Patient Safety Technologies, Inc
Form 10-K/A
July 13, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A
(Amendment No. 2)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER: 001-09727

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

Delaware	13-3419202
(State of Incorporation)	(I.R.S. Employer Identification Number)

43460 Ridge Park Drive, Suite 140, Temecula, CA 92591
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (951) 587-6201

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 x .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ¨

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 past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨ .

Indicate by check mark, 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller Reporting Company x

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock as reported on the OTC.BB on June 30, 2008 was approximately $18.5 million.

The number of outstanding shares of the registrant's common stock, par value $0.33 per share, as of March 31, 2009 was 17,197,872.

EXPLANATORY NOTE

This Amendment No. 2 on Form 10-K/A, or the "Amendment", amends the Patient Safety Technologies, Inc. (the "Company") Annual report on Form 10-K for the fiscal year ended December 31, 2008 originally filed on April 16, 2009 (the "Original Filing") as amended by Amendment No. 1 on Form 10-K/A filed on May 1, 2009 ("Amendment No. 1"). The purposes of this Amendment are:

- To reflect the revised report of the Company's independent registered public accounting firm, originally dated April 15, 2009, (the "Audit Report"), included in Item 8 of the Original Filing which now includes an explanatory paragraph with respect to the previously reported restatement of the Company's December 31, 2007 consolidated financial statements and certain December 31, 2006 account balances;

- To amend Part III to include the updated information now contained in our definitive proxy statement on Schedule 14A relating to the Company's 2009 annual meeting of stockholders.

Neither the revision of the Audit Report nor any of the other revisions has had an impact on, or reflected any changes to, any of the financial statements or related note disclosures included in the Original Filing as amended by Amendment No. 1. Except as described above, no other changes have been made to the Original Filing as amended by Amendment No. 1. The Original Filing continues to speak as of the dates described in the Original Filing, and we have not updated the disclosures contained therein to reflect any events that occurred subsequent to such dates. Accordingly, the Amendment should be read in conjunction with our filings made with the Securities and Exchange Commission subsequent to April 16, 2009, as information in such filings may update or supersede certain information contained in this amendment. In this Amendment unless the context indicates otherwise, the terms "we", "us", and "our" refer to Patient Safety Technologies, Inc. and our subsidiary.

PATIENT SAFETY TECHNOLOGIES, INC.

FORM 10-K FOR THE FISCAL YEAR
ENDED DECEMBER 31, 2008

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Forward-looking Statements

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations", contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933 and the Securities Exchange Act of 1934. These statements are based on current expectations, estimates, forecasts and projections about the industries in which we operate and the beliefs and assumptions of our management. We use words such as "anticipate", "believe", "continue", "could", "estimate", "expect", "goal", "intend", "may", "plan", "project", "see", "should", "target", "will", "would" and varia and similar expressions to identify forward-looking statements. In addition, statements that refer to projections of earnings, revenue, costs or other financial items; anticipated growth and trends in our business or key markets; future growth and revenue from our products; future economic conditions and performance; anticipated performance of products or services; plans, objectives and strategies for future operations; and other characterizations of future events or circumstances, are forward-looking statements. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict, including those identified under the heading "Risk Factors" in Item 1A, elsewhere in this report and our other filings with the SEC. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

PART I

ITEM 1. BUSINESS

Company Overview

Organizational History

Patient Safety Technologies, Inc. (referred to in this report as the "Company," "we," "us," and "our") (formerly known as Franklin Capital Corporation) is a Delaware corporation. Currently we conduct out operations through a single wholly-owned operating subsidiary: SurgiCount Medical, Inc. ("SurgiCount"), a California corporation.

The Company was incorporated on March 31, 1987, under the laws of the state of Delaware. Beginning in July 1987 until March 31, 2005 we operated as an investment company registered pursuant to the Investment Company Act of 1940, as amended (the "1940 Act"). From July 2005 through August 2007, the Company's wholly-owned subsidiary, Automotive Services Group, Inc., a Delaware corporation, held the Company's investment in Automotive Services Group, LLC ("ASG"), its wholly-owned express car wash subsidiary. During 2007, all assets of Automotive Services Group, Inc. were sold.

SurgiCount Medical, Inc., developer of the Safety-Sponge™ System, was acquired in 2005 to focus our efforts in the medical patient safety markets.

