectiveness of this internal control over financial reporting. Based on the current Securities and Exchange Commission, or SEC rules, we will be required to have our independent registered public accounting firm perform an audit and report on the effectiveness of our internal control over financial reporting as of December 31, 2010 and subsequent years. We expect to incur significant costs to comply with this requirement. In connection with our assessment of internal control over financial reporting included in our Form 10-K for the periods ended December 31, 2009 and 2008, we identified certain material weaknesses in our internal control over financial reporting. Even if we are successful in remedying these material weaknesses, we may in the future discover other areas of our internal control over financial reporting that need improvement. There can be no assurance that the recent remedial measures we implemented to address prior and current material weaknesses will result in adequate internal control over financial reporting in the future. Any failure to implement our improved controls, or difficulties encountered in the future, could cause us to fail to meet our reporting obligations. If we are unable to conclude that we have effective internal control over financial reporting, or if our auditors are unable to provide an unqualified report regarding the effectiveness of internal control over financial reporting when required by applicable rules and regulations of the SEC, investors may lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities and negatively affect our efforts to obtain necessary financing. In addition, failure to comply with Section 404 could potentially subject us to sanctions or investigation by the SEC or other regulatory authorities. This could have a material adverse effect on our financial condition and results of operations.

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 United States at the end of 2008 has increased the focus of many of our current and potential customers on implementing cost containment measures. Cost containment measures instituted by healthcare providers and insurers could negatively affect our efforts to expand adoption of our Safety-Sponge® System, which would have a have a material adverse effect on our business, prospects, financial condition and results of operations.

The effects of general healthcare reform on our industry are uncertain, and there is a risk that it could adversely affect our ability to market our Safety-Sponge® System, which would have a material adverse effect on our business.

General healthcare reform is the subject of ongoing debate in the United States. There is uncertainty regarding the legislation recently signed into law and how it will affect our industry and our business prospects. We cannot predict the effect such healthcare reform legislation might have on demand for our Safety-Sponge® System. If such healthcare reform has a negative effect on our efforts to expand adoption of our Safety-Sponge® System, it would have a material adverse effect on our business, prospects, financial condition and results of operations.

The volatility of our stock price can have a material adverse effect on our reported profit or loss.

At December 31, 2009, we had a warrant derivative liability of \$3,666,336, which represented just over 22% of our current liabilities at such date. Under applicable accounting rules, we are required to “mark to market” this liability each reporting period and record changes in the fair value associated with this liability in our consolidated statement of operations (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies—Warrant Derivative Liability”). As such, when our stock price increases, the fair value of this liability increases, and we recognize an expense associated with this change. Similarly, when our stock price decreases, the fair value of this liability decreases, and we recognize a gain associated with this change in fair value. As such, the volatility of our stock price (which ranged from a high of \$2.25 to a low of \$0.47 in the year ended December 31, 2009) has a direct impact on our reported profit or loss.

Our future financial results could be adversely impacted by asset impairments or other charges.

As of December 31, 2009, we had goodwill of \$1,832,027 and other intangible assets of \$3,114,025 (or 15.9% and 27.0%, respectively of our total assets). We are required to test goodwill and other intangible assets determined to have indefinite lives for impairment on an annual, or on an interim basis if certain events occur or circumstances change that would reduce the fair value of a reporting unit below its carrying value or if the fair value of intangible assets with indefinite lives falls below their carrying value (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies” below). If circumstances change such that we are required to take an impairment charge, the amount of any such annual or interim impairment charge could be significant. If so, this could have a material adverse effect on our financial condition and results of operations.

We have limited marketing experience, and our failure to build and manage our sales force or to market our products effectively would negatively affect our ability to implement our growth strategy.

Currently, we do not have an in-house marketing team, nor have we retained a third party to perform the function. If we do not build an in-house marketing capability or hire a third party provider, it could have a material adverse effect on our financial condition and results of operations.

While we currently employ a seven person sales team, no assurance can be given that we will be able to hire additional qualified sales personnel with the necessary skills and experience to sell and market our Safety-Sponge® System effectively. Even if we are able to hire well qualified sales personnel, if we do not provide adequate training in the use and benefits of our products, it could have a material adverse effect on our 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 additional sales personnel with appropriate skills and experience. Our failure to retain our current sales personnel could have a material adverse effect on our financial condition and results of operations.





No assurance can be given that any particular marketing program which we may adopt or acquire, itself, will be effective in building sales. If we are unable to develop or acquire an effective marketing program, it could have a material adverse effect on our financial condition and results of operations.

Any failure in our customer education efforts could negatively affect our efforts to expand adoption of our Safety-Sponge® System.

It is important to the success of our sales efforts that our clinical support staff properly educates operating room nurses in the techniques of using our Safety-Sponge® System. Such training is a key component of our sales process (see “Business—Sales and Clinical Support” above). Positive results using our Safety-Sponge® System are highly dependent upon proper technique. If our Safety-Sponge® System is used suboptimally or improperly, such use may contribute to unsatisfactory patient outcomes or fail to prevent an RFO event. 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 financial condition or 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 or results of operations.

Our Safety-Sponge® System is highly dependent on proper technique, including the proper handling and use of the surgical sponge and towel products used therein. There are a number of third parties that handle such products in our supply and distribution chain, as well as at the hospitals who have adopted our system, over which and whom we have no control. Although we have put in place contractual arrangements to ensure quality control in the supply and distribution chain, and although we engage in extensive training and provide clinical support to ensure proper technique and use at our hospital customers, we cannot guarantee that such third parties will not mishandle or misuse the surgical sponge and towel products used in our Safety-Sponge® System. Because we are not directly involved in the supply and distribution chain, we might not be aware of quality control issues that arise. 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 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 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 manufacture an adequate supply of our products. 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 have access to product for resale would have a material adverse effect on our delivery schedules, which could have a material adverse effect on our financial condition and results of operations.

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

We rely on a number of third parties in the execution of our business plan. For example, we use third party developers to maintain and improve the technological elements of our Safety-Sponge® System; we have an exclusive manufacturing arrangement with A Plus (see above) and have an exclusive distribution arrangement with Cardinal

Health for the distribution of 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 these third-parties are good, if such third parties fail to honor their contract obligations, it could lead to disruptions in our business while we negotiate replacement agreements and find other suppliers or distributors for our products. In addition, there is no guarantee that we would be able to negotiate a distribution agreement with a contract party comparable to Cardinal Health, or be able to obtain comparable contract provisions in terms of pricing and quality control. These disruptions, or inability to effectively distribute our products, could harm our reputation and customer relationships, which could have a material adverse effect on our financial condition and results of operations.

We 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 skills of our management team. In particular, our success depends in part upon the continued service and performance of: Steven H. Kane, our President and Chief Executive Officer, and Marc L. Rose, our Chief Financial Officer. Although we have employment agreements with Mr. Kane, and Mr. Rose, the loss of the services of one or both of these executive officers could adversely affect our ability to implement our growth strategy.

The competition for qualified personnel is intense, and we cannot assure you 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 turnover in our chief executive officer position and if we continue with frequent executive turnover we may have difficulty implementing our business strategy.

In January 2007, Milton “Todd” Ault, III resigned as our Chief Executive Officer and Chairman, and our Board of Directors appointed William B. Horne as Chief Executive Officer. In April 2008, our Board of Directors appointed William Adams, as our President and Chief Executive Officer. In January 2009, Mr. Adams resigned, and our Board of Directors appointed David I. Bruce as our President and Chief Executive Officer. Mr. Bruce resigned in May 2009 and our Board of Directors appointed Steven H. Kane as our President and Chief Executive Officer. If we are not able to attain stability of our Chief Executive Officer position, we may have difficulty implementing our business strategy.

#### 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, 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 law outside the United States is uncertain and in many countries is currently undergoing review and revision. 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, we may face increased competition outside the United States, which could materially and adversely affect our financial condition and results of operations.

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

The medical devices industry is subject to rapid and substantial technological development and product innovations. To be successful, we must respond to new developments in technology and new applications of our existing technology. Our limited resources may limit our ability to innovate and respond to such developments. In addition, we compete against several companies offering alternative systems, some of which could have 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 would have a material adverse effect on our financial condition and results of operations.

The nature of our business exposes us to potential product liability risks, among others, which may not be covered by insurance.

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. Although we maintain liability insurance, insurance coverage may not be adequate to cover all risks and continuing insurance coverage may not be available at an acceptable cost, if at all. In addition, we are exposed to the risks under our indemnification program if our Safety-Sponge® System is used properly but does not prevent an RFO. 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 RFO events may result in decreased demand for our products, injury to our reputation and loss of revenues. As a result, regardless of whether we are insured or are required to indemnify a significant number of customers, a product liability claim or product recall may result in losses that could have a material adverse effect upon our financial condition and results of operations.

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

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

Laws and regulations regarding the manufacture 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 could subject us to enforcement actions, including, but not limited to, product seizures, injunctions, recalls, possible withdrawal of product clearances, civil penalties and criminal prosecutions, and of which could have a material adverse effect on our financial condition and results of operations.

#### Risks Related to our Investments

We have an investment in non-marketable investment securities, which may subject us to significant impairment charges.

We have investments in illiquid non-marketable equity securities acquired in private transactions as a result of our legacy business (see “Business—Organizational History” above and Note 8 to our Consolidated Financial Statements appearing elsewhere in this annual report on Form 10-K). At December 31, 2009, 5.8% of our consolidated assets were comprised of investment securities, which are illiquid investments. Investments in illiquid, or non-marketable, securities are inherently risky and difficult to value. We account for our investments in non-marketable investment securities on a cost basis. We review our investment in non-marketable securities on a quarterly basis for indicators of impairment, however, for non-marketable equity securities; the impairment analysis requires significant judgment to identify events or circumstances that would likely have a material adverse effect on the fair value of the investment. Because a significant amount of our assets are comprised of non-marketable investment securities, any future impairment charges from the write down in value of these securities will most likely have a material adverse effect on our financial condition.

#### Risks Related to Our Common Stock

Our stock price is expected to continue to be volatile, and the market price of our common stock could drop significantly.

In the year ended December 31, 2009, our stock price ranged from a high of \$2.25 to a low of \$0.47 per share. Stock markets in general have experienced substantial volatility 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. These 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 could involve the issuance of equity securities, which would dilute your investment and could result in a decline in 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 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.



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

Our common stock is quoted on the OTC Bulletin Board. The OTC Bulletin Board is a significantly more limited market than the New York Stock Exchange, NASDAQ system, or our former trading market, the American Stock Exchange. The quotation of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, could depress the trading price of our common stock and could have a 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, you may not be able to sell your shares of common stock when you desire to do so. In the year ended December 31, 2009, our stock price ranged from a high of \$2.25 to a low of \$0.47 per share. The inability to sell your shares in a rapidly declining market may substantially increase your risk of loss as a result of such illiquidity and because the price for our common stock may suffer greater declines due to its 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, may preclude us from paying these dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

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' dividends, until such time as all dividends in arrears have been paid, such holders shall have the right to elect a majority of our Board of Directors. If we are not able to obtain financing, we may not be able to continue to pay dividends on our preferred stock. If this were to occur, holders of our common stock would lose their ability to control our Board of Directors as the holders of the Series A Preferred Stock would have the right to elect a majority of our Board of Directors.

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

SEC regulations generally define "penny stocks" as equity securities that have a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. As of March 29, 2010, the last sale price for our common stock was \$1.04 per share. For transactions in securities that are not exempt from the "penny stock" definition, the SEC has adopted rules and regulations that impose additional sales practice requirements on broker-dealers prior to selling penny stocks, which may make it burdensome to conduct transactions in our shares. Because our shares are subject to these rules, it may be difficult to sell shares of our stock, and because it may be difficult to find quotations for shares of our stock, it may be impossible to accurately price an investment in our shares. In addition, the SEC has the authority to restrict any person from participating in a distribution of a penny stock if the SEC determines that such a restriction would be in the public interest.

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

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

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

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

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

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our Board of Directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

#### ITEM 2. PROPERTIES

We do not own any real estate or other physical properties materially important to our operations. In January 2010, we relocated our headquarters to 5 Caufield Place, Suite 102, Newtown, PA 18940, upon effectiveness of a sublease entered into on December 31, 2009 for 5,670 square feet of office space. We continue to maintain our approximate 4,000 square feet of office space at our former headquarters located at 43460 Ridge Park Drive, Suite 140, Temecula, CA 92590, pursuant to a lease signed on November 7, 2007 that terminates December 31, 2010. We are responsible for paying \$11,576 per month in rent for our new Pennsylvania headquarters and expect to continue to pay \$9,757 per month in rent for our California office space until termination of the lease.

#### ITEM 3. LEGAL PROCEEDINGS

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

On July 28, 2005, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. filed another lawsuit against our company, Sunshine and four other defendants affiliated with Winstar. That lawsuit attempted to collect a federal default judgment of \$5 million entered against two entities, Winstar Radio Networks, LLC and Winstar Global Media, Inc., by attempting to enforce the judgment against our company and others under the doctrine of de facto merger. The action was tried before a Los Angeles County Superior Court judge, without a jury, in 2008. On August 5, 2009, the Superior Court issued a statement of decision in our favor, and on October 8, 2009, the Superior Court entered judgment in our favor, and judged plaintiffs' responsible for \$2,708.70 of our court costs. On November 6, 2009, the plaintiffs filed a notice of appeal in the Superior Court of the State of California, County of Los Angeles Central District. We have engaged appellate counsel, believe the plaintiff's case to be without merit and intend to continue to defend the case vigorously.

