Patient Safety Technologies, Inc Form 10-Q November 05, 2012

#### **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

OR

..

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_ TO \_\_\_\_

COMMISSION FILE NUMBER: 001-09727

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

Delaware
(State or other jurisdiction of incorporation or organization)

13-3419202 (I.R.S. Employer Identification No.)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No "

Indicate by check mark 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 " Accelerated filer "

filer

Non-accelerated " (Do not check if smaller Smaller Reporting x

filer reporting company) Company

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

The number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, as of October 30, 2012 was 36,998,489.

# PATIENT SAFETY TECHNOLOGIES, INC.

# FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2012

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. Our forward-looking statements relate to future events or our future performance and include, but are not limited to, statements concerning our business strategy, future commercial revenues, market growth, capital requirements, new product introductions, expansion plans and the adequacy of our funding. Other statements contained in this Report that are not historical facts are also forward-looking statements. You can sometimes identify forward-looking statements by our use of forward-looking words like "may," "will," "could," "should," "expects," "intends," "plans," "ant "believes," "estimates," "seeks," "predicts," "potential," or "continue" or the negative of these terms and other similar express and terminology.

We caution investors that any forward-looking statements presented in this Report, or that we may make orally or in writing from time to time, are based on the beliefs of, assumptions made by, and information currently available to us. Although we believe that the plans, objectives, expectations and intentions reflected in or suggested by our forward-looking statements are reasonable, those statements are based only on the current beliefs and assumptions of our management and on information currently available to us and, therefore, they involve uncertainties and risks as to what may happen in the future. Accordingly, we cannot guarantee that our plans, objectives, expectations or intentions will be achieved. Our actual results, performance (financial or operating) or achievements could differ from those expressed in or implied by any forward-looking statement in this Report as a result of many known and unknown factors, many of which are beyond our ability to predict or control, and those differences may be material. These factors include, but are not limited to, those described under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 26, 2012 and amended on April 30, 2012, including without limitation the following:

our ability to successfully implement hospitals under contract but not yet implemented;

the early stage of adoption of our Safety-Sponge® System and the need to expand adoption of our Safety-Sponge® System;

the impact on our future revenue and cash flow from the Forward Order (described herein) and ordering patterns of our exclusive distributor, Cardinal Health, Inc;

our need for additional financing to support our business;

our reliance on third-party manufacturers, some of whom are sole-source suppliers, and on our exclusive distributor;

any inability to successfully protect our intellectual property portfolio; and

the impact on our revenues and financial position from managing our growth, including the initial costs typically associated with hospital implementations.

This Report and all other written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in or referred to in this section.

Our forward-looking statements speak only as of the date they are made and should not be relied upon as representing our plans, objectives, expectations and intentions as of any subsequent date. Although we may elect to update or

revise forward-looking statements at some time in the future, we specifically disclaim any obligation to do so, even if our plans, objectives, expectations or intentions change.

## **HELPFUL INFORMATION**

As used throughout this Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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<sup>TM</sup> and SurgiCount360<sup>TM</sup>, among others, are registered or unregistered trademarks of Patient Safety Technologies, Inc. (including its subsidiary).

# PART I – FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS

# PATIENT SAFETY TECHNOLOGIES, INC. Condensed Consolidated Balance Sheets

	September 30, 2012 (Unaudited)	December 31, 2011
Assets	(Chadanea)	
Current assets:		
Cash and cash equivalents	\$ 5,454,408	\$ 3,668,524
Accounts receivable	1,653,263	1,307,510
Inventories, net	3,977,381	2,772,117
Prepaid expenses	81,752	180,802
Total current assets	11,166,804	7,928,953
Property and equipment, net	4,733,249	1,691,961
Goodwill	1,832,027	1,832,027
Patents, net	2,220,436	2,464,142
Other assets	37,462	40,463
Total assets	\$ 19,989,978	\$ 13,957,546
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,009,689	\$ 2,808,524
Accrued liabilities	602,402	574,917
Deferred revenue – current portion	821,766	278,002
Total current liabilities	6,433,857	3,661,443
Deferred revenue	1,085,040	267,025
Total liabilities	7,518,897	3,928,468
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$1.00 par value, 1,000,000 shares authorized:		
Series A preferred stock, \$1.00 par value, cumulative 7% dividend: 500,000 shares		
designated; 10,950 issued and outstanding at September 30, 2012 and December 31,		
2011; (Liquidation preference of \$1.1 million at September 30, 2012 and December		
31, 2011)	10,950	10,950
Series B convertible preferred stock, \$1.00 par value, cumulative 7% dividend:	,	,
150,000 shares designated; 69,257 issued and outstanding at September 30, 2012 and		
65,864 issued and outstanding at December 31, 2011; (Liquidation preference of \$6.9		
million at September 30, 2012 and \$6.6 million at December 31, 2011)	69,257	65,864
Common stock, \$0.0001 par value: 100,000,000 shares authorized; 36,998,489 shares	3,700	3,402
issued and outstanding at September 30, 2012 and 34,020,255 shares issued and		