SurgiCount

SurgiCount's Safety-Sponge System is designed to reduce the number of retained sponges and towels unintentionally left in patients during surgical procedures by allowing faster and more accurate counting of surgical sponges and towels. The SurgiCount Safety-SpongeSystem is a patented turn-key line of modified surgical sponges, SurgiCounter™ scanners, and software file and database elements integrated to form a comprehensive counting and documentation system. Our business model consists of selling our unique surgical sponge products and selling or renting the scanners and software to hospitals. We use an exclusive supplier to manufacture our sponge products and we sell through a direct sales force for initial hospital conversions and through distributor organizations for the ongoing

supply of sponge products to customers.

The Safety-Sponge System works much like a grocery store checkout process: Every surgical sponge and towel is affixed with a unique inseparable two-dimensional data matrix bar code and used with a SurgiCounter scanner to scan and record the sponges at the initial and final counts during a surgical procedure. Because each sponge is identified with a unique code, a SurgiCounter will not allow the same sponge to be counted more than one time. When counts have been completed at the end of a procedure, the system stores a documented electronic record of all sponges used and removed and can output recordsto a hospitalelectronic records system. The Safety-Sponge System is the first FDA 510k approved computer assisted sponge counting system.

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Healthcare Patient Safety Industry

We believe that the healthcare delivery system is highly receptive to cost-effective medical solutions which can quickly lower costs, reduce liability and eliminate preventable errors. Increased litigation and a renewed focus on patient safety by regulators is spurring demand for medical device solutions.

The medical community recognizes the importance of improving patient safety, not only to enhance the quality of care, but also to help manage medical costs and related litigation costs. We believe that healthcare professionals will embrace solutions like the SurgiCount system that both reduce costs and eliminate medical errors.

We are dedicated to leading this effort through the development and introduction of the patented Safety-Sponge™ System, which we believe will allow us to capture a significant portion of United States surgical sponge sales. In addition, we believe that our Safety-Sponge™ System could save over $750 million annually in retained sponge litigation and other costs. The estimated size of the surgical sponge market and actual savings derived from utilizing the Safety-Sponge™ System from retained sponge litigation is based on management’s estimates and assumptions made by management.

Customers and Distribution

We currently target our sales to hospitals in the US that perform surgery in multiple operating rooms, OB/GYN departments and other surgical locations. Our sales process typically involves multiple stakeholders in a hospital institution. Representatives from OR management, risk management, surgeons, medical and nursing officers, and financial management evaluate the economics and effectiveness of our system. We typically will also conduct a product validation event in which a subset of hospital clinicians are trained and use the system on a suitable number of cases to understand the functionality and integration requirements to adopt use of the SurgiCount system hospital wide. Assuming a positive outcome of the validation event, the entire hospital OR staff must then be trained to use the system prior to the hospitalwide adoption. We currently estimate that the validation process within prospect institutions ranges between two to six months before a final decision is made to implement our Safety-SpongeSystem.

On November 14, 2006, SurgiCount entered into a Supply Agreement withCardinal Health, Inc. ("Cardinal"). Pursuant to the agreement, Cardinal became the exclusive distributor of SurgiCount's products in the United States, with the exception that SurgiCount may sell its products to one other specified hospital supply company, solely for its sale/distribution to its hospital customers. Under the agreement, SurgiCount agrees to maintaina specified fill rate on all orders for products. The term of the agreement is36 months, ending November 14, 2009 unless earlier terminated as set forth therein. Otherwise, theagreement automatically renews for successive 12 month periods.

SurgiCount may not assign its interest under the agreement without Cardinal's prior written consent. Further as part of the agreement, SurgiCount executed a Continuing Guaranty agreeing, among other things, to indemnify Cardinal for any loss or claim a) for property damage on account of any SurgiCount product except as may be caused by gross negligence or reckless disregard on the part of Cardinal or any of its employees, and b) arising on account of any infringement by any SurgiCount product of any patent, trademark or other proprietary right of any other party

In addition, the agreement provides that if we decide to divest, spin-off or otherwise sell SurgiCount or any material assets of SurgiCount (such as intellectual property) during the term of the agreement, Cardinal shall have a right of first refusal to purchase SurgiCount.

Product Development

SurgiCount received confirmation from the U.S. Food and Drug Administration ("FDA") that the modification to surgical sponges required by the Safety-Spongeline did not warrant a new product listing. In March 2006, the Company received 510(k) clearance to market and sell its patented Safety-Sponge™ System. The Safety-SpongeSystem is the first computer-assisted sponge counting system cleared by the FDA.