## ITEM 4. (REMOVED AND RESERVED)

Not applicable.

## PART II

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

## Market Information

Since February 16, 2007 our common stock has been quoted on the OTC Bulletin Board under the symbol "PSTX.OB." Prior to such time, our stock was listed on the American Stock Exchange under the symbol "PST."

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

	High	Low
<b>Year Ended December 31, 2009</b>		
First Quarter	\$ 1.20	\$ 0.47
Second Quarter	1.10	0.60
Third Quarter	1.40	0.70
Fourth Quarter	2.25	1.06
<b>Year Ended December 31, 2008</b>		
First Quarter	\$ 0.96	\$ 0.33
Second Quarter	1.25	0.50
Third Quarter	1.49	0.95
Fourth Quarter	1.50	0.85

## Stockholders

As of March 29, 2010, there were 622 holders of record of our common stock. We have 100,000,000 shares of common stock authorized, of which 23,456,063 were issued and outstanding at March 29, 2010. We have 1,000,000 shares of authorized convertible preferred stock, of which 10,950 shares were issued and outstanding at March 29, 2010.

## Dividends

We paid \$95,812 and \$76,650 in dividends to holders of our Series A Preferred Stock during 2009 and 2008, respectively, and have not paid any dividends to common stockholders. Dividends to our preferred stockholders are cumulative and paid at the rate of 7% per annum. We currently have no intention of paying dividends on our common stock, and the terms of our Series A Preferred Stock may limit our ability to pay any such dividends.

#### Recent Sales of Unregistered Securities

On November 19, 2009, in connection with the execution of our new supply and distribution agreement with Cardinal Health (see “Business—Customers and Distribution—Cardinal Health – Exclusive U.S. Distributor,” above), 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 pursuant to a Warrant Purchase Agreement dated effective November 19, 2009. The warrants have a term of five-years, but are subject to early expiration in certain circumstances, and grant the holder a right of first refusal for the initial year of the term with respect to certain issuances of common stock. We also granted Cardinal Health certain mandatory and “piggyback” registration rights, which require us to register the shares issuable upon exercise of the warrants under the Securities Act in certain circumstances pursuant to a Registration Rights Agreement dated November 19, 2009. The warrants (and shares issuable upon exercise of the warrants) have not been registered under the Securities Act or state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

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

#### Issuer Repurchases of Equity Securities

Not applicable.

#### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

#### 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 sales of products and services in the medical patient safety markets. Our proprietary 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 eliminate the possibility of retained surgical sponges being unintentionally left inside of patients during surgical procedures by allowing faster and more accurate counting of surgical sponges. We sell our Safety-Sponge® System to hospitals through our direct sales force, but rely on an exclusive distributor for the ongoing supply of our proprietary surgical sponge products to hospitals that have adopted our system. Our business model

consists of selling our unique surgical sponge products, which are manufactured for us by an exclusive supplier, on a recurring basis to those hospitals that have adopted our Safety-Sponge® System. One of the ways in which we differentiate our products from other competing products is by working closely with hospital personnel through education and implementation services. We currently sell our Safety-Sponge® System only in the United States and we had revenues of \$4,503,535 and \$2,779,871 in the years ended December 31, 2009 and 2008, respectively, and at December 31, 2009 we reached a milestone of having had a cumulative total of an estimated 25,000,000 sponges used in 1,000,000 procedures without a single sponge unintentionally left inside a surgical patient.

## Sources of Revenues and Expenses

### Revenues

**Surgical Sponge Revenues.** We generate revenues primarily from the sale of surgical sponges used in our Safety-Sponge® System to our exclusive distributor, who then sells directly and through sub-distributors to hospitals that have adopted our Safety-Sponge® System. We expect hospitals that adopt our Safety-Sponge® System to commit to its use and thus provide a recurring source of revenues from ongoing sales of surgical sponges and other products used in our system. We recognize revenues from the sale of surgical sponges upon shipment to our distributor because most of our surgical sponge sales are to our distributor, FOB shipping point. Note that because of the way our sales cycle works (see “Business—Customers and Distribution”), there is a gap between the time we begin incurring costs associated with our new customer arrangements and when we begin generating revenues from such arrangements.

**Hardware, Software and Maintenance Agreement Revenues.** We also generate revenues from the sale of related hardware and software to hospitals that have adopted our Safety-Sponge® System. The sale of our Safety-Sponge® System includes hardware (the SurgiCounter™ scanners), our proprietary file management software (Citadel™) and an initial one-year maintenance agreement (which may be renewed). All of these items are considered to be separate deliverables within a multiple-element arrangement and, accordingly, we allocate the total price of this arrangement among each respective deliverable, and recognize revenue as each element is delivered. For the hardware and software elements of our Safety-Sponge® System, we recognize revenues on delivery, which is the time of shipment (if terms are FOB shipping point) or upon receipt by the customer (if terms are FOB destination). Delivery with respect to our initial one-year maintenance agreements is considered to occur on a monthly basis over the term of the one-year period; we recognize revenues related to this element on a pro-rata basis during this period. Because of the change in our business model discussed below under “—Factors Affecting Future Results,” we do not expect these sales to represent a significant portion of our revenues going forward.

Prior to the third quarter of 2009, our business model included the sale of our SurgiCounter™ scanners and related software used in our Safety-Sponge® System to most hospitals that adopted our system. Beginning with the third quarter of 2009, we modified our business model and began to provide our SurgiCounter™ scanners and related software to all hospitals at no cost when they adopt our Safety-Sponge® System. Because we no longer engage in direct SurgiCounter™ scanner sales and generally anticipate only recognizing revenues associated with our SurgiCounter™ scanners in connection with reimbursement arrangements under the our agreement with Cardinal Health. Therefore, we do not expect that our SurgiCounter™ scanners will represent a sizable source of future revenues for us. Deferred scanner revenue associated with the reimbursement from Cardinal Health, will be recognized over the life of the specific hospital contract.

### Cost of revenues

Our cost of revenues consists primarily of our direct product costs for surgical sponges and products from our exclusive third-party manufacturer. We also include a reserve expense for obsolete and slow moving inventory in cost of revenues. In addition, when we provide scanners to hospitals for their use (rather than sell), we include only the depreciation expense of the scanners in cost of revenues (not the full product cost). We estimate the useful life of the scanners to be three years. However, should we sell the scanners to hospitals, our cost of revenue include the full product 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. We also include salaries and related employee benefits, research-related overhead expenses and fees paid to external service providers in our research and development expenses.

#### Sales and marketing expenses

Our sales and marketing expenses consist primarily of salaries and related employee benefits, sales commissions and support costs, professional service fees, travel, education, trade show and marketing costs.

#### General and administrative expenses

Our general and administrative expenses consist primarily of salaries and related employee benefits, 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 quarter, 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) on our income statement.

#### Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies used in the preparation of our financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 3 to our audited consolidated financial statements, appearing elsewhere in this annual report on Form 10-K.

#### Warrant Derivative Liability

Under applicable accounting guidance, an evaluation of outstanding warrants is made to determine whether warrants issued are required to be classified as either equity or a liability. Because certain warrants we have issued in connection with past financings contain certain provisions that may result in an adjustment to their exercise price, we classify them as derivative liabilities, and accordingly, we are then required to estimate the fair value of such warrants, at the end of each fiscal quarter. We use the Black-Scholes option pricing model to estimate such fair value, which requires the use of numerous assumptions, including, among others, expected life (turnover), volatility of the underlying equity security, a risk-free interest rate and expected dividends. The use of different values by management in connection with these assumptions in the Black Scholes option pricing model could produce substantially different results. Because we record changes in the fair value of warrants classified as derivative liabilities in total other income (expense), materially different results could have a material effect on our results of operations.

## 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 goodwill for impairment at least annually in the fourth quarter, as well as whenever events or changes in circumstances indicate its carrying value may not be recoverable. We are required to perform a two-step impairment test on goodwill. In the first step, we will compare the fair value to its carrying value. If the fair value exceeds the carrying value, goodwill will not be considered impaired and we are not required to perform further testing. If the carrying value exceeds the fair value, then we must perform the second step of the impairment test in order to determine the implied fair value of goodwill and record an impairment loss equal to the difference. Determining the implied fair value involves the use of significant estimates and assumptions. These estimates and assumptions include revenue growth rates and operating margins used to calculate projected future cash flows, risk-adjusted discount rates, future economic and market conditions and determination of appropriate market comparables. We base our fair value estimates on assumptions we believe to be reasonable but that are unpredictable and inherently uncertain. Actual future results may differ from those estimates. To the extent additional events or changes in circumstances occur, we may conclude that a non-cash goodwill impairment charge against earnings is required, which could have an adverse effect on our financial condition and results of operations.

## 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 option pricing model, which is a standard option pricing model, this model still requires the use of numerous assumptions, including, among others, the expected life (turnover), volatility of the underlying equity security, a risk free interest rate and expected dividends. The model and assumptions also attempt to account for changing employee behavior as 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 these assumptions 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 to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Considerable judgment is necessary to estimate the fair value of the assets and accordingly, actual results could vary significantly from such estimates. Our most significant estimates and judgments relating to the long-lived asset impairments include 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 from the 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 rules 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 (or continue to recognize) tax positions meeting the more-likely-than-not recognition threshold (or that met such 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.

#### Recent Accounting Pronouncements

On July 1, 2009, the Financial Accounting Standards Board, or FASB, released the FASB Accounting Standards Codification<sup>TM</sup>, sometimes referred to as the "Codification" or "ASC." The Codification does not change how we account for our transactions or the nature of related disclosures made, and was made effective for periods ending on or after September 15, 2009. Accordingly, we have updated references in this annual report on Form 10-K to reflect the Codification Topics as applicable.

In June 2008, the FASB ratified guidance regarding accounting treatment for contracts that are to be settled in an entity's own equity, which guidance is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application was not permitted. Under this guidance, a contract that would otherwise meet the definition of a derivative but is both (a) indexed to an entity's own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. The guidance provided a new two-step model to determine whether a financial instrument or an embedded feature is indexed to an entity's own stock and thus able to qualify for an exception. When we adopted this guidance effective January 1, 2009, we identified certain warrants we had issued contained provisions that could result in an adjustment to their exercise price, making them ineligible for classification in stockholders' equity. Accordingly, we reclassified these warrants as liabilities upon the effective date of the guidance, and now measure them at fair value on each balance sheet date and recognize changes in fair value in our income statement. We recognized the cumulative effect of the change in accounting for these warrants as an adjustment to our opening balance of accumulated deficit at January 1, 2009, which amount was based on the difference between the amounts recognized in the consolidated balance sheet before the initial adoption and the amounts recognized in the consolidated balance sheet as a result of the initial application of this guidance.

In October 2009, the FASB updated its guidance regarding accounting for multiple deliverable arrangements in order to enable vendors to account for products and services (deliverables) separately rather than as a combined unit. These changes are effective prospectively for revenue arrangements entered into or materially modified in the fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We have not yet evaluated the effects of this accounting update on our financial statements.

In October 2009, the FASB changed the accounting model for revenue arrangements that include both tangible products and software elements that are "essential to the functionality," and carves these products out of current software revenue guidance. The new guidance will include factors to help companies determine what software elements are considered "essential to the functionality." These changes are effective prospectively for revenue arrangements entered into or materially modified in the fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We have not yet evaluated the effects of this accounting update on our financial statements.

In January 2010, the FASB issued guidance designed to improve disclosures about fair value measurements as well as disclosures related to significant transfers between each level and additional information about Level 3 activity. This guidance begins phasing in the first fiscal period after December 15, 2009, and we are currently assessing the effects on our financial statements.

For additional discussion regarding these, and other recent accounting pronouncements, see Note 4 to our audited consolidated financial statements, appearing elsewhere in this annual report on Form 10-K.

#### Internal Control Over Financial Reporting

In connection with our assessment of the effectiveness of internal control over financial reporting as of December 31, 2009 and 2008, we identified certain material weaknesses in our internal control over financial reporting.

The material weaknesses identified in connection with our assessment at December 31, 2008 included an ineffective general control environment, ineffective risk assessment processes, and ineffective internal control policies and procedures relating to equity transactions and share-based payments, the proper reporting of income and accounting for payroll taxes, and the integrity of spreadsheets and other "off system" work papers used in the financial reporting process. In part, to address the weaknesses identified in our general control environment, our board of directors hired a new Chief Executive Officer and restructured the board to include two independent directors, one of whom meets the requirements of an audit committee financial expert, and both of whom have significant corporate governance

experience. To address the weaknesses identified relating to equity transactions, we implemented a new software program specifically designed to track and account for share-based payments and equity transactions. In addition, we engaged an internal control specialist to design and help implement effective risk assessment processes. Although we implemented these remedial actions, we nevertheless still continued to have material weaknesses in our internal control over financial reporting as of December 31, 2009.