outstanding at December 31, 2011		
Additional paid-in capital	73,804,378	68,957,072
Accumulated deficit	(61,417,204)	(59,008,210)
Total stockholders' equity	12,471,081	10,029,078
Total liabilities and stockholders' equity	\$ 19,989,978	\$ 13,957,546

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

# PATIENT SAFETY TECHNOLOGIES, INC. Condensed Consolidated Statements of Operations (Unaudited)

					Septem	onths Ended ember 30, 2011		
Davanuas	¢	4 072 476	Φ	2 196 220	¢.	12 479 210	Φ	6 725 646
Revenues Cost of revenue	Ф	4,972,476 2,704,140	Ф	2,186,220 1,190,879	Ф	12,478,210 7,118,019	Ф	6,725,646 3,528,110
Gross profit		2,764,140		995,341		5,360,191		3,197,536
Gioss pioni		2,200,330		))J,J+1		3,300,171		3,177,330
Operating expenses:								
Research and development		111,227		1,460		400,712		55,220
Sales and marketing		1,350,924		716,491		3,734,531		2,049,943
General and administrative		955,840		806,544		3,200,409		2,864,024
Total operating expenses		2,417,991		1,524,495		7,335,652		4,969,187
Operating loss		(149,655)		(529,154)		(1,975,461)		(1,771,651)
Other income (expense):								
Interest income (expense), net		672		347		3,756		(3,632)
Interest expense – related party		(35,926)		_	_	(35,926)		_
Gain on change in fair value of warrant derivative								
liability		_	_	303,222		_	_	527,844
Other income		_	_	_	_	_	-	227,617
Total other (expense) income		(35,254)		303,569		(32,170)		751,829
Loss before income taxes:		(184,909)		(225,585)		(2,007,631)		(1,019,822)
Income tax provision		(546)		(2,543)		(4,258)		(6,316)
Net loss		(185,455)		(228,128)		(2,011,889)		(1,026,138)
Preferred dividends		(134,215)		(125,498)		(397,105)		(374,954)
Net loss applicable to common shareholders	\$	(319,670)	\$	(353,626)	\$	(2,408,994)	\$	(1,401,092)
Loss per common share:								
Basic and Diluted	\$	(0.01)	\$	(0.01)	\$	(0.07)	\$	(0.05)
2 40.10 41.40 2 11.40 4	Ψ	(0.01)	Ψ	(0.01)	Ψ	(0.07)	Ψ	(0.05)
Weighted average common shares outstanding:								
Basic and Diluted		35,260,243		33,782,033		35,449,156		30,606,468