We use third party developers to create, document and test our proprietary software that operates in the SurgiCounter scanners and interfaces with our custom Citadel™ desktop application. The scanner software controls the individual procedure with easy -to-learn and easy-to-use touch screen or bar code driven menu items. The Citadel database software typically resides on a PC environment and consolidates individual case data from the scanner software in a central database for departmental statistics, documented outcomes records and output to patient electronic records systems.

We also seek qualified input from professionals in the healthcare profession as well as University hospitals to guide us in the definition, development and testing our products. We meet on an as needed basis to discuss medical, technology and development issues. Through direct contracts and sponsorship of studies, recommendations from these professionals have improved various aspects of the Safety-SpongeSystem. Examples where recommendations were utilized include: the ideal location for labels, label coarseness and thickness, improved operating room procedures, label structure and scanner functionality.

In 2005, we entered into a clinical trial agreement with Brigham and Women's Hospital, the teaching affiliate of Harvard Medical School, relating to SurgiCount's Safety-Sponge TM System. Under terms of the agreement, Brigham and Women's Hospital collected data on how the 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 hospitalson techniques to easily integrate the Safety-SpongeSystem into operating room protocols. Brigham and Women's Hospital received a non-exclusive license to use the Safety-SpongeSystem, while we will own all technical innovations and other intellectual properties derived from the study. We provided a research grant to Brigham and Women's Hospital over the course of the clinical trial in the aggregate amount of $431thousand. The final amount due under the terms of the clinical trial agreement, of $68thousand, was paid in February 2008.

Researchers at Brigham and Women's Hospital have found that using bar-code technology to augment the counting of surgical sponges during an operative procedure increases 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 and instruments, resulting in the surgical team believing that all the sponges are accounted for. In this study, researchers compared the traditional counting protocol with or without augmentation by the bar-code technology in 300 general surgery operations. The researchers found that our technology can substantially reduce the incidence of retained surgical sponges at a materially lower cost than the legal/medical costs of retained events.

Manufacturing

SurgiCount entered into an agreement on August 17, 2005 for A Plus International, Inc., a major supplier of surgical sponge products to be the exclusive manufacturer and provider of the Safety-Sponge™ products, which includes bar coded gauze sponges, bar coded laparotomy sponges, bar coded O.R. towels and bar coded specialty sponges. Services to be provided by A Plus include manufacturing, packaging, sterilization, logistics and all related quality and regulatory compliance.During the term of the agreement, A Plus agreed not to manufacture, distribute or otherwise supply any bar coded sponges for any third party. While we believe the manufacturing capacity of A Plus will be sufficient to meet our expected demand, in the event A Plus cannot meet our requirements the agreement allows us to retain additional providers of the Safety-Sponge™ products.

On January 29, 2007, we entered into a successor agreement with A-Plus, titled"Exclusive License and Supply Agreement"(the "Supply Agreement"). Pursuant to the Supply Agreement, A Plus was granted the exclusive, world-wide license to manufacture and import SurgiCount's products, including the right to sublicense to the extent necessary to carry out the grant. The pricing schedule shall remain at its current price for the first three (3) years of the Supply Agreement; thereafter, the pricing schedule shall be based upon the Cotlook Index and the RMB exchange rate. The term of Supply Agreement is eight years.

In conjunction with entering into the Supply Agreement on January 29, 2007, the Company entered into a subscription agreement with A Plus, pursuant to which the Company sold to A Plus 800 thousand shares of its common stock and warrants to purchase an additional 300 thousand shares of its common stock. The Company received gross proceeds of $500 thousand in cash and a $500 thousand deposit against future shipments. The deposit was fully utilized at December 31, 2007. The warrants have a term of five (5) years and an exercise price equal to $2.00 per share.

Research and Development

Research and development activities are important to our business. We use contract firms with suitable expertise for much of the research and development activities related to improving our existing products or expanding our intellectual property to similar products. We incurred costs of $271 thousand and $133 thousand, respectively during the fiscal years ended December 31, 2008 and 2007 relating to the development of new products, the improvement of existing products, technical support of products and compliance with governmental regulations.

Patents and Trademarks

Our patents and trademarks are protected by registration in the United States and other countries where our products are marketed.