In connection with our assessment of internal controls over financial reporting as of December 31, 2009, we identified the following material weaknesses in our internal control over financial reporting due to:

- Ineffective control environment due to the following identified weaknesses:
  - o Failure to retain individuals competent in the application of generally accepted accounting principles (“GAAP”) to complex accounting transactions.
  - o Failure to establish sufficiently detailed accounting policies and procedures and to properly train accounting department staff.
  - Ineffective internal control policies and procedures relating to the period end close process including lack of controls relating to journal entries, post closing adjustments and management review of conclusions regarding accounting and financial reporting matters.
  - Ineffective internal control policies and procedures designed to provide reasonable assurance regarding the accuracy and integrity of spreadsheets used in the financial reporting system.

To remedy these material weaknesses, we have implemented policies and procedures to formalize our period end close process as well as to address the application of our accounting policies to ensure conformity with GAAP. We are also seeking to hire qualified personnel, or engage outside resources, as applicable, with appropriate knowledge/experience in the application of GAAP to complex accounting transactions and we are strengthening internal policies and procedures designed to ensure the accuracy and integrity of spreadsheets used in the financial reporting system.

For information regarding our evaluation of the effectiveness of our disclosure controls and procedures, our evaluation of our internal control over financial reporting, as well as any changes in our internal control over financial reporting, see “Controls and Procedures” below.

#### Factors Affecting Future Results

**Cardinal Health Supply Agreement.** On November 19, 2009 we entered into a new exclusive Supply and Distribution Agreement with Cardinal Health. Cardinal Health is the exclusive distributor of current products used in our proprietary Safety-Sponge® System in the United States, Puerto Rico and Canada. In connection with the execution of the new supply and distribution agreement, Cardinal Health issued a \$10,000,000 purchase order, paid us \$8,000,000 in cash as a partial prepayment and agreed to pay \$2,000,000 directly to A Plus, our exclusive manufacturer, upon delivery of product to Cardinal Health. Because we did not ship any product pursuant to this purchase order in 2009, all \$10,000,000 of incremental revenue from this purchase order is expected to be recognized in 2010. In addition, Cardinal Health agreed to issue a \$5,000,000 purchase order before the end of the third quarter 2010 if certain milestones are achieved. If the second purchase order is issued, Cardinal Health will pay us \$4,000,000 in cash as a partial prepayment and pay \$1,000,000 directly to A Plus upon delivery of product to Cardinal Health. Assuming the second purchase order is issued and we can meet our delivery requirements, we expect to have minimum incremental revenue of \$10,500,000 in 2010, with the remaining \$4,500,000 from the second purchase order recognized when product is shipped in 2011 in accordance with the agreement. Because of this arrangement, we expect that our reported revenues for 2010 will be at a significantly higher level than that which would be reflected based on sales by our exclusive distributors’ to its end-user hospital customers. In contrast, we anticipate that our revenues for 2011 and 2012 will be at levels below actual sales by our exclusive distributors’ to its end-user hospital customers because we anticipate that Cardinal Health will satisfy customer demand, in part, by working down this inventory. For more information relating to our distribution and other arrangements with Cardinal Health, see “Business—Customers and Distribution—Cardinal Health-Exclusive U.S. Distributor” above.

**Effect of Stocking Sales and Backlog on Revenues.** Our revenues reflect primarily the sale of surgical sponges to our main distributor. Because we recognize revenues when we ship product, the timing of orders by our main distributor

and the management of its inventory may affect the comparability of revenues between periods. Additionally, because we primarily recognize revenues when we ship our products to our main distributor, to the extent there is a backlog in receipt of products from our exclusive supplier of our surgical sponges, we may not always be able to recognize revenues in the same period in which a product order is received. In addition, our main distributor may be required to sell down its inventory more than it anticipated, which could result in a larger than normal product order. Thus, certain changes in our revenues between periods are not necessarily reflective of actual hospital demand for our surgical sponge products.



Reduction in Hardware Sales – Effect on Revenues and Cost of Revenues. Prior to the third quarter of 2009, our business model included the sale of our SurgiCounter™ scanners and related software used in our Safety-Sponge® System to most hospitals that adopted our system. Beginning with the third quarter of 2009, we modified our business model and began to provide our SurgiCounter™ scanners and related software to all hospitals at no cost when they adopt our Safety-Sponge® System. Because we no longer engage in direct SurgiCounter™ scanner sales and generally anticipate only to recognize revenues associated with our SurgiCounter™ scanners in connection with reimbursement arrangements under our agreement with Cardinal Health, we do not expect our SurgiCounter™ scanners to continue to represent a sizable source of revenues for our company. Notably, in 2009, surgical sponge sales accounted for 94.0% of our revenues, and sales of hardware accounted for 6.0%, compared to 86.5% and 13.5% for the same period in 2008, respectively. In addition to its effect on our revenue, this change in our business model also affected our costs of revenues because rather than recognizing the full product cost for all SurgiCounter™ scanners at the time of shipment in our cost of revenues, we now recognize only the depreciation expense for those SurgiCounter™ scanners that we have provided to certain hospitals for their use at no cost. This business model change led to a significant improvement in our gross margin in the year ended December 31, 2009 based on the shift in product mix resulting in a significantly higher percentage of surgical sponge sales, which are sold at a higher margin than our SurgiCounter™ scanners included in our cost of revenue. Going forward, we anticipate that the shift in product mix and anticipated increase in volume of surgical sponge sales will more than offset the effects of including depreciation expense for the scanners in cost of revenue without generating the corresponding revenue from the sale of the scanner.

## Results of Operations

### Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

#### Revenues

We had revenues of \$4,503,535 for the year ended December 31, 2009, an increase of 62.0% compared to \$2,779,871 for the same period in 2008. In the year ended December 31, 2009, surgical sponge sales accounted for 94.0% of revenues, and sales of hardware accounted for 6.0%, compared to 86.5% and 13.5% for the same period in 2008, respectively. The primary reason for the increase in revenues was an increase in sales of surgical sponges used in our Safety-Sponge® System. The increase in sales activity was attributable to an upgraded sales force and changes made in our sales program, including the indemnification program (See “Business – Indemnification Program”) and providing scanners and associated software at no additional cost to our end-user hospital customers.

#### Cost of revenues

Cost of revenues increased by \$902,524 or 50.1%, to \$2,703,931 for the year ended December 31, 2009 from \$1,801,871 for the same period in 2008. The primary reason for the increase in costs was an increase in sales of our products used in our Safety-Sponge® System, reflecting an increase in the number of hospitals that have adopted and implemented our system. The increase in costs associated with the increase in sales of products more than offset the decrease in costs that resulted from the change in our business model with respect to the provision of our SurgiCounter™ scanners, which resulted in approximately \$395,000 of cost now being depreciated and recognized over the life of the hardware.

#### Gross profit

We had gross profit of \$1,799,604 for the year ended December 31, 2009, an increase of \$821,604, or 84.0%, compared to \$978,000 in the same period in 2008. The primary reason for the increase in gross profit during 2009 was the higher revenue growth achieved, combined with the shift in product mix, resulting in a significantly higher percentage of surgical sponge sales, which are sold at a higher margin than our SurgiCounter™ scanners. We had

gross margin of 40.0% for the year ended December 31, 2009, compared to 35.2% for the same period in 2008, which improvement is primarily attributable to our change in business model, and only partially offset by the increase in inventory reserves and customer rebates.

#### Operating expenses

We had total operating expenses of \$12,604,717 for the year ended December 31, 2009, an increase of \$4,611,240, or 57.7%, compared to \$7,993,477 in the same period in 2008. The primary reason for the increase in operating expenses was the significant increase in our general and administrative expenses, which increased as a result of increased personnel-related expenses and warrant and stock based compensation expenses.

#### Research and development expenses

We had research and development expenses of \$321,116 for the year ended December 31, 2009, an increase of \$50,258, or 18.5%, compared to \$270,858 in the same period in 2008. The primary reason for the increase in research and development expenses was an increase in personnel and associated compensation costs.

#### Sales and marketing expenses

We had sales and marketing expenses of \$1,926,580 for the year ended December 31, 2009, a decrease of \$589,465, or 23.4%, compared to \$2,516,045 in the same period in 2008. The primary reason for the decrease in sales and marketing expenses was a decrease in travel and trade show related expenses.

#### General and administrative expenses

We had general and administrative expenses of \$10,357,021 for the year ended December 31, 2009, an increase of \$5,150,447, or 98.9%, compared to \$5,206,574 in the same period in 2008. The primary reason for the increase is \$2,429,242 relating to the warrants associated with the Cardinal Health supply agreement, (see “Business—Customers and Distribution—Cardinal Health-Exclusive U.S. Distributor” above). Personnel related expenses, such as salaries, benefits, severance, travel and equity based compensation expenses, also accounted for a portion of the increase.

#### Total other income (expense)

We had total other expense of \$6,904,539 for the year ended December 31, 2009, compared to total other income of \$2,202,524 in the same period in 2008. The primary reason for the change was a significant increase in the fair value of our warrant derivative liability, which resulted in expense of \$5,564,125 in the year ended December 31, 2009, compared to income of \$2,582,043 in the same period in 2008. This liability, and the related expense, increases and decreases as a direct result of fluctuations in the price of our common stock, which trades on the over the counter market. In addition, for the year ended December 31, 2009 we had \$588,374 of amortization of debt discount and \$537,919 loss on extinguishment of debt compared to nil in 2008 due to our December 2009 payment in full of the senior secured notes issued in January 2009. Because we repaid the notes in full, we had to accelerate the amortization of the debt discount we recorded in January 2009 at the time of issuance of the notes and warrants, rather than over the two-year life of the notes.

#### Net loss

For the foregoing reasons, we had a net loss of \$17,531,255 for the year ended December 31, 2009 compared to a net loss of \$4,373,524 for the year ended December 31, 2008.

#### Financial Condition, Liquidity and Capital Resources

We had cash and cash equivalents of \$3,446,726 at December 31, 2009 compared to \$296,185 at December 31, 2008, and total current liabilities of \$16,495,410 at December 31, 2009 compared to \$6,791,397 at December 31, 2008. As

of December 31, 2009 we had a working capital deficit of approximately \$11,369,127, of which \$8,000,000 and \$3,666,336, respectively, are associated with deferred revenue relating to the partial prepayment from Cardinal Health and the warrant derivative liability.

Our principal sources of cash have included the issuance of equity and debt securities. We expect that as our revenues grow, our operating expenses will continue to grow and, as a result, we will need to generate significant additional net revenues to achieve profitability. Because of the way our sales cycle works (see “Business—Customers and Distribution”), we often begin to incur significant expenses in advance of the time we generate revenues from our new customer arrangements. Thus, as our business grows and we expand our customer base, our cash needs will increase prior to the time we generate cash from such new customer arrangements. As such, we do not believe that our current cash and cash equivalents will be adequate to fund our projected operating requirements for the next 12 months. Although we engaged in a financing transaction in July 2009 that resulted in the receipt of \$1,706,143 in cash in the third quarter of 2009, and repaid a significant amount of indebtedness in December 2009 following receipt of \$8,000,000 in cash in November 2009 from Cardinal Health in connection with its prepayment of a \$10,000,000 purchase order (see “—Factors Affecting Future Results—Cardinal Health Supply Agreement” above), we must still obtain additional financing and achieve profitable operations in order to provide a sufficient source of operating capital. If we are unable to obtain this additional financing, the absence of capital will have a material adverse impact on our business and operations during 2010.

#### Operating activities

We generated \$3,105,638 of net cash from operating activities in the year ended December 31, 2009. Non-cash adjustments to reconcile net loss to net cash provided by operating activities plus changes in operating assets and liabilities provided \$20,636,893 of cash in the year ended December 31, 2009. These significant non-cash adjustments primarily reflect the increase in deferred revenue as a result of the \$8,000,000 proceeds from the November 2009 renewal of our agreement with Cardinal Health order (see “—Factors Affecting Future Results—Cardinal Health Supply Agreement” above), as well as significant non-cash adjustments to reflect stock and warrant based compensation to employees and directors and adjustments to reflect the change in fair value of our warrant derivative liability.

#### Investing activities

We used \$411,388 of net cash in investing activities for the year ended December 31, 2009, primarily for the purchase of scanners and related hardware used in our Safety Sponge® System.

#### Financing activities

We generated \$456,291 of net cash from financing activities during the year ended December 31, 2009, primarily from the issuance of common stock and warrants, offset by the December 2009 repayment of a significant amount of our outstanding indebtedness.

#### Description of Indebtedness

At December 31, 2009, we had aggregate indebtedness of \$1,424,558 pertaining to the Ault Glazer Capital Partners LLC note as described below.

#### December 2009 Debt Reduction

In December 2009, following receipt of the \$8,000,000 payment from Cardinal Health in connection with its \$10,000,000 purchase order (see “Factors Affecting Future Results—Cardinal Health Supply Agreement” above), we used approximately \$3,422,000 to repay in full the principal and related accrued interest of senior secured notes issued in January 2009, the two outstanding promissory notes issued in favor of the Herbert Langsam Irrevocable Trust and the discount convertible debenture issued to David Spiegel. During the year ended December 31, 2009, we incurred

interest expense of \$219,384 on the senior secured notes, and during the years ended December 31, 2009 and 2008, we incurred interest expense of \$68,682 and \$48,395, respectively, on the Langsam promissory notes, and interest expense and amortization of the debt discount of \$15,113 and \$1,337, respectively, on the Spiegel debenture. For more information relating to these debt instruments, see Note 9 to our Consolidated Financial Statements appearing elsewhere in this annual report on Form 10-K.