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

# PATIENT SAFETY TECHNOLOGIES, INC. Condensed Consolidated Statements of Cash Flows (Unaudited)

	Nine Mont Septem	
	2012	2011
Operating activities: Net loss	¢ (2 011 000)	¢ (1 026 129)
	\$ (2,011,889)	\$ (1,020,138)
Adjustments to reconcile net loss to net cash provided by (used) in operating activities: Depreciation	1,226,933	205 412
^		395,412 243,706
Amortization of patents Stock-based compensation	243,706 606,939	· · · · · · · · · · · · · · · · · · ·
Gain on reduction of contingent tax liability	000,939	512,953 - (223,524)
Gain on change in fair value of warrant derivative liability	_	- (223,324)
Changes in operating assets and liabilities:	_	- (327,044)
Transfer from restricted cash in connection with tax escrow account		- 223,630
Accounts receivable	(345,753)	(270,712)
Inventories	(1,205,263)	(566,268)
Prepaid expenses	99,051	50,198
Other assets	3,000	4,805
Accounts payable	2,201,165	(900,964)
Accrued liabilities	27,486	(282,971)
Deferred revenue	1,361,779	(1,147,411)
Net cash provided by (used in) operating activities	2,207,154	(3,515,128)
The cash provided by (asea in) operating activities	2,207,13	(3,313,123)
Investing activities:		
Purchase of property and equipment	(4,268,221)	(527,276)
Net cash used in investing activities	(4,268,221)	(527,276)
		, ,
Financing activities:		
Proceeds from issuance of common stock	3,499,997	7,112,500
Payments for common stock issuance costs	(65,240)	(325,241)
Payments of preferred stock series A dividends	(57,488)	(57,488)
Payments of convertible preferred stock series B dividends	(318)	(906)
Proceeds from exercise of stock options	470,000	375,000
Net cash provided by financing activities	3,846,951	7,103,865
Net increase in cash and cash equivalents	1,785,884	3,061,461
Cash and cash equivalents at beginning of period	3,668,524	1,896,034
Cash and cash equivalents at end of period	\$ 5,454,408	\$ 4,957,495
Supplemental disclosures of cash flow information:		
Cash paid during the period for taxes	\$ 4,258	\$ 6,316
Non cash investing and financing activities:		
Payment of Series B preferred dividends in preferred B shares	\$ 339,618	\$ 317,468
Issuance of common shares previously earned	\$ —	-\$ 26,674

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

Notes to Condensed Consolidated Interim Financial Statements (Unaudited)

#### 1. DESCRIPTION OF BUSINESS

Patient Safety Technologies, Inc. (the "Company", "us", "we") 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<sup>TM</sup> 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. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with the instructions to Form 10-Q and applicable sections of Regulation S-X and do not include all the information and disclosures required by accounting principles generally accepted in the United States of America. The condensed consolidated interim financial information is unaudited but reflects all normal adjustments that are, in the opinion of management, necessary to make the financial statements not misleading. The condensed consolidated balance sheet as of December 31, 2011 was derived from the Company's audited financial statements. The condensed consolidated interim financial statements should be read in conjunction with the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 (as amended). Results of the nine months ended September 30, 2012 are not necessarily indicative of the results to be expected for the twelve months ended December 31, 2012.

# Principles of Consolidation

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

#### Reclassifications

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

#### Use of Estimates

The condensed consolidated interim 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, 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.

Patient Safety Technologies, Inc. Notes to Condensed Consolidated Interim Financial Statements

## Revenue Recognition

Revenue related to surgical products is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectability is reasonably assured and risk of loss transfers, usually when products are shipped. Advanced payments are classified as deferred revenue and recognized as product is shipped to the customer. Reimbursements related to scanners and related equipment provided to hospitals are recognized on a straight-line basis over the expected term of the related customer contract, while the cost of the scanners and related equipment is carried in hardware equipment within property, plant and equipment and depreciated as a component of cost of revenue over its estimated useful life. Generally, the expected term of the customer contracts and the estimated useful life of the scanners are both 3 years. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any rebates given to the buyer.

#### **Inventories**

Inventories are stated at the lower of cost or market on the first-in, first-out (FIFO) basis. Inventory consists of the Company's sponge and towel product as well as scanners and related hardware used in the Safety Sponge System ®. The FIFO cost for all inventories approximates replacement cost.

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

#### Property and Equipment

Property and equipment is stated at cost. The Company's property and equipment consists mainly of scanners and related hardware used in the Safety Sponge System® which are located at our customer facilities for their use at no additional cost. Depreciation expense associated with this hardware is recorded in cost of revenue. Depreciation is amortized straight-line over the estimated useful lives of three to seven years. Upon retirement or disposition of equipment, the related cost and accumulated depreciation or amortization is removed and a gain or loss is recorded, as applicable.

### 3. LOSS PER COMMON SHARE

Loss per common share is determined by dividing the loss applicable to common stockholders by the weighted average number of common shares outstanding. The Company complies with FASB ("Financial Accounting Standards Board") Accounting Standards Codification ("ASC") 260-10 Earnings Per Share, which requires dual presentation of basic and diluted loss per share on the face of the condensed 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 earnings per common share reflects the potential dilution that could occur if convertible preferred stock, 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.

For the three and nine month periods ended September 30, 2012 and 2011, potential shares associated with the convertible preferred stock plus warrants and options of 17,060,387 and 18,176,144, have a value in excess of the average stock price during the three and nine month periods ending September 30, 2012 and 2011, respectively. Because the effects of these securities are anti-dilutive, shares of common stock underlying these instruments have been excluded from the computation of loss per common share for the three and nine months ended September 30, 2012.