We currently own patents issued in the United States and Europe related to the Safety-SpongeSystem. This is covered by patent #5,931,824 registered with the United States Patent and Trademark Office and patent #1 032 911 B1 registered with the European Patent Office, which permits the holder to label or identify a dressing with a unique identifier. Patent #5,931,824 and #1 032 911 B1 will expire in August of 2019 and March of 2017, respectively. U.S Patent #5,931,824 recently underwent a reexamination proceeding in the U.S. Patent Office. During 2007, the U. S. Patent Office granted a reexamination certificate affirming the validity of the reexamined patent with certain amendments to the claims.

Competition

There are two known companies that compete with SurgiCount's Safety-Sponge System: RF Surgical and ClearCount Medical, providing products usingradio frequency identification ("RF") technology to identify surgical sponges with RF chips embedded.

Regulation of the Medical Products and Healthcare Industry

The FDA administers the Food, Drug and Cosmetics Act (the "FDC Act"). Under the FDC Act, most medical devices must receive FDA clearance through the Section 510(k) notification process ("510(k)") or the more lengthy premarket approval ("PMA") process before they can be sold in the United States. Class I and II devices also have subsets of "exempt devices" which are exempt from the PMA approval requirement subject to certain limitations. 21 CFR 878.4450 ("Gauze/Sponge, Internal, X-Ray Detectable") is the defined device group of the Safety-Sponge line of products. This defined device group is specifically denoted as "exempt" from the premarket notification process. SurgiCount submitted specific information on its Safety-Sponge product directly to the CDRH and received confirmation of the 510(k) exempt status of this line of products.

FDA's quality system regulations also require companies to adhere to certain 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. 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.

The regulatory agencies under whose purview we operate have administrative powers that may subject us to such actions as product recalls, seizure of products and other civil and criminal sanctions. In some cases we may deem it advisable to initiate product recalls voluntarily. 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.

In addition, sales and marketing practices in the health care industry have come under increased scrutiny by government agencies and state attorney generals and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

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 the Company and our operations.

Investments

Our investment portfolio, also known as our non-core assets, as of December 31, 2008 and 2007, is valued at $667 thousand and is composed of our investment in Alacra Corporation.

Alacra Corporation

At December 31, 2008 and 2007, we had an investment in Alacra Corporation ("Alacra"), valued at $667 thousand, which represents 8.4% and 8.2% of our total assets at December 31, 2008 and 2007, respectively. On April 20, 2000, we purchased $1.0 million worth of Alacra Series F Convertible Preferred Stock. We have the right, subject to Alacra having the available cash, to have the preferred stock redeemed by Alacra over a period of three years for face value plus accrued dividends beginning on December 31, 2006. Pursuant to this right, in December 2006 we informed management of Alacra that we were exercising our right to put back one-third of our preferred stock. Alacra completed the initial redemption of one-third of our preferred stock in December 2007. We received proceeds of $333 thousandfrom this redemption, which accounted for the entire amount of the decrease in value of our Alacra investment in December 2007. We continue to exercise our right to put back our remaining preferred stock to Alacra. In December 2008,Alacra informed the Company that their Board of Directors had authorized the preferred stock redemption for the second one-third of our preferred stock and that they expected the redemption to occur in the second or third quarter of 2009. As there is no readily determinable fair value of the Alacra Series F Convertible Preferred Stock, we account for this investment under the cost method.

Real Estate Investments

In 2008, we disposed of all investments in real estate by completing the sale of the undeveloped land in Springfield, Tennessee for net proceeds of $91 thousand, which resulted in a realized loss of $91 thousand. In March 2008, we completed the sale of the undeveloped land in Heber Springs for net proceeds of $226 thousand.

Code of Business Conduct and Ethics

Each executive officer and director as well as every employee of the Company is subject to the Company's Code of Business Conduct and Ethics (the "Code of Ethics") which was adopted by the Board of Directors on November 11, 2004 and is filed as Appendix D to the definitive proxy materials filed with the SEC on March 2, 2005. The Code of Ethics applies to all directors, officers and certain employees of the Company, including the chief executive officer, chief financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Ethics may be obtained, without charge, upon a written request mailed to: Patient Safety Technologies, Inc., c/o Corporate Secretary, 43460 Ridge Park Drive, Suite 140, Temecula, CA 92590.