#### Ault Glazer Capital Partners, LLC

On September 5, 2008, we entered into an Amendment and Early Conversion of Secured Convertible Promissory Note or Amendment, with Ault Glazer Capital Partners, LLC, or Ault Glazer, to modify the terms of our outstanding \$2,530,558 convertible secured promissory note (issued to Ault Glazer effective as of June 1, 2007). This convertible secured note was to have matured on December 31, 2010, bore interest at a rate of 7% per annum, was convertible into shares of our common stock at \$2.50 per share in certain circumstances, and was secured by all of our assets. Under the amendment, we agreed to pay Ault Glazer \$450,000 in cash and, contingent upon satisfaction of certain conditions by Ault Glazer, convert the remaining balance of the convertible secured note into 1,300,000 shares of our common stock. Notably, one condition was that Ault Glazer transfers certain leases from our name into its name. On September 12, 2008, we entered into an Agreement for the Advancement of Common Stock Prior to Close of the Amendment and Early Conversion of Secured Convertible Promissory Note or Advancement, whereby we agreed to issue shares of our common stock to Ault Glazer in advance of its satisfaction of the conditions for the conversion of the convertible secured note that were set out in the amendment agreement. As of the date of this annual report on Form 10-K, we have paid Ault Glazer \$450,000 in cash and issued Ault Glazer an aggregate 800,000 shares of our common stock, valued at \$656,000 in settlement of the note in advance of conversion of the note. Ault Glazer has not yet satisfied the conditions set out in the amendment and the issuance of the remaining shares of our common stock to Ault Glazer remains contingent upon its satisfaction of such conditions. In light of the Amendment agreement and issuance of shares pursuant to the Advancement, we are no longer incurring interest expense on this convertible secured promissory note. As of December 31, 2009, the outstanding principal balance on this note was \$1,424,558. For further information relating to this note, see Note 9 to our Consolidated Financial Statements appearing elsewhere in this annual report on Form 10-K.

Ault Glazer is controlled by Milton “Todd” Ault III, our former Chairman and Chief Executive Officer, and Louis Glazer, M.D. Ph.G, a Director of our company. Dr. Glazer currently has a significant beneficial ownership interest in our common and preferred stock.

#### Investment Portfolio

At December 31, 2009 and 2008, we had an investment in preferred stock of Alacra Corporation, with a carrying value of \$666,667, which represented 5.8% and 8.4% of our total assets at December 31, 2009 and 2008, respectively. In December 2007, we received proceeds of \$333,000 from the redemption of one-third of our initial \$1,000,000 investment. In accordance with the terms of our investment, we have exercised our right to put back our remaining preferred stock to Alacra, and based on discussions with Alacra management, we anticipate redemption and subsequent receipt of funds in the fourth quarters of 2010 and 2011, respectively. As there is no readily determinable fair value of the Alacra preferred stock, we account for this investment under the cost method. For additional information relating to this investment, see “Business—Investment Portfolio” and Note 8 to our Consolidated Financial Statements appearing elsewhere in this annual report on Form 10-K.

#### Related Party Transactions

Herbert Langsam is a member of our Board of Directors. As described above under “—Description of Indebtedness—December 2009 Debt Reduction,” Mr. Langsam provided financing to our company in exchange for equity and interest payments and a security interest in our assets.

Ault Glazer Capital Partners, LLC is controlled by Milton “Todd” Ault III, our former Chairman and Chief Executive Officer, and Louis Glazer, M.D. Ph.G. Dr. Glazer is a member of our Board of Directors and currently has a significant beneficial ownership interest in our common and preferred stock.

Catalysis Offshore Ltd and Catalysis Partners, LLC (collectively, “Catalysis”), which are controlled by Francis Capital Management, LLC, participated in the January 2009 Senior Secured Note Offering described above under “Description of Indebtedness—December 2009 Debt Reduction,” and received interest payments and a security interest in our assets. In addition, Catalysis and Francis Capital Management, LLC, have participated in other equity financings of our company. John P. Francis, a member of our Board of Directors, is President of Francis Capital Management, LLC, which is the managing partner of Catalysis.



We have an exclusive supply agreement for surgical sponges used in our Safety-Sponge® System with A Plus International Inc (see “Business—Manufacturing” above). Wenchen Lin, a member of our Board of Directors, is a founder and significant beneficial owner of A Plus. In addition, Mr. Lin has participated in equity financings of our company. During the years ended December 31, 2009 and 2008, our cost of revenue included \$2,049,426 and \$1,382,164, respectively, in connection with this supply arrangement, and our accounts payable included \$1,683,080 and \$164,341 at December 31, 2009 and 2008, respectively, payable to A Plus under this supply agreement.

From time to time, we may use the services of an aircraft owning partnership principally owned by Steven H. Kane, our Chief Executive Officer, for air travel. During the years ended December 31, 2009 and 2008, we incurred \$15,800 and \$0 respectively, of expenses related to the use such air travel services.

For additional information relating to these and other related party transactions, see Note 16 to our Consolidated Financial Statements appearing elsewhere in this annual report on Form 10-K.

#### Off-Balance Sheet Arrangements

As of December 31, 2009, we had no off-balance sheet arrangements.

#### Commitments and Contingencies

As of December 31, 2009, other than our office leases and employment agreements with key executive officers, we had no material commitments other than the liabilities reflected in our consolidated financial statements.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PATIENT SAFETY TECHNOLOGIES, INC.  
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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, 2009 and 2008, 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 was 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 financial statements referred to above present fairly, in all material respects, the financial position of Patient Safety Technologies, Inc. as of December 31, 2009 and 2008, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred significant recurring net losses through December 31, 2009 and has a significant working capital deficit as of December 31, 2009. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans as to these matters are described in Note 2. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 3 to the consolidated financial statements, effective January 1, 2009, the Company changed the way certain financial instruments that are settled in the Company's common stock are accounted for.

Squar, Milner, Peterson, Miranda & Williamson, LLP

San Diego, California  
March 31, 2010

## PATIENT SAFETY TECHNOLOGIES, INC.

## Consolidated Balance Sheets

For the Year Ended December 31,

	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,446,726	\$ 296,185
Accounts receivable	906,136	418,525
Inventories, net	565,823	199,909
Prepaid expenses	207,598	187,551
Total current assets	5,126,283	1,102,170
Restricted certificate of deposit	—	93,630
Notes receivable	—	121,065
Property and equipment, net	744,646	622,410
Goodwill	1,832,027	1,832,027
Patents, net	3,114,025	3,438,966
Long-term investment	666,667	666,667
Other assets	43,246	37,481
Total assets	\$ 11,526,894	\$ 7,914,416
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
Current liabilities		
Accounts payable	\$ 2,043,166	\$ 909,333
Current portion of convertible note	1,424,558	1,424,558
Current portion of notes payable	—	1,100,000
Current portion of capital lease	19,330	—
Warrant derivative liability	3,666,336	1,761,878
Deferred revenue	8,099,144	—
Accrued liabilities	1,242,876	1,595,628
Total current liabilities	16,495,410	6,791,397
Long-term convertible notes, less current portion	—	51,377
Long-term capital lease, less current portion	58,274	—
Deferred tax liability	805,768	1,042,400
Total liabilities	17,359,452	7,885,174
Commitments and contingencies (Note 18)		
Stockholders' (deficit) equity:		
Series A preferred stock, \$1.00 par value, cumulative 7% dividend: 1,000,000 shares authorized; 10,950 issued and outstanding at December 31, 2009 and December 31, 2008; (Liquidation preference of \$1.2 million at December 31, 2009 and December 31, 2008)	10,950	10,950
	7,740,501	5,675,298

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Common stock, \$0.33 par value: 100,000,000 shares authorized; 23,456,063 shares issued and outstanding at December 31, 2009; 17,197,511 shares issued and outstanding at December 31, 2008		
Additional paid-in capital	44,834,321	36,033,542
Accumulated deficit	(58,418,330)	(41,690,548)
Total stockholders' (deficit) equity	(5,832,558)	29,242
Total liabilities and stockholders' (deficit) equity	\$ 11,526,894	\$ 7,914,416

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

## PATIENT SAFETY TECHNOLOGIES, INC.

## Consolidated Statements of Operations

	For the Year Ended December 31,	
	2009	2008
Revenues	\$ 4,503,535	\$ 2,779,871
Cost of revenue	2,703,931	1,801,871
Gross profit	1,799,604	978,000
Operating expenses:		
Research and development	321,116	270,858
Sales and marketing	1,926,580	2,516,045
General and administrative	10,357,021	5,206,574
Total operating expenses	12,604,717	7,993,477
Operating loss	(10,805,113)	(7,015,477)
Other income (expenses)		
Loss on extinguishment of debt	(537,919)	—
Interest expense	(383,485)	(332,755)
Loss (gain) on change in fair value of warrant derivative liability	(5,564,125)	2,582,043
Amortization of debt discount	(588,374)	—
Realize loss on sale of assets, net	—	(90,564)
Gain on warrant exchange	164,226	—
Other income	5,138	43,800
Total other income (expense)	(6,904,539)	2,202,524
Loss before income taxes	(17,709,652)	(4,812,953)
Income tax benefit	178,397	439,429
Net loss	(17,531,255)	(4,373,524)
Preferred dividends	(76,650)	(76,650)
Net loss applicable to common shareholders	\$ (17,607,905)	\$ (4,450,174)
Net loss per common share – basic and diluted	\$ (0.90)	\$ (0.31)
Weighted average common shares outstanding:		
Basic and diluted	19,537,938	14,451,582

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

## PATIENT SAFETY TECHNOLOGIES, INC.

## Consolidated Statements of Stockholder's (Deficit) Equity

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Issued Shares	Common Stock Issued Amount	Paid – In Capital	Accumulated Deficit	Total Stockholders Equity
BALANCES, December 31, 2007	10,950	\$ 10,950	12,054,166	\$ 3,978,019	\$ 34,320,133	\$ (37,240,374)	\$ 1,068,628
Preferred dividend	—	—	—	—	—	(76,650)	(76,650)
Common stock issued	—	—	3,661,606	1,208,328	3,368,672	—	4,577,000
Common stock issued for settlement of accounts payable	—	—	136,634	45,021	139,729	—	184,750
Common stock issued in connection with conversion of debt	—	—	1,293,939	427,045	884,835	—	1,311,880
Common stock issued to extend debt maturity	—	—	25,000	8,250	6,750	—	15,000
Common stock issued for services provided	—	—	26,166	8,635	24,072	—	32,707
Warrants reclassified from equity to liability	—	—	—	—	(4,343,922)	—	(4,343,922)
Stock-based compensation-Restricted stock	—	—	—	—	713,384	—	713,384
Stock-based compensation-Stock options	—	—	—	—	919,889	—	919,889
Net loss	—	—	—	—	—	(4,373,524)	(4,373,524)
BALANCES, December 31, 2008	10,950	\$ 10,950	17,197,511	\$ 5,675,298	\$ 36,033,542	\$ (41,690,548)	\$ 29,242
Preferred dividend	—	—	—	—	—	(76,650)	(76,650)
Cumulative effect of change in accounting principal	—	—	—	—	(1,582,843)	875,123	(707,720)
Debt discount related to warrants issued in connection with January debt financing	—	—	—	—	1,311,311	—	1,311,311
Issuance of warrants	—	—	—	—	3,752,075	—	3,752,075
Warrants reclassified from equity to liability	—	—	—	—	(3,532,780)	—	(3,532,780)
Warrant exchange	—	—	5,965,495	1,968,494	5,254,640	5,000	7,228,134

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Warrants reclassified from liability to equity	—	—	—	—	2,152,940	—	2,152,940
Extinguishment of related party debt discount	—	—	—	—	(245,571)	—	(245,571)
Stock-based compensation – Stock options	—	—	—	—	1,279,216	—	1,279,216
Stock-based compensation – Warrants	—	—	—	—	195,416	—	195,416
Common stock issued in connection with exercise of stock options	—	—	21,868	7,217	20,119	—	27,336
Common stock issued in connection with conversion of debt	—	—	246,189	81,242	177,256	—	258,498
Common stock issued to extend debt maturity	—	—	25,000	8,250	19,000	—	27,250
Net loss	—	—	—	—	—	(17,531,255)	(17,531,255)
<b>BALANCES, December 31, 2009</b>	<b>10,950</b>	<b>\$ 10,950</b>	<b>23,456,063</b>	<b>\$ 7,740,501</b>	<b>\$ 44,834,321</b>	<b>\$ (58,418,330)</b>	<b>\$ (5,832,558)</b>