Patient Safety Technologies, Inc. Notes to Condensed Consolidated Interim Financial Statements

#### 4. INVENTORIES, net

Inventories, net consist of the following:

	As of
	September 30, December 31,
	2012 2011
Surgical sponges and towels	\$ 3,542,285 \$ 1,150,253
Scanners and related hardware	604,093 1,790,861
Reserve of obsolescence	(168,997) (168,997)
Total inventories, net	\$ 3,977,381 \$ 2,772,117

## 5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consists of the following:

	As	of
	September	December
	30,	31,
	2012	2011
Computer software and equipment	\$ 1,605,049	\$ 1,504,971
Furniture and equipment	85,394	70,571
Hardware for customer use	6,441,941	2,288,621
Property and equipment, gross	8,132,384	3,864,163
Less: accumulated depreciation	(3,399,135)	(2,172,202)
Property and equipment, net	\$ 4,733,249	\$ 1,691,961

Depreciation expense for the three and nine months ended September 30, 2012 was \$519 thousand and \$1.2 million, of which \$491 thousand and \$1.1 million was recorded as hardware cost of revenues, respectively. Depreciation expense for the three and nine months ended September 30, 2011 was \$144 thousand and \$395 thousand, of which \$132 thousand and \$348 thousand was recorded as hardware cost of revenue, respectively.

#### 6. DEFERRED REVENUE

The Company generally provides its SurgiCounter<sup>TM</sup> scanners and related software to most hospitals at no cost when they adopt its Safety-Sponge® System. Under the Company's existing distribution agreement with Cardinal Health, Inc. ("Cardinal Health"), Cardinal Health has agreed to reimburse the Company for a percentage of the scanner costs supplied to certain hospitals. Payments received from Cardinal Health relating to scanner cost reimbursements are deferred, and recognized as revenue on a pro-rata basis over the life of the scanner (which approximates the term of the hospital purchase commitment as they are refundable in the event a hospital contract is cancelled). Revenue recognized related to these reimbursements for the three and nine months ended September 30, 2012 was \$209 thousand and \$481 thousand. Revenue recognized related to these reimbursements for the three and nine months ended September 30, 2011 was \$50 thousand and \$137 thousand.

#### 7. STOCKHOLDER'S EQUITY

## Change in Par value

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

#### Issuance of Common stock

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

Pursuant to the Purchase Agreement, the Company issued to the Buyers an aggregate of 2,499,998 shares of our Common Stock at a purchase price of \$1.40 per share (or \$3,499,997 in gross proceeds), payable in cash. The Company incurred common stock issuance costs of approximately \$65 thousand. The use of proceeds is for general corporate purposes.

## Registration Rights Agreement

As contemplated by the Purchase Agreement, on the Closing Date the Company also entered into a Registration Rights Agreement with the Buyers, (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, the Company agreed to file a registration statement to register the stock issued to the Buyers in the Financing within 45 days, and have such registration statement declared effective within 150 days of the closing date. In addition to the foregoing mandatory registration, the Company also granted to the Buyers demand and "piggyback" registration rights. The Company has agreed to pay substantially all of the costs and expenses related to the filing of the registration statement and any underwritten public offering required pursuant to the Registration Rights Agreement. The mandatory registration was filed on Form S-1 on July 2, 2012 and declared effective by the Securities and Exchange Commission ("SEC") on July 16, 2012 and the Company has agreed to use commercially reasonable efforts to maintain the effectiveness of the registration statement for three years after the registration statement becomes effective.

Notes to Condensed Consolidated Interim Financial Statements

# 8. WARRANTS

The following table summarizes warrants to purchase common stock activity for the period ended September 30, 2012:

		Range of
	Number of	Exercise
	Warrants	Price
Warrants outstanding at December 31, 2011	4,962,645	\$ 0.75- 4.00
Cancelled/Expired	(602,000)	\$ 2.00
Exercised	(38,377)	\$ 0.75
Warrants outstanding at September 30, 2012	4,322,268	\$ 0.75-4.00

At September 30, 2012, stock purchase warrants will expire as follows:

		Range of
	# of	Exercise
	Warrants	Price
2012 (remaining)	216,000	\$ 1.40-2.00
2013	1,711,060	\$ 0.75-1.40
2014	1,890,000	\$ 1.82-4.00
2015	505,208	\$ 1.25
Total	4,322,268	\$ 0.75-4.00

Notes to Condensed Consolidated Interim Financial Statements

#### 9. STOCK OPTION PLANS

The following tables set forth information on our equity compensation plans.