Available Information

Copies of our quarterly reports on Form 10-Q, annual reports on Form 10-K and current reports on Form 8-K, and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to the Corporate Secretary, Patient Safety Technologies, Inc., 46430 Ridge Park Drive, Suite 140, Temecula, CA 92590 or by calling (951) 587-6201. You may also obtain the documents filed by Patient Safety Technologies, Inc. with the SEC for free at the Internet website maintained by the SEC at www.sec.gov. The Company does not currently make these documents available on its website.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. Before you invest in our securities you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Each of the following risks may materially and adversely affect our business, results of operations and financial condition. These risks may cause the market price of our common stock to decline, which may cause you to lose all or a part of the money you paid to buy our securities. We provide the following cautionary discussion of risks, uncertainties and possible inaccurate assumptions relevant to our business and our products. These are factors that we think could cause

our actual results to differ materially from expected results.

Risks relating to our business and structure

We have just begun to generate sales from our safety-sponge system and the revenues have just now begun to represent a significant source of revenue for our Company.

During the years ended December 31, 2008 and 2007 sales from our Safety-Sponge System amounted to $2.8 million and $1.1 million, respectively. Our future success is dependent on our ability to develop our patient-safety related assets into a successful business, which depends upon wide-spread acceptance of and commercializing our Safety-Sponge System. None of these factors is demonstrated by our historic performance to date and there is no assurance we will be able to accomplish them in order to sustain our operations. As a result, you should not rely on our historical results of operations as an indication of the future performance of our business.

We intend to undertake additional financings to meet our growth, operating and/or capital needs, which may result in dilution to your ownership and voting rights.

We anticipate that revenue from our operations for the foreseeable future will not be sufficient to meet our growth, operating and/or capital requirements. We believe that in order to have the financial resources to meet our operating requirements for the next twelve months we will need to undertake additional equity or debt financings to allow us to meet our future growth, operating and/or capital requirements. We currently have no commitments for any such financings. Any equity financing may be dilutive to our stockholders, and debt financing, if available, may involve restrictive covenants or other adverse terms with respect to raising future capital and other financial and operational matters. We may not be able to obtain additional financing in sufficient amounts or on acceptable terms when needed, which could adversely affect our operating results and prospects. If we fail to arrange for sufficient capital in the future, we may be required to reduce the scope of our business activities until we can obtain adequate financing.

Failure to properly manage our potential growth would be detrimental to our business.

Any growth in our operations will place a significant strain on our resources and increase demands on our management and on our operational and administrative systems, controls and other resources. There can be no assurance that our existing personnel, systems, procedures or controls 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. As part of this growth, we may have to implement new operational and financial systems, procedures and controls to expand, train and manage our employee base and maintain close coordination among our technical, accounting, finance, marketing, and sales staffs. 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 staff and systems. We may fail to adequately manage our anticipated future growth. We will also need to continue to attract, retain and integrate personnel in all aspects of our operations. Failure to manage our growth effectively could hurt our business.

If the protection of our intellectual property rights is inadequate, our ability to compete successfully could be impaired.

We rely on a combination of patent, trademark and copyright law and trade secret protection to protect our proprietary rights. Nevertheless, the steps we take to protect our proprietary rights may be inadequate. Detection and elimination of unauthorized use of our products is difficult. We may not have the means, financial or otherwise, to prosecute infringing uses of our intellectual property by third parties. Further, effective patent, trademark, service mark, copyright and trade secret protection may not be available in every country in which we will sell our products and offer our services. If we are unable to protect or preserve the value of our patents, trademarks, copyrights, trade secrets or other proprietary rights for any reason, our business, operating results and financial condition could be harmed.

Litigation may be necessary in the future to enforce our intellectual property rights, to protect our trade secrets, to determine the validity and scope of the proprietary rights of others, or to defend against claims that our products infringe upon the proprietary rights of others or that proprietary rights that we claim are invalid. Litigation could result in substantial costs and diversion of resources and could harm our business, operating results and financial condition regardless of the outcome of the litigation.