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



PATIENT SAFETY TECHNOLOGIES, INC.  
Consolidated Statements of Cash Flows

	For the Year Ending December 31,	
	2009	2008
<b>Operating activities:</b>		
Net loss	\$ (17,531,255)	\$ (4,373,524)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	366,755	351,957
Amortization of patents	324,941	324,941
Amortization of debt discount	588,374	—
Issuance of common stock for extension of note term	27,250	—
Non-cash interest	—	168,104
Issuance of warrants	3,752,075	—
Provision for obsolete inventory	168,996	—
Loss on write off of fixed assets	55,233	91,030
Issuance of common stock for loan fees	—	15,000
Write-off of notes receivable	121,064	(36,663)
Gain on warrant exchange	(164,226)	—
Loss on extinguishment of debt	537,919	—
Stock and warrant based compensation	1,474,632	1,665,981
Change in fair value of warrant derivative liability	5,564,125	(2,582,043)
Write off of restricted certificate of deposit	93,630	—
Write off of security deposit	9,080	—
Change in deferred tax liability	(236,632)	(452,079)
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(487,611)	(314,205)
Inventories	(585,679)	(199,909)
Prepaid expenses	(20,047)	20,272
Other assets	(14,844)	(15,308)
Accounts payable	1,133,836	250,739
Accrued liabilities	(171,122)	514,864
Deferred revenue	8,099,144	—
Net cash provided by (used in) operating activities	3,105,638	(4,570,843)
<b>Investing activities:</b>		
Purchase of property and equipment	(411,388)	(282,312)
Proceeds of asset sales, net	—	315,957
Net cash (used in) provided by investing activities	(411,388)	33,645
<b>Financing activities:</b>		
Proceeds from issuance of notes payable	2,000,000	650,000
Proceeds from issuance of common stock and warrants	—	4,577,000
Proceeds from issuance of common stock in connection with warrant exchange	1,706,143	—
Principal payments on notes payable	(3,181,376)	(722,380)
Proceeds from exercise of stock options	27,336	—
Payments of preferred dividends	(95,812)	(76,650)
Net cash provided by financing activities	456,291	4,427,970

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Net increase (decrease) in cash and cash equivalents	3,150,541	(109,228)
Cash and cash equivalents at beginning of period	296,185	405,413
Cash and cash equivalents at end of period	\$ 3,446,726	\$ 296,185
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	\$ 110,000	\$ 5,737
Cash paid during the period for taxes	\$ 9,799	\$ 800
Non cash investing and financing activities:		
Dividends accrued	\$ 76,650	\$ 76,650
Reclassification of accrued interest to notes payable	\$ 227,673	\$ —
Debt discount recorded in connection with issuance of notes payable	\$ 1,311,311	\$ —
Reclassification of warrant equities to derivative liability	\$ (4,240,500)	\$ (4,343,922)
Reclassification of warrant derivative liability to equity	\$ 2,152,940	\$ —
Issuance of common stock in payment of notes payable and accrued interest	\$ 211,722	\$ 1,166,728
Issuance of common stock in connection with warrant exchange	\$ (5,752,227)	\$ 103,101
Reclassification of related party unamortized debt discount	\$ (245,571)	\$ —
Acquisition of fixed assets pursuant to capital lease	\$ 77,604	\$ —
Forgiveness of debt	\$ —	\$ 36,663
Issuance of common stock for an accrued liability	\$ —	\$ 134,750
Issuance of common stock for accounts payable	\$ —	\$ 50,000

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

Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

## 1. DESCRIPTION OF BUSINESS

Patient Safety Technologies, Inc. ("PST" or 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 AND GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. At December 31, 2009, the Company has an accumulated deficit of \$58,418,330 and a working capital deficit of \$11,369,127. For the year ended December 31, 2009, the Company incurred a loss of \$17,531,255 and generated positive cash flow from operating activities of \$3,105,638, primarily from the \$8,000,000 proceeds from the November 2009 renewal of its agreement with Cardinal Health. Given the operating requirements of the Company, these conditions raise substantial doubt about the Company's ability to continue as a going concern.

Management believes that existing cash resources, combined with projected cash flow from operations, will not be sufficient to fund the Company's working capital requirement for the next twelve months, and that in order to continue to operate as a going concern it will be necessary to raise additional funds. Management plans to raise the additional required funds through debt and/or equity financing transactions.

The Company believes that it will be successful in raising additional new funds, as required. However no assurances can be made that it will be successful obtaining a sufficient amount of financing to continue to fund its operations or that the Company will achieve profitable operations and positive cash flow. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## 3. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Principles of Consolidation

The accompanying consolidated financial statements for 2009 include the accounts of the Company and its subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

### Cumulative Effect of Changes in Accounting Principles

On January 1, 2009, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity ("ASC 815-40"). In accordance with ASC 815-40, the cumulative effect of the change in accounting principle recorded by the Company in connection with certain warrants to acquire shares of the Company's common stock (see Note 12), was recognized by the Company as an adjustment to the opening balances of accumulated deficit, additional paid in capital and warrant liability based the difference between amounts recognized in the statement of financial position before and after the initial application of this guidance as summarized in the following table:



Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

	As reported on December 31, 2008	As adjusted on January 1, 2009	Effect of change in accounting principle
Warrant Liability	\$ 1,761,878	\$ 2,469,598	\$ 707,720
Additional paid in capital	\$ 36,033,542	\$ 34,450,699	\$ (1,582,843)
Accumulated deficit	\$ (41,690,548)	\$ (40,815,425)	\$ 875,123

#### 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, impairment of goodwill and other intangible assets, the fair value of stock-based compensation and 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 2009 presentation. These reclassifications had no effect on previously reported results of operations or accumulated deficit.

#### Revenue Recognition

The Company recognizes revenue from the sale of products to end-users and distributors when persuasive evidence of a sale exists, the product is complete, tested and has been shipped which coincides with transfer of title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and the Company does not have significant obligations for future performance. When collectability is not reasonably assured, the Company defers the revenue over the cash collection period. 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 trade-in allowances given to the buyer.

The Company derives its revenue primarily from the sale of the surgical sponges and towels used in its Safety-Sponge® System to its distributors. The Company’s revenues are generated by the sales and marketing efforts of its direct sales force and independent distributor. Its products are ordered directly by the hospitals through an independent distributor and the product is shipped and billed directly by the independent distributor. Although hardware sales are not considered a recurring item, the Company expects that once an institution adopts its Safety-Sponge® System, they will be committed to its use and therefore provide a recurring source of revenues for sales of products (surgical sponges and towels) used in the Safety-Sponge® System.

- **Hardware Cost Reimbursement Revenues:** During fiscal year 2009, the Company began a program in which the scanners and related hardware used in the Safety-Sponge® System are provided to the hospitals without charge for their use. Prior to the third quarter of 2009, the Company’s business model included the sale of its SurgiCounter™ scanners and related software used in its Safety-Sponge® System to most hospitals that adopted the Company’s system. Beginning with the third quarter of 2009, the Company modified its business model and began to provide

its SurgiCounter™ scanners and related software to all hospitals at no cost when they adopt its Safety-Sponge® System. Under the new supply and distribution agreement with Cardinal Health entered into in November 2009, the Company is reimbursed an agreed upon percentage of the cost of the scanners provided by the Company to hospitals which receive their surgical sponges and towels through Cardinal. Reimbursements received from Cardinal are initially deferred and are recognized as revenue on a pro-rata basis over the life of the specific hospital contract. Because the Company no longer engages in direct SurgiCounter™ scanner sales and generally anticipate only recognizing revenues associated with its SurgiCounter™ scanners in connection with reimbursement arrangements under its agreement with Cardinal Health.

Patient Safety Technologies, Inc.

Notes to Consolidated Financial Statements

- **Hardware, Software and Maintenance Agreement Revenues:** As the software included in the Company's SurgiCounter™ scanner is not incidental to the product being sold, the sale of the software falls within the scope of Accounting Standards Codification ("ASC") ASC 985-605, formerly Statement of Position ("SOP") 97-2. The SurgiCounter™ scanner is considered to be a software-related element, as defined in ASC 985-605, because the software is essential to the functionality of the scanner, and the maintenance agreement, which provides for product support including unspecified product upgrades and enhancements developed by the Company during the period covered by the agreement is considered to be post-contract customer support ("PCS") as defined in ASC 985-605. These items are considered to be separate deliverables within a multiple-element arrangement, and based on the fact that there is vendor specific objective evidence for the non-delivered element the total price of this arrangement is allocated to each respective deliverable based on the residual fair value of each element, and recognized as revenue as each element is delivered. For the hardware and software elements, delivery is generally considered to be at the time of shipment where terms are FOB shipping point. In the event that terms of the sale are FOB customer, the delivery is considered to occur at the time that delivery to the customer has been completed. Delivery with respect to the initial one-year maintenance agreement is considered to occur on a monthly basis over the term of the one-year period, and revenues related to this element are recognized on a pro-rata basis during this period.
- **Surgical Sponge Revenues:** The surgical products (sponges and towels) used in the Company's Safety-Sponge® System are sold separately from the hardware and software described above and those products are not considered to be part of a multiple-element arrangement. Accordingly, revenues related to the sale of products used in the Company's Safety-Sponge® System are recognized in accordance with Staff Accounting Bulletin ("SAB") 104. Generally revenues from the sale of surgical products used in the Safety-Sponge® System are recognized upon shipment as most surgical products used in the Safety-Sponge® System are sold FOB shipping point. In the event that terms of the sale are FOB customer, revenue is recognized at the time delivery to the customer has been completed. Advanced payments are classified as deferred revenue and recognized as product is shipped to the customer.

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 or trade in allowances given to the buyer.

#### 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. Convertible debentures and note payable arrangements were based on borrowing rates currently available to the Company for loans with similar terms and maturities, and were reported at their carrying values, which the Company believes approximates fair value. Warrants classified as derivative liabilities are reported at their estimated fair value using the Black Scholes valuation model, with changes in fair value being reported in current period earnings (loss) in other income/(expense) (see Note 14).

#### Cash and Cash Equivalents

Cash equivalents are short-term, highly liquid investments with maturities of three months or less at the time of purchase. These investments generally consist of money market funds and commercial paper and are stated at cost, which approximates fair market value.





Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

#### Concentration of Credit Risk

From time to time, the Company maintains its cash balances in accounts at a financial institution that exceed the Federal Deposit Insurance Corporation coverage of \$250,000. The Company has not experienced any losses in such accounts.

#### Accounts Receivable

Accounts receivable are recorded at the invoice amount and do not bear interest. Historically, the Company has not incurred any 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, additional allowances for doubtful accounts would be required.

#### Inventories

Inventories at December 31, 2009, 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, Plant and Equipment

Property, plant and equipment is stated at cost. Depreciation is amortized straight-line over the estimated useful lives of 3 to 5 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, 2009 and 2008 there was no impairment recorded.

#### Impairment of Goodwill

The Company evaluates the carrying value of goodwill during the fourth quarter of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. Such circumstances could include, but are not limited to (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, or (3) an adverse action or assessment by a regulator. When evaluating whether goodwill is impaired, the Company compares the fair value of the reporting unit to which the goodwill is assigned to the reporting unit's carrying amount, including goodwill. The fair value of the reporting unit is estimated using a combination of the income, or discounted cash flows, and the market approach, which utilizes comparable companies' data. If the carrying amount of a reporting unit exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss would be calculated by comparing the implied fair value of the reporting unit goodwill to its carrying amount. In calculating the implied fair value of the reporting unit goodwill, the fair value of the reporting unit is allocated to all of the other assets and liabilities of that unit based on their fair values. The excess of the fair value of a reporting unit over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value. The Company's evaluation of goodwill completed during 2009 and 2008 resulted in no impairment losses.

Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

Cost Method Investment

The investment balance at December 31, 2009 and 2008 represents non-marketable shares of preferred stock owned by the Company in a privately held company that is reported using the cost method. Under the cost method, the Company does not record its proportional share of earnings and losses of the investee, and income on the investment is only recorded to the extent of dividends distributed from earnings of the investee received subsequent to the date of acquisition.

The Company reviews the carrying value of its cost-method investment for impairment each reporting period in which the Company determines that an impairment indicator is present. If an impairment is present, the fair value of the investment must be estimated in order to test impairment of the investment. Examples of impairment indicators include: 1) a significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee, 2) a significant adverse change in the regulatory, economic, or technical environment of the investee, 3) a significant adverse change in the general market condition of either the geographic area or the industry in which the investee operates, 4) a bona fide offer to purchase (whether solicited or unsolicited), an offer by the investee to sell, or a completed auction process for the same or similar security for an amount less than the cost of the investment, 5) factors that raise significant concerns about the investee's ability to continue as a going concern, such as negative cash flow from operations, working capital deficiencies, or non-compliance with statutory capital requirements or debt covenants.

When an impairment test demonstrates that the fair value of an investment is less than its carrying value, Company management will determine whether the impairment is either temporary or other-than-temporary. Examples of factors that may be indicative of an other-than-temporary impairment include: i) the length of time and extent to which market value has been less than cost, ii) the financial condition and near-term prospects of the issuer, iii) and the intent and ability of the Company to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

If the decline in fair value is determined by management to be other-than-temporary, the cost basis of the investment is written down to its estimated fair value as of the balance sheet date of the reporting period in which the assessment is made. This fair value becomes the investment's new cost basis, which is not changed for subsequent recoveries in fair value. Any recorded impairment write-down will be included in earnings as a realized loss in the period such write-down occurs. As of December 31, 2009 and 2008, the Company determined that no impairment indicators were present.