On July 18, 2012 the Company amended its 2009 stock option Plan to increase the number of shares issuable under the Plan from 3,000,000 to 4,500,000.

All options that the Company granted during the nine months ended September 30, 2012 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:

		Nine Mont	hs En	ded
		Septemb	oer 30	),
	2	2012	2	011
Weighted average risk free interest rate		1.01%		1.70%
Weighted average life (in years)		6.09		6.07
Weighted average volatility		89.0%		90.8%
Expected dividend yield		0%		0%
Weighted average grant-date fair value per share of options granted	\$	0.98	\$	0.72
Estimated forfeiture rate		5%		%

A summary of stock option activity for the nine months ended September 30, 2012 is presented below:

# **Outstanding Options**

	-			Weighted Average	
		W	eighted	Remaining	Aggregate
		Α	verage	Contractual	Intrinsic
Number of		E	Exercise	Life	Value
Shares			Price	(years)	(1)
Balance at December 31, 2011	6,179,377	\$	1.19	7.52	\$ 2,044,176
Options granted (2)	513,400	\$	1.33	9.44	
Exercised	(450,000)	\$	1.04	_	
Forfeited	(519,500)	\$	1.66	_	_
Balance at September 30, 2012	5,723,277	\$	1.17	7.69	\$ 4,056,662
Vested and exercisable as of September 30, 2012	3,423,934	\$	1.29	7.20	\$ 2,369,769
Unvested and expected to vest as of September 30, 2012	2,184,455	\$	1.00	8.41	\$ 1,602,599

- (1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$1.73 of the Company's common stock at September 30, 2012.
- (2) Includes 230,000 non-qualified options and 40,000 incentive stock options that were issued outside the 2005 and 2009 stock option plans which are all outstanding as of September 30, 2012.

Notes to Condensed Consolidated Interim Financial Statements

The total grant date fair value of stock options granted for the three and nine months ended September 30, 2012 was \$95 thousand and \$502 thousand, respectively. For the three and nine months ended September 30, 2012, stock option based compensation expensed was \$210 thousand and \$607 thousand, respectively.

The total grant date fair value of stock options granted during the three and nine months ended September 30, 2011 was \$194 thousand and \$274 thousand, respectively. For the three and nine months ended September 30, 2011 stock option based compensation expensed was \$177 thousand and \$513 thousand, respectively.

As of September 30, 2012, there was \$1.7 million of unrecognized compensation costs related to outstanding employee stock options. This amount is expected to be recognized over a weighted average period of 2.31 years. To the extent the forfeiture rate is different from what the Company anticipated, stock-based compensation related to these awards will be different from the Company's expectations.

#### 10. RELATED PARTY TRANSACTIONS

During the three and nine months ended September 30, 2012 the Company purchased approximately \$3.4 million and \$8.2 million and \$1.1 million and \$3.0 million for the three and nine months September 30, 2011, respectively, in connection with the manufacture of surgical products used in the Safety-Sponge® System by A Plus International, Inc. ("A Plus"), of which the vast majority was recognized in cost of revenue and recorded on the balance sheet as inventory. At September 30, 2012 and December 31, 2011, the Company's accounts payable included \$3.7 million and \$1.2 million owed to A Plus in connection with the purchase of surgical products used in the Safety-Sponge® System, respectively. In addition the Company recognized during the three and nine months ended September 30, 2012 \$36 thousand in interest expense related to the Company incurring interest charges for payables aging outside of contractual terms. Such interest was classified as a financing cost in the accompanying condensed consolidated financial statements. Wayne Lin, a Director and significant beneficial owner of the Company is a founder and significant owner of A Plus.

## 11. MAJOR CUSTOMERS, SUPPLIERS, SEGMENT AND RELATED INFORMATION

#### **Major Customers**

During the three and nine months ended September 30, 2012 and 2011, due to its exclusive distribution agreement with Cardinal Health, the Company had one customer which for both periods represented in excess of 99% of total revenue, and 99% of total accounts receivables (of which 60% related to receivables on surgical sponge and towel sales and 38% related to reimbursements for hardware costs).