Other parties may assert infringement or unfair competition claims against us. We cannot predict whether third parties will assert claims of infringement against us, or whether any future claims will prevent us from operating our business as planned. If we are forced to defend against third-party infringement claims, whether they are with or without merit or are determined in our favor, we could face expensive and time-consuming litigation, which could distract technical and management personnel. If an infringement claim is determined against us, we may be required to pay monetary damages or ongoing royalties. Further, as a result of infringement claims, we may be required, or deem it advisable, to

develop non-infringing intellectual property or enter into costly royalty or licensing agreements. Such royalty or licensing agreements, if required, may be unavailable on terms that are acceptable to us, or at all. If a third party successfully asserts an infringement claim against us and we are required to pay monetary damages or royalties or we are unable to develop suitable non-infringing alternatives or license the infringed or similar intellectual property on reasonable terms on a timely basis, it could significantly harm 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. InJanuary 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. Mr. Kane also serves as the Company’s Chairman of the Board. If we are not able to attain stability of our Chief Executive Officer position we may have difficulty implementing our business strategy.

Auditors’ opinion includes going concern explanatory paragraph.

The report of our independent registered public accounting firm dated April 15, 2009 for the years ended December 31, 2008 and 2007 includes a going concern explanatory paragraph which states that our significant operating losses and working capital deficit cause substantial doubt about the Company’s ability to continue as a going concern.

Risks related to our medical products and healthcare-related business

We rely on a third party manufacturer and supplier to manufacture our safety-sponge system, the loss of which may interrupt our operations.

On January 29, 2007, SurgiCount entered into an agreement for A Plus International Inc. to be the exclusive manufacturer and provider of SurgiCount's Safety-Sponge products and granted A Plus the exclusive, world-wide license to manufacture and import SurgiCount's products including the right to sublicense to the extent necessary to carry out the grant. While our relationship with A Plus International Inc. is currently on good terms, we cannot assure you that we will be able to maintain our relationship with A Plus International Inc. or secure additional suppliers and manufacturers on favorable terms as needed. Although we believe the raw materials used in the manufacture of the Safety-Sponge System are readily available and can be purchased and/or produced by multiple vendors, the loss of our agreement with A Plus International Inc., deterioration of our relationship with A Plus International Inc., changes in the specifications of components used in our products, or our failure to establish good relationships with major new suppliers or manufacturers as needed, could have a material adverse effect on our business, financial condition and results of operations.

The unpredictable product cycles of the medical device and healthcare-related industries and uncertain demand for products could cause our revenues to fluctuate.

Our target customer base includes hospitals, physicians, nurses and clinics. The medical device and healthcare-related industries are subject to rapid technological changes, short product life cycles, frequent new product introductions and evolving industry standards, as well as economic cycles. If the market for our products does not grow as rapidly as our management expects, our revenues could be less than expected. We also face the risk that changes in the medical device industry, for example, cost-cutting measures, changes to manufacturing techniques or production standards, could cause our manufacturing, design and engineering capabilities to lose widespread market acceptance. If our products do not gain market acceptance or suffer because of competing products, unfavorable regulatory actions, alternative treatment methods or cures, product recalls or liability claims, they will no longer have the need for our products and we may experience a decline in revenues. Adverse economic conditions affecting the medical device and healthcare-related industries, in general, or the market for our products in particular, could result in diminished sales, reduced profit margins and a disruption in our business.

We are subject to changes in the regulatory and economic environment in the healthcare industry, which could adversely affect our business.

The healthcare industry in the United States continues to experience change. In recent years, the United States Congress and state legislatures have introduced and debated various healthcare reform proposals. Federal, state and local government representatives will, in all likelihood, continue to review and assess alternative healthcare delivery systems and payment methodologies, and ongoing public debate of these issues is expected. Cost containment initiatives, market pressures and proposed changes in applicable laws and regulations may have a dramatic effect on pricing or potential demand for medical devices, the relative costs associated with doing business and the amount of reimbursement by both government and third-party payors to persons providing medical services. In particular, the healthcare industry is experiencing market-driven reforms from forces within the industry that are exerting pressure on healthcare companies to reduce healthcare costs. Managed care and other healthcare provider organizations have grown substantially in terms of the percentage of the population in the United States that receives medical benefits through such organizations and in terms of the influence and control that they are able to exert over an increasingly large portion of the healthcare industry. Managed care organizations are continuing to consolidate and grow, increasing the ability of these organizations to influence the practices and pricing involved in the purchase of medical devices, including our products, which is expected to exert downward pressure on product margins. Both short-and long-term cost containment pressures, as well as the possibility of continued regulatory reform, may have an adverse impact on our business, financial condition and operating results.

We are subject to government regulation in the United States and abroad, which can be time consuming and costly to our business.