Research and Development

Research and development costs are expensed in the period incurred. Research and development expenses for the years ended December 31, 2009 and 2008 were \$321,116 and \$270,858, respectively.

Marketing

Marketing costs are expensed in the period incurred and reported under sales and marketing expenses. Marketing expenses, which include sales related travel, trade shows, promotional products and advertising for the years ended December 31, 2009 and 2008, were \$893,127 and \$834,426, 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.

Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

### Derivative Financial Instruments

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are embedded derivative instruments, including an embedded conversion option, that are required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible instrument contains more than one embedded derivative instrument, including conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, the Company may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as charges or credits to income. When the convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face amount.

The discount from the face value of the convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to income, using the effective interest method.

### Stock-Based Compensation

At December 31, 2009, the Company had two stock option plans, which are described more fully in Note 15 to the Consolidated Financial Statements. Pursuant to the provisions of the Compensation-Stock Compensation Topic of the FASB Codification, the Company measures the cost of employee stock options based on the grant-date fair value and recognizes that cost using the straight line method over the period during which a recipient is required to provide services in exchange for the options, typically the vesting period. 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.

### Beneficial Conversion Feature of Convertible Notes Payable

The convertible feature of certain notes payable provides for a rate of conversion that is below market value. Such feature is normally characterized as a Beneficial Conversion Feature ("BCF"). Pursuant to ASC 470-20, (formerly EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratio, EITF No. 00-27, Application of EITF Issue No. 98-5 To Certain Convertible Instruments and APB 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants), the estimated fair value of the BCF is recorded in the consolidated financial statements as a discount from the face amount of the notes. Such discounts are amortized to expense over the term of the notes (or conversion of the notes, if sooner).

### Warrant Derivative Liability

Pursuant to ASC 815-40 Derivatives and Hedging, an evaluation of outstanding warrants is made to determine whether warrants issued are required to be classified as either equity or a liability. If the classification required under ASC 815-40 changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. In the event that this evaluation results in a partial reclassification, the Company's policy is to first reclassify warrants with the latest date of issuance. The estimated fair value of warrants classified as derivative liabilities is determined using the Black-Scholes option pricing model. The fair value of warrants classified as derivative liabilities is adjusted for changes in fair value at each reporting period, and the corresponding non-cash gain or loss is recorded in current period earnings (loss). There is no limit on the number of times a contract may be reclassified.

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Net Loss per Common Share

Loss per common share is determined by dividing the 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 (previously SFAS No. 128, Earnings per Share), which requires dual presentation of basic and diluted earnings per share on the face of the consolidated statements of operations. Basic 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 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.

Because the effects of outstanding options, warrants and the conversion of convertible preferred stock and convertible debt are anti-dilutive in all periods presented, shares of common stock underlying these instruments as shown below have been excluded from the computation of loss per common share:

	2009	2008
Convertible Debentures	500,000	543,409
Convertible Preferred Stock	246,375	246,375
Warrants	8,064,978	10,719,896
Stock Options	5,821,000	1,627,000
Total	14,632,353	13,136,680

Segment Information

The Company presents its business as one reportable segment due to the similarity in nature of products marketed, financial performance measures, 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.

Legal and Other Contingencies

The Company is involved in various proceedings, legal actions and claims arising in the normal course of business that are more fully described in Note 19 to the Consolidated Financial Statements. 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 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.

Recent Accounting Pronouncements

In June 2009, the FASB issued Statement No. 168, The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162 (the "ASC"). Effective for interim and annual periods ended after September 15, 2009, the ASC became the source of authoritative GAAP recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities

and Exchange Commission (“SEC”) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This statement does not change existing GAAP, but reorganizes GAAP into Topics. In circumstances where previous standards require a revision, the FASB will issue an Accounting Standards Update (“ASU”) on the Topic. The Company’s adoption of this standard during the year ended December 31, 2009 did not have any impact on the Company’s consolidated financial statements.



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On January 1, 2009, the Company adopted the guidance codified in ASC 350-30, Intangibles – Goodwill and Other (previously FASB FAS 142-3, Determination of Useful Life of Intangible Assets). ASC 350-30 amends the factors that should be considered in developing the renewal or extension assumptions used to determine the useful life of a recognized intangible asset also requires expanded disclosure related to the determination of intangible asset useful lives and is effective for fiscal years beginning after December 15, 2008. Earlier adoption is not permitted. The Company's adoption of ASC 350-30 did not have a material impact on its consolidated financial statements.

In June 2008, the FASB ratified guidance issued by the EITF as codified in ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity (previously EITF Issue No. 07-5, Determining whether an Instrument (or Embedded Feature) is indexed to an Entity's own Stock). ASC 815-40 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application is not permitted. ASC 815-10 – specifies that a contract that would otherwise meet the definition of a derivative but is both (a) indexed to the Company's own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. ASC 815-40 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify for the ASC 815-10 scope exception. The Company's adoption of ASC 815-40 effective January 1, 2009, resulted in the identification of certain warrants that were determined to be ineligible for equity classification because of certain provisions that may result in an adjustment to their exercise price. Accordingly, these warrants were reclassified as liabilities upon the effective date of ASC 815-40 and re-measured at fair value as of December 31, 2009 with changes in the fair value recognized in other income for the year ended December 31, 2009. The cumulative effect of the change in accounting for these warrants was recognized as an adjustment to the opening balance of accumulated deficit at January 1, 2009 based on the difference between the amounts recognized in the consolidated balance sheet before the initial adoption of ASC 815-40 and the amounts recognized in the consolidated balance sheet as a result of the initial application of ASC 815-40. (See Notes 3 and 13).

In May 2009, the FASB issued ASC 855-10, Subsequent Events (ASC 855-10). The objective of this statement is to establish principles and requirements for subsequent events. In particular, ASC 855-10 sets forth the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. ASC 855-10 is effective for interim or annual financial statements issued after June 15, 2009. In February 2010, the FASB issued ASU 2010-09, Subsequent Events (ASC Topic 855) — Amendments to Certain Recognition and Disclosure Requirements. ASU 2010-09 removes the requirement for an SEC filer to disclose a date in both issued and revised financial statements. The adoption of these pronouncements did not have a material effect on its consolidated financial statements.

In October 2009, the FASB issued ASU 2009-13, Multiple Deliverable Revenue Arrangements, which addresses the accounting for multiple deliverable arrangements to enable vendors to account for products and services (deliverables) separately rather than as a combined unit. The amendments in ASU 2009-13 are effective prospectively for revenue arrangements entered into or materially modified in the fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The impact of this accounting update on the Company's consolidated financial statements has not been evaluated.

In October 2009, the FASB issued ASU 2009-14, Certain Revenue Arrangements That Include Software Elements, which changes the accounting model for revenue arrangements that include both tangible products and software

elements that are “essential to the functionality,” and scopes these products out of current software revenue guidance. The new guidance will include factors to help companies determine what software elements are considered “essential to the functionality.” The amendments included in ASU 2009-14 are effective prospectively for revenue arrangements entered into or materially modified in the fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The impact of this accounting update on the Company’s consolidated financial statements has not been evaluated.

Patient Safety Technologies, Inc.  
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In January 2010, the FASB issued FASB ASU 2010-06, Improving Disclosures about Fair Value Measurements which clarifies certain existing disclosure requirements in ASC 820 as well as requires disclosures related to significant transfers between each level and additional information about Level 3 activity. FASB ASU 2010-06 begins phasing in the first fiscal period after December 15, 2009. The impact of this accounting update on the Company's consolidated financial statements has not been evaluated.

#### 4. RESTRICTED CERTIFICATE OF DEPOSIT

At December 31, 2008, the Company had a restricted certificate of deposit of \$93,630, which included accrued interest income of \$6,130 held by a financial institution securing a letter of credit. This restricted certificate of deposit was held to cover a portion of the security deposit related to a lease on the Company's prior corporate offices sublet to a third party lessee that runs through January 2012. In October 2009, the third party lessor defaulted on the lease, requiring the beneficiary to draw on the letter of credit being secured by the restricted certificate of deposit, thus resulting in a charge to general and administrative expenses for \$93,630 in 2009.

#### 5. INVENTORY

Inventories consisted of the following:

	December 31, 2009	December 31, 2008
Finished goods	\$ 734,819	\$ 199,909
Reserve of obsolescence	(168,996)	—
Total inventory, net	\$ 565,823	\$ 199,909

#### 6. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2009 and 2008 are comprised of the following:

	December 31, 2009	December 31, 2008
Computer software and equipment	\$ 1,097,181	\$ 1,085,961
Furniture and equipment	298,333	215,423
Hardware for customer use	394,861	—
Property and equipment, gross	1,790,375	1,301,384
Less: accumulated depreciation	(1,045,729)	(678,974)
Property and equipment, net	\$ 744,646	\$ 622,410

The furniture and equipment balance at December 31, 2009 includes \$77,604 of office furniture acquired as part of the Newtown, PA sublease, which has been recorded as a capital lease, and which will be amortized over the term of the sublease through April 2013 (see Note 19). Depreciation expense for the years ended December 31, 2009 and 2008 was \$366,755 and \$351,957, respectively.

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## 7. GOODWILL AND PATENTS

The Company recorded goodwill in the amount of \$1,700,000 in connection with its acquisition of SurgiCount Medical, Inc. in February 2005. During the year ended December 31, 2007, cumulative gross revenues of SurgiCount exceeded \$1,000,000 and as such the Company issued 100,000 shares of common stock, valued at approximately \$145,000 to the SurgiCount founders, as contingent consideration, which was recorded as additional goodwill. In addition, in connection with the SurgiCount acquisition, the Company recorded patents acquired that were valued at \$4,700,000.

The Company performs its annual impairment analysis of goodwill in the fourth quarter of each year according to the provisions of ASC- 350 Valuation Analysis (formerly SFAS 142, Goodwill and Other Intangible Assets. This statement requires that the Company perform a two-step impairment test on goodwill. In the first step, the Company compares the fair value of each reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets assigned to the reporting unit, goodwill is not impaired and the Company is not required to perform further testing. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the Company must perform the second step of the impairment testing to determine the implied fair value of the reporting unit's goodwill. The implied fair value of goodwill is calculated by deducting the fair value of all tangible and intangible assets of the reporting unit, excluding goodwill, from the fair value of the reporting unit as determined in the first step. If the carrying value of a reporting unit's goodwill exceeds its implied fair value, then an impairment loss equal to the difference would be recorded.

During 2009, the Company conducted its annual test for impairment, at year-end and determined goodwill was not impaired.

Goodwill was \$1,832,027 of December 31, 2009 and 2008.

Patents, net, as of December 31, 2009 and 2008 are composed of the following:

	December 31, 2009	December 31, 2008
Patents	\$ 4,684,576	\$ 4,684,576
Accumulated amortization	(1,570,551)	(1,245,610)
	\$ 3,114,025	\$ 3,438,966

The patents are subject to amortization over their estimated useful life of 14.4 years. Amortization expense was \$324,941 for the years ended December 31, 2009 and 2008. The following table presents estimated amortization expense for each of the succeeding five calendar years and thereafter:

2010	\$ 324,941
2011	324,941
2012	324,941
2013	324,941
2014	324,941
Thereafter	1,489,320
Total	\$ 3,114,025

8. LONG-TERM INVESTMENTS

Long-term investments at December 31, 2009 and 2008 are comprised of the following:

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Patient Safety Technologies, Inc.  
Notes to Consolidated Financial Statements

	December 31, 2009	December 31, 2008
Alacra Corporation	\$ 666,667	\$ 666,667
	\$ 666,667	\$ 666,667

#### Alacra Corporation

At December 31, 2009 and 2008, the Company had an investment in shares of Series F convertible preferred stock of Alacra, Inc. ("Alacra"), a global provider of business and financial information in New York, recorded at its cost of \$666,667. The Company has the right, to the extent that Alacra has sufficient available capital, to have the Series F convertible preferred stock redeemed by Alacra for face value plus accrued dividends beginning on December 31, 2006. During the year ended December 31, 2007, Alacra redeemed one-third of the Series F convertible preferred stock. The Company expects to receive proceeds from the redemption of one-half of the current carrying value in 2010 and the remaining balance in 2011.

#### 9. CONVERTIBLE NOTE & NOTES PAYABLE

##### Convertible Note

Convertible notes at December 31, 2009 and 2008 are comprised of the following:

	2009	2008
Ault Glazer Capital Partners, LLC (a) *	\$ 1,424,558	\$ 1,424,558
David Spiegel (b)	—	65,115
Total convertible notes	1,424,558	1,489,673
Less: unamortized discount	—	(13,738)
	1,424,558	1,475,935
Less: current portion	(1,424,558)	(1,424,558)
Convertible notes - long term portion	\$ —	\$ 51,377

Maturities of the convertible notes at December 31, 2009 are as follows:

Years Ending December 31,	
2010	\$ 1,424,558
2011	—
Thereafter	—
Total	\$ 1,424,558

\* Related Party (See Note 16 to the Consolidated Financial Statements)

(a) Effective June 1, 2007, the Company restructured the entire unpaid principal and interest under promissory notes issued to Ault Glazer Capital Partners, LLC ("Ault Glazer") into a new Convertible Secured Promissory Note (the "AG Capital Partners Convertible Note") in the principal amount of \$2.5 million. The AG Capital Partners Convertible Note bears interest at the rate of 7% per annum and is due on the earlier of December 31, 2010, or the occurrence of an event of default.