#### **Suppliers**

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

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

Patient Safety Technologies, Inc. Notes to Condensed Consolidated Interim Financial Statements

## 12. COMMITMENTS AND CONTINGENCIES

#### **Legal Proceedings**

The Company discloses material loss contingencies deemed to be reasonably possible and accrues for loss contingencies when, in consultation with the Company's legal advisors, the Company concludes that a loss is probable and reasonably estimable. Except as otherwise indicated, the possible losses relating to the matters described below are not reasonably estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates.

On June 12, 2012, the Company filed a complaint in the United States District Court for the Central District of California (Case No. SACV12-00937 DOC) alleging infringement of United States Patent No. 5,931,824 entitled "Identification and Accountability System for Surgical Sponges" by ClearCount Medical Solutions, Inc. (the "Complaint"). The Complaint seeks damages and injunctive relief relating to ClearCount's allegedly infringing sales of its SmartSponge System and SmartSponge Flex Products.

## 13. SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after September 30, 2012 through the date of the filing of this Report. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements.

# ITEM 2. 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 unaudited condensed consolidated interim financial statements and the related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto and the description of our business appearing in our annual report on Form 10-K for the year ended December 31, 2011 (as amended). This discussion contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements".

#### Overview

We focus on the development, marketing and sale of products designed to improve patient outcomes and reduce costs in the healthcare industry. We conduct our business through our wholly owned subsidiary, SurgiCount Medical, Inc. Our proprietary Safety-Sponge® System is a patented solution designed to eliminate one of the most common errors in surgery, retained surgical sponges, and the human and economic costs associated with this surgical mistake. The Safety-Sponge® System consists of a line of uniquely identified surgical sponges and towels and a turnkey hardware and software offering integrated to form a comprehensive accounting and documentation system. We generate recurring revenue derived from the sale of surgical sponges and towels to our customer facilities that utilize our products in surgical procedures. We estimate that since inception of the Safety Sponge System® and as of the date of the filing of this Report, over 120 million of our Safety-Sponges® have been successfully used in more than 5.7 million surgical procedures. We sell our Safety-Sponge® System to hospitals through our direct sales force and by leveraging the sales and marketing capabilities of our distribution partners. Our proprietary line of surgical sponges and towels are manufactured for us by our exclusive manufacturer, A Plus, a leading China-based manufacturer of disposable medical and surgical supplies. Our sponge and towel products are distributed through Cardinal Health, which provides us sales, marketing and logistics support and the fulfillment of our products to our end user hospitals by both delivering our products directly to our end user hospitals and where appropriate through alternative distributors. As of the quarter ended September 30, 2012 and as of the date of the filing of this Report we had approximately 265 and 269 facilities using the Safety-Sponge® System, respectively, all of which are located in the U.S. This compares to approximately 79 facilities using our system as of the quarter ended September 30, 2011. Although not necessarily proportionally related to future revenue, growth in the number of hospitals using our products is a good indicator of our underlying business. Once implemented, the vast majority of our user hospitals use the Safety-Sponge® System across all of their relevant surgical and OB/GYN procedures.

We generated revenues of \$12.5 million and \$6.7 million during the nine months ended September 30, 2012 and 2011, respectively. The nine months ended September 30, 2011 revenue included approximately \$1.1 million of revenue from the fulfillment of a \$10.0 million stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health (the "Forward Order"). There was no revenue reported in the nine months ended September 30, 2012 from fulfilling the Forward Order. Under certain circumstances the Forward Order inventory held by Cardinal Health could negatively impact our future 2012 and 2013 revenues and cash flows. Please refer to the section called "Factors Affecting Past and Future Results— Cardinal Health Supply Agreement" below in this Form 10-Q for more information on the potential impact of the Forward Order.

#### Factors Affecting Past and Future Results

# 140+ Hospital Integrated Delivery Network Agreement

On September 28, 2011, the Company announced that it signed an agreement, effective October 1, 2011, to implement the SurgiCount Safety-Sponge ® System in hospitals of one of the largest hospital operators in the U.S. Though the agreement itself did not call for or require a minimum number of hospitals to be implemented, SurgiCount and the operator planned for the implementation of the Safety-Sponge® System across all of the more than 140 hospitals that it operates. To date, the Company has successfully implemented the Safety-Sponge ® System in approximately 95% of these hospitals, with the remaining hospitals expected to be implemented in the fourth quarter 2012. The addition of these incremental hospitals has significantly expanded the Company's installed base