Our products and operations are subject to extensive regulation by numerous governmental authorities, including, but not limited to, the FDA and state and foreign governmental authorities. In particular, we must obtain specific clearance or approval from the FDA before we can market new products or certain modified products in the United States. The FDA administers the Food, Drug and Cosmetics Act (the "FDC ACT"). Under the FDC Act, most medical devices must receive FDA clearance through the Section 510(k) notification process ("510(K)") or the more lengthy premarket approval ("PMA") process before they can be sold in the United States. The Safety-Sponge System has received 510(k) clearance to from the FDA. To obtain 510(k) marketing clearance, a company must show that a new product is "substantially equivalent" in terms of safety and effectiveness to a product already legally marketed. The process of obtaining such clearances or approvals can be time-consuming and expensive, and there can be no assurance that all clearances or approvals sought by us will be granted or that FDA review will not involve delays adversely affecting the marketing and sale of our products. FDA's quality system regulations also require companies to adhere to certain 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. In addition, we are required to comply with FDA requirements for labeling and promotion. The Federal Trade Commission also regulates most device advertising.

In addition, international regulatory bodies often establish varying regulations governing product testing and licensing standards, manufacturing compliance, such as compliance with ISO 9001 standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements and pricing and reimbursement levels. Our inability or failure to comply with the varying regulations or the imposition of new regulations could restrict our ability to sell our products internationally and thereby adversely affect our business, financial condition and operating results.

Failure to comply with applicable federal, state or foreign 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, any one or more of which could have a material adverse effect on our business, financial condition and operating results. Federal, state and foreign laws and regulations regarding the manufacture and sale of medical devices are subject to future changes, as are administrative interpretations of regulatory requirements. Any such changes may have a material adverse effect on our business, financial condition and operating results.

We are subject to intense competition in the medical products and health-care related markets, which could harm our business.

The medical products and healthcare solutions industry is highly competitive. We compete against other medical products and healthcare solutions companies, some of which are much larger and have significantly greater financial resources, management resources, research and development staffs, sales and marketing organizations and experience in the medical products and healthcare solutions industries than us. In addition, these companies compete with us to acquire technologies from universities and research laboratories. We also compete against large companies that seek to license medical products and healthcare solutions technologies for themselves. We cannot assure you that we will be able to successfully compete against these competitors in the acquisition, development, or commercialization of any medical products and healthcare solutions, funding of medical products and healthcare solutions companies or marketing of our products and solutions. If we cannot compete effectively against our competitors, our business, financial condition and results of operations may be materially adversely affected.

We may be subject to product liability claims and if our insurance is not sufficient to cover product liability claims our business and financial condition will be materially adversely affected.

The nature of our business exposes us to potential product liability risks, which are inherent in the distribution of medical equipment and healthcare products. We may not be able to avoid product liability exposure, since third parties develop and manufacture our equipment and products. If a product liability claim is successfully brought against us or any third party manufacturer then we would experience adverse consequences to our reputation, we might be required to pay damages, our insurance, legal and other expenses would increase, we might lose customers and/or suppliers and there may be other adverse results.

Through our subsidiary SurgiCount Medical, Inc. we have general liability insurance to cover claims up to $3,000,000. In addition, A Plus International, Inc., the manufacturer of our surgical sponges, maintains general liability insurance for claims up to $4,000,000. These general liability insurance policies cover product liability claims against SurgiCount Medical, Inc. There can be no assurance that one or more liability claims will not exceed the coverage limits of any of such policies. If we or our manufacturer are subjected to product liability claims, the result of such claims could harm our reputation and lead to less acceptance of our products in the healthcare products market. In addition, if our insurance or our manufacturer's insurance is not sufficient to cover product liability claims, our business and financial condition will be materially adversely affected.

Risks related to our investments

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

We have investments in illiquid equity securities acquired directly from issuers in private transactions. At December 31, 2008, 8.4% 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. In the event the value of the securities we hold are deemed impaired this could have a material impact on our financial condition. We review our investment in non-marketable securities on an annual basis for indicators of impairment, however, for non-marketable equity securities, the impairment analysis required significant judgment to identify events or circumstances that would likely have a material adverse effect on the fair value of the investment. Because such valuations are inherently uncertain and may be based on estimates, our determinations of fair value may differ materially from the values that would be assessed if a ready market for these securities existed. We account