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On September 5, 2008, the Company entered into an Amendment and Early Conversion of the Secured Convertible Promissory Note (the "Amendment") in respect of the AG Capital Partners Convertible Note. The Amendment allowed for the conversion, prior to the maturity date, of the outstanding principal balance of the AG Capital Partners Convertible Note into 1,300,000 shares of the Company's common stock and \$450,000 in cash payments. According to the Amendment, after the cash payments were made, the AG Capital Partners Convertible Note could be converted into 1,300,000 shares of common stock upon Ault Glazer's satisfaction of certain conditions. The Company made the agreed upon \$450,000 cash payment on September 5, 2008.

On September 12, 2008, the parties executed an Agreement for the Advancement of Common Stock Prior to Close of the Amendment and Early Conversion of Secured Convertible Promissory Note, dated September 5, 2008 (the "Advancement"). Pursuant to the Advancement, the Company agreed to issue 300,000 shares of the Company's common stock on September 12, 2008 to Ault Glazer in advance of the satisfaction of the conditions in the Amendment with the understanding that Ault Glazer would satisfy the conditions stated in the Amendment prior to September 19, 2008. The stated purpose of the Advancement was to facilitate Ault Glazer's satisfaction of each of the conditions stated in the Amendment.

Ault Glazer failed to satisfy the conditions by the September 19, 2008 deadline as stated in the Advancement. Although the conditions remained unsatisfied, the Company made two additional issuances of shares to Ault Glazer pursuant to the Amendment as follows: the Company issued another 250,000 shares on October 10, 2008 and another 250,000 shares on November 6, 2008. As of this date, there remain 500,000 shares issuable to Ault Glazer upon Ault Glazer meeting the conditions of the Amendment.

During the fiscal year ended December 31, 2008, the Company incurred interest expense of \$127,637 on the AG Capital Partners Convertible Note. During the fiscal year ended December 31, 2009, in light of the failure to satisfy the conditions of the Amendment and the Advancement, the Company did not accrue interest expense on the AG Capital Partners Convertible Note.

(b) On October 27, 2008, the Company issued a Discount Convertible Debenture to David Spiegel in the principal amount of \$65,115 (the "Spiegel Note") with a 9% original issue discount of \$15,115. The Spiegel Note was convertible at any time at the option of the holder, in whole or in part, into the Company's common stock at a conversion price of \$1.50 per share. During the year ended December 31, 2009 and 2008, the Company incurred interest expense and amortization of the debt discount of \$13,738 and 1,337, respectively on the Spiegel Note. The Spiegel Note was paid in full on December 15, 2009.

Notes Payable

Notes payable at December 31, 2009 and 2008 are comprised of the following:

	2009	2008
Herbert Langsam (a)*	\$ 600,000	—
Catalysis Offshore (b)*	—	250,000
Catalysis Partners (b)*	—	250,000
Total notes payable – current	\$ 600,000	\$ 500,000

\* Related party (see Note 15 to the Consolidated Financial Statements)



(a) On May 1, 2006, the Company executed a \$500,000 Secured Promissory Note (the “First Langsam Note”) due November 1, 2006, payable to the Herbert Langsam Irrevocable Trust. Herbert Langsam is a Member of the Board of Directors of the Company. The First Langsam Note accrued interest at the rate of 12% per annum, although from November 1, 2006 through December 2008; the First Langsam Note accrued interest at rate of 16% per annum as the Company was in default. In December 2008, Mr. Langsam agreed to extend the maturity of the First Langsam Note to June 30, 2009, and then in August 2009, agreed to further extend the maturity of this note to December 31, 2009. The Company also entered into a Security Agreement on May 1, 2006, granting the Herbert Langsam Irrevocable Trust a security interest in all of the Company’s assets as collateral for the satisfaction and performance of the Company’s obligations pursuant to the First Langsam Note.

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On November 13, 2006, the Company executed an additional \$100,000 Secured Promissory Note (the “Second Langsam Note” and, together with the First Langsam Note, the “Langsam Notes”) due May 13, 2007 payable to the Herbert Langsam Irrevocable Trust. The Second Langsam Note accrued interest at the rate of 12% per annum, although from May 13, 2007 through December 2008, the Second Langsam Note accrued interest at rate of 16% per annum as the Company was in default. As additional consideration for entering into the Second Langsam Note, the Company granted Mr. Langsam warrants to purchase 50,000 shares of the Company’s common stock at an exercise price of \$1.25 per share. These warrants were subsequently exchanged in the first warrant exchange transaction that closed July 21, 2009 (see Note 12 to the Consolidated Financial Statements). On November 13, 2006, the Company also entered into a Security Agreement granting the Herbert Langsam Irrevocable Trust a security interest in all of the Company’s assets as collateral for the satisfaction and performance of the Company’s obligations pursuant to the Second Langsam Note. In December 2008, Mr. Langsam agreed to extend maturity of the Second Langsam Note to June 30, 2009, and then in August, 2009, agreed to further extend maturity of this note to December 31, 2009.

On December 29, 2008, in connection with his agreement to extend the maturity dates of both the Langsam Notes to June 30, 2009, the Company granted Mr. Langsam 25,000 shares of the Company’s common stock. On August 13, 2009, in connection with the further extension of the maturity date of these notes from June 30, 2009 to December 31, 2009, the Company granted Mr. Langsam an additional 25,000 shares of the Company’s common stock.

During the year ended December 31, 2009 and 2008, the Company incurred interest expense, excluding amortization of debt discount, of \$68,862 and \$48,395, respectively, on the Langsam Notes. At December 31, 2009 and 2008, accrued interest on the Langsam Notes totaled \$0 and \$184,708, respectively. The Langsam Notes, principal balance of \$600,000 and accrued interest of \$184,708 was paid on December 15, 2009.

(b) Between February 28, 2008 and March 20, 2008, Catalysis Offshore, Ltd. and Catalysis Partners, LLC (collectively “Catalysis”), related parties, each loaned \$250,000 to the Company. As consideration for the loans, the Company issued Catalysis promissory notes in the aggregate principal amount of \$500,000 (the “Catalysis Notes”). The Catalysis Notes accrued interest at the rate of 8% per annum and had maturity dates of May 31, 2008. The managing partner of Catalysis is Francis Capital Management, LLC (“Francis Capital”), an investment management firm. John Francis, a Director of the Company and President of Francis Capital, has voting and investment control over the securities held by Catalysis. Francis Capital, including shares directly held by Catalysis, beneficially owns approximately 3,200,000 shares of the Company’s common stock and warrants for purchase of 45,000 shares of the Company’s common stock. On January 29, 2009 the Catalysis Notes were converted into new notes as part of the Senior Secured Note and Warrant Purchase Agreement described below.

On January 29, 2009, the Company entered into a Senior Secured Note and Warrant Purchase Agreement, pursuant to which, the Company sold Senior Secured Promissory Notes (the “Senior Notes”) in the principal amount of \$2,550,000 and warrants to purchase 1,530,000 shares of the Company’s common stock (the “January Warrant”), to several accredited investors (the “January Investors”). The January Investors paid \$2,000,000 in cash and converted \$550,000 of existing debt and accrued interest on the Catalysis Notes into the Senior Notes. The Senior Notes accrued interest, which was compounded to principal quarterly in arrears, at 10% per annum, throughout the term of the Senior Notes, and unless earlier converted in a Financing Round, had a maturity date of January 29, 2011. During the year ended December 31, 2009 a total of \$177,984 was reclassified from accrued interest to principal on notes payable. The January Warrants have an exercise price of \$1.00 and expire on January 29, 2014. The Company recorded a debt discount in the amount of \$1,311,311 based on the estimated relative fair value allocated to the warrants.

On August 18, 2009 the Company converted approximately \$212,000 of existing Senior Notes and accrued interest owed to Arizona Bay Technology Ventures, LP into 246,189 shares of common stock at \$0.86 per share. The Company recognized a loss on extinguishment of debt in the amount of \$46,776.

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On December 15, 2009, the Company repaid the Senior Notes in the amount of \$2,569,384 including principal and accrued interest. The Company recognized a loss on extinguishment of debt in the amount of \$491,143 relating to the unamortized debt discount associated with the Senior Notes. In accordance with ASC 470-50, the remaining unamortized debt discount on related party debt of \$245,571 was recorded to additional paid in capital.

For the year ended December 31, 2009 the Company recognized \$574,636 in debt discount amortization. During the year ended December 31, 2009, the Company incurred interest expense of \$229,690 on the Senior Notes.

#### 10. ACCRUED LIABILITIES

Accrued liabilities at December 31, 2009 and 2008 are comprised of the following:

	2009	2008
Accrued interest	\$ —	\$ 236,605
Accrued lease liability	7,547	56,251
Accrued dividends on preferred stock	114,976	134,138
Accrued salaries	47,449	16,726
Accrued officer severance	—	268,413
Accrued director's fees	162,500	145,000
Contingent tax liability	740,726	701,046
Accrued commissions	13,200	—
Other	156,478	37,449
Total accrued liabilities	\$ 1,242,876	\$ 1,595,628

#### 11. DEFERRED REVENUE

Deferred revenue as of December 31, 2009 and 2008 consists of the following:

	2009	2008
Cardinal Health advance payment on purchase order	\$ 8,000,000	\$ —
Scanner reimbursement revenue	99,144	—
Total	\$ 8,099,144	\$ —

In November 2009, the Company renewed its distribution arrangement with Cardinal Health through the execution of a new Supply and Distribution Agreement on November 19, 2009. This new agreement has a five-year term and names Cardinal Health as the exclusive distributor in the United States, Puerto Rico and Canada of current products used in the Company's Safety-Sponge® System. In connection with the execution of the new supply and distribution agreement, Cardinal Health issued a \$10,000,000 purchase order for products used in the Company's Safety-Sponge® System, calling for deliveries over the 12-month period ending November 2010 and paid the Company \$8,000,000 upon execution of agreement as partial pre-payment for such products, and agreed to pay up to \$2,000,000 directly to the Company's supplier upon delivery of invoices for product delivered under the purchase order. As of December 31, 2009, no product covered by the \$10,000,000 purchase order had been delivered to Cardinal Health, and accordingly, the entire amount of the pre-payment received was recorded as deferred revenue.



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Prior to the third quarter of 2009, the Company's business model included the sale of its SurgiCounter™ scanners and related software used in the Company's Safety-Sponge® System to most hospitals that adopted its system. Beginning with the third quarter of 2009, the Company modified its business model and began to provide its SurgiCounter™ scanners and related software to all hospitals at no cost when they adopt its Safety-Sponge® System. Because the Company no longer engages in direct SurgiCounter™ scanner sales and generally anticipates only recognizing revenues associated with its SurgiCounter™ scanners in connection with reimbursement arrangements under the Company's agreement with Cardinal Health, the Company does not expect its SurgiCounter™ scanners to continue to represent a sizable source of revenues. Deferred scanner revenue associated with the reimbursement from Cardinal Health, will be recognized over the life of the specific hospital contract.

As of December 31, 2009, there was no deferred revenue associated with maintenance agreements.

## 12. EQUITY TRANSACTIONS

### Series A Preferred Stock

The Series A preferred stock has a cumulative 7% 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. In the event the Company subdivides its outstanding shares of common stock into a greater number of shares of common stock the conversion price in effect would be reduced, thereby increasing the total number of shares of common stock that the convertible preferred stock is convertible into. At any time until February 22, 2010, the holder had the right to convert the shares of convertible preferred stock into the Company's common stock. 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. At any time on or after February 22, 2003, 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 Company incurred \$76,650 in Series A Preferred Stock dividend expense for the years ended December 31, 2009 and 2008.

### Common Stock

In May 2008 the Company entered into a subscription agreement with several accredited investors in a private placement exempt from the registration requirements of the Securities Act. The Company issued and sold to these accredited investors an aggregate of 2,100,000 shares of its common stock and warrants to purchase an additional 1,300,000 shares of its common stock. The warrants are exercisable for a period of five years, have an exercise price equal to \$1.40. These issuances resulted in aggregate gross proceeds to the Company of approximately \$2,200,000 and the extinguishment of approximately \$426,000 in existing debt. The Company used the net proceeds from this private placement transaction primarily for general corporate purposes and repayment of existing liabilities.

Between April 2008 and June 2008, the Company issued approximately 1,700,000 warrants to officers, directors and consultants of the Company. The warrants were issued in place of prior issuances of stock options with exercise prices well above market price that were cancelled. The exercise prices of the warrants were \$1.25 and \$1.75 and vested over four years. During this same time period, approximately 263,000 warrants were issued to directors and

consultants with an exercise price of \$1.25 and \$1.75 that vested upon grant. The Company recognized \$195,416 and \$713,384 in stock-based compensation warrant expense for the year ended December 31, 2009 and 2008, respectively.

On July 31, 2008, the Company issued 153,000 shares of its common stock to Ault Glazer. The shares were issued in satisfaction of unpaid accrued interest of approximately \$103,000 due on the senior secured promissory note held by Ault Glazer and prepaid interest of approximately \$128,000. The accrued interest paid, which was in default, was converted into shares of the Company's common stock at a conversion price of \$1.50 per share. (See Note 9).

On August 1, 2008 the Company entered into a subscription agreement with several accredited investors in a private placement exempt from the registration requirements of the Securities Act. The Company issued and sold to these accredited investors an aggregate of 2,000,000 shares of its common stock and warrants to purchase an additional 1,200,000 shares of its common stock. The warrants are exercisable for a period of five years, have an exercise price equal to \$1.40. These issuances resulted in aggregate gross proceeds to the Company of approximately \$2,400,000 million and \$83,000 in debt extinguishment which included \$50,000 paid in common stock and \$37,000 was forgiven. The Company used the net proceeds from this private placement transaction primarily for general corporate purposes and repayment of existing liabilities.

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Between September 12, 2008 and November 6, 2008 the Company issued 800,000 shares of common stock to Ault Glazer. The shares were issued in partial satisfaction of the convertible secured note held by Ault Glazer. The issuance of the Company's common stock reduced the principal balance of the note. (See Note 9).

On December 29, 2008, in connection with his agreement to extend the maturity dates of both the Langsam Notes to June 30, 2009, the Company granted Mr. Langsam 25,000 shares of the Company's common stock. On August 13, 2009, in connection with the further extension of the maturity date of these notes from June 30, 2009 to December 31, 2009, the Company granted Mr. Langsam an additional 25,000 shares of the Company's common stock.

On January 2, 2009, the Company issued 2,576,326 million warrants to purchase shares of the Company's common stock to warrant holders, pursuant to the anti-dilution clauses in their original warrants. The warrants are exercisable through the term of the original warrant and have an exercise price of \$0.75.

On January 29, 2009, the Company entered into a Senior Secured Note and Warrant Purchase Agreement, pursuant to which, the Company sold Senior Notes in the principal amount of \$2,550,000 and January Warrants to purchase 1,530,000 shares of the Company's common stock to the January Investors in consideration for \$2,000,000 in cash proceeds and conversion of \$550,000 owed under existing promissory notes. The January Warrants have an exercise price of \$1.00 and expire on January 29, 2014. (See Note 12).

On July 29, 2009, the Company completed the first closing of a private placement of its common stock. The shares were issued and sold to accredited investors who were holders of common stock warrants of the Company. The shares of common stock were issued at a per share price of \$0.86, paid by cancellation of the common stock warrants held by these holders, and in some cases an additional cash contribution by the holders. Holders not making cash investment tendered warrants to purchase 1,774,994 million shares of common stock and received 597,190 shares of the Company's common stock. Holders who elected to make cash investment tendered warrants to purchase 4,780,990 shares of common stock and \$1,511,727 in cash, and received 4,780,990 shares of the Company's common stock. The exchange resulted in a recognized net gain of \$163,377.

On September 18, 2009, the Company completed the second and final closing of a private placement of its common stock. The shares were issued and sold to accredited investors who were holders of common stock warrants of the Company. The shares of common stock were issued at a per share price of \$0.86, paid by cancellation of the common stock warrants held by these holders, and in some cases an additional cash contribution by the holders. Holders not making cash investment tendered warrants to purchase 59,460 shares of common stock and received 20,383 shares of the Company's common stock. Holders who elected to make cash investment tendered warrants to purchase 566,571 shares of common stock and \$194,691 in cash, and received 567,571 shares of the Company's common stock. The exchange resulted in a recognized net gain of \$849.

For the warrants classified in equity prior to the exchange, the Company accounted for the warrants cancelled as an exchange of warrants for common shares, whereby the repurchase price of the warrants was considered to be the fair value of the common shares issued in the exchange, less any cash received by the Company from the warrant holders. Under this treatment, the fair value of the warrant exchanged was estimated at the date of the exchange based on the original terms of the warrant and was compared to the repurchase price, and additional expense was recognized by the Company to the extent that the repurchase price exceeded the fair value of the warrant prior to the exchange.

For the warrants classified as derivative liabilities prior to the exchange, the Company accounted for the warrants exchanged as an issuance of common shares to extinguish a liability, and as such, the difference between the



reacquisition price and the net carrying amount of the debt was recognized in earnings in the period of extinguishment. The Company determined that the value of the common stock issued was more clearly evident than the value of the debt, and therefore should be used in the determination of the reacquisition price. In exchanges of warrants classified as derivative liabilities, whereby the Company also receives cash from the warrant holder as part of the exchange, the amount of cash received was netted against the value of the common shares issued to determine the reacquisition price. Warrants classified as derivative liabilities prior to the exchange were adjusted to the then current fair value on the date of the exchange, and the change in fair value was recognized through earnings. The adjusted fair value was used in the exchange transaction to determine the gain or loss.

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### 13. WARRANTS AND WARRANT DERIVATIVE LIABILITY

The following table summarizes warrants to purchase common stock activity for the two years ended December 31, 2009:

	Amount	Range of Exercise Price
Warrants outstanding December 31, 2007	6,114,521	\$ 1.25 - 6.05
Issued	4,617,875	\$ 1.40 - 2.00
Cancelled/Expired	(12,500)	\$ 3.55
Warrants outstanding December 31, 2008	10,719,896	\$ 1.25 - 6.05
Issued	5,996,326	\$ 0.75 - 4.00
Cancelled/Expired	(8,651,244)	\$ 0.75 - 5.95
Warrants outstanding December 31, 2009	8,064,978	\$ 0.75 - 6.05

At December 31, 2009, stock purchase warrants will expire as follows:

	# of Warrants	Range of Exercise Price
2010	337,000	\$ 2.00 - 6.05
2011	2,301,419	\$ 0.75 - 4.50*
2012	818,000	\$ 2.00
2013	1,786,267	\$ 0.75 - 1.40*
2014	1,890,000	\$ 1.82 - 4.00
2015	932,292	\$ 1.25
Total	8,064,978	\$ 0.75 - 6.05

\* Included are certain warrants which contain antidilution rights if the Company grants or issues securities for less than exercise price.

#### Warrants

On January 2, 2009, the Company issued 2,576,326 million warrants to purchase shares of the Company's common stock to warrant holders, pursuant to the anti-dilution clauses in their original warrants. The warrants are exercisable through the term of the original warrant and have an exercise price of \$0.75. This resulted in a one-time expense of \$1,324,075.

In connection with the January Warrants, the Company issued 1,530,000 warrants to purchase the Company's common stock. The January Warrants have an exercise price of \$1.00 and expire on January 29, 2014. The Company recorded a debt discount in the amount of \$1,311,311 based on the estimated relative fair value allocated to the warrants.

On November 17, 2009, the Company issued 15,000 warrants to Tatum Partners, LLP in connections with services provided by Mary A. Lay, the former Interim Chief Financial Officer. This resulted in a one-time expense of \$20,633.

On November 19, 2009, in connection with the execution of a new supply and distribution agreement with Cardinal Health (see “Business—Customers and Distribution—Cardinal Health – Exclusive U.S. Distributor,” above), the Company issued Cardinal Health warrants to purchase 1,250,000 shares of its common stock at \$2 per share and 625,000 shares of its common stock at \$4 per share pursuant to a Warrant Purchase Agreement dated effective November 19, 2009. This resulted in a one-time expense of \$2,407,813.

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Warrant Derivative Liability

As of December 31, 2008, warrants to purchase a total of 5,339,172 shares, with an estimated fair value of \$1,761,878 were recorded as a warrant derivative liability due to a lack of sufficient authorized shares outstanding based on the Company's evaluation of criteria under FASB guidance as codified in ASC 815-40, Derivatives and Hedging (previously EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock).

During 2009, an additional 6,938,082 warrants with a value of \$4,240,000 were reclassified from additional paid in capital to liability in accordance with ASC 815-40. On August 6, 2009, the shareholders voted to approve a proposal to increase the total number of authorized shares from 25,000,000 to 100,000,000 shares of common stock and the Company amended its articles of incorporation reflecting the increase. As such, in accordance with ASC 815-40, certain warrants previously classified as liabilities due to a lack of sufficient authorized shares outstanding were reclassified to equity at fair value on the date of the increase in authorized shares of common stock. A total of 2,853,577 warrants with a fair value of \$2,152,940 were reclassified from liability to additional paid in capital.

Effective January 1, 2009, upon the adoption of guidance codified in FASB ASC 815-40, Derivatives and Hedging (previously EITF 07-5, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock), the Company reclassified approximately 1,200,000 outstanding warrants that were previously classified as equity to a derivative liability. This reclassification was necessary as the Company determined that certain terms included in these warrant agreements provided for a possible future adjustment to the warrant exercise price, and accordingly, under the provisions of ASC 815-40, these warrants did not meet the criteria for being considered to be indexed to the Company's stock. As such, these warrants no longer qualified for the exception to derivative liability treatment provided for in ASC 815-10. The estimated fair value of the warrants reclassified at January 1, 2009 pursuant to ASC 815-40 was determined to be \$707,720. The cumulative effect of the change in accounting for these warrants of \$875,123 was recognized as an adjustment to the opening balance of accumulated deficit at January 1, 2009 based on the difference between the amounts recognized in the consolidated balance sheet before the initial adoption of ASC 815-40 and the amounts recognized in the consolidated balance sheet as a result of the initial application of ASC 815-40. The amounts recognized in the consolidated balance sheet as a result of the initial application of ASC 815-40 on January 1, 2009 were determined based on the amounts that would have been recognized if ASC 815-40 had been applied from the issuance date of the warrants.

At December 31, 2009, warrants to purchase a total of 2,567,686, with an estimated fair value of \$3,666,336, are included in liabilities in the accompanying balance sheet. Based on the change in fair value of the warrant derivative liability, the Company recorded a non-cash loss of \$5,564,125 for the year ended December 31, 2009.

#### 14. FAIR VALUE MEASUREMENTS

##### Fair Value Hierarchy

The Company adopted the fair value measurement and disclosure requirements of FASB guidance as codified in ASC 820 (previously SFAS No. 157, Fair Value Measurements) 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 generally accepted accounting principles 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.

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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.

#### Financial Instruments Measured at Fair Value on a Recurring Basis

ASC 820 requires disclosure of the level within the fair value hierarchy used by the Company to value financial assets and liabilities that are measured at fair value on a recurring basis. At December 31, 2009, the Company had outstanding warrants to purchase common shares of its stock that are classified as warrant derivative liabilities with a fair value of \$3,666,336. The warrants are valued using Level 3 inputs because there are significant unobservable inputs associated with them.

The table below sets forth a summary of changes in the fair value of the Company's Level 3 assets and liabilities for the year ended December 31, 2009:

	January 1, 2009	Transfers into Level 3	Transfers from Level 3	Net realized losses included in earnings	December 31, 2009
Warrant derivative liability	\$ (2,469,598)	\$ (3,532,780)	\$ 7,900,167	\$ (5,564,125)	\$ (3,666,336)

The balance as of January 1, 2009 includes the initial reclassification of warrants based on the adoption of ASC 815-40 in the amount of \$707,720 (see Note 3 and 13). Losses included in earnings for the period ended December 31, 2009, are reported in other income/expense in the amount of \$5,564,125.

#### 15. STOCK OPTION PLANS

In September 2005, the Board of Directors of the Company approved the Amended and Restated 2005 Stock Option and Restricted Stock Plan (the "2005 SOP") and the Company's stockholders approved the 2005 SOP in November 2005. 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.

On March 11, 2009, the Board of Directors of the Company approved the 2009 Stock Option Plan (the "2009 SOP") and the Company's stockholders approved the 2009 SOP August 6, 2009. The 2009 SOP reserves 3,000,000 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 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.

All options that the Company granted during the year ended December 31, 2009 and 2008 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:

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	Year Ended December 31,	
	2009	2008
Weighted average risk free interest rate	2.37%	3.5%
Weighted average life (in years)	6.0 years	5 years
Volatility	141%	106%
Expected dividend yield	0%	0%
Weighted average grant-date fair value per share of options granted	\$ 0.88	\$ 0.93

A summary of stock option activity for the year ended December 31, 2009 is 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, 2007	1,650,000	\$ 3.49	8.43	\$ —
Options Granted	745,000	\$ 1.53	9.76	
Exercised	—	\$ —	—	
Forfeited	—	\$ —	—	
Cancelled	(768,000)	\$ 4.59	8.25	
Balance at December 31, 2008	1,627,000	\$ 2.40	8.44	\$ —
Options Granted (2)	6,392,500	\$ 0.96	9.31	
Exercised	(21,868)	\$ 1.25	8.45	
Forfeited	(15,000)	\$ 4.30		
Cancelled	(2,161,632)	\$ 0.81		
Balance at December 31, 2009	5,821,000	\$ 1.41	8.96	\$ 4,301,385
Vested and exercisable as of December 31, 2009	2,314,490	\$ 1.88	8.28	\$ 1,478,390
Unvested as of December 31, 2009	3,506,510	\$ 1.09	9.40	\$ 2,822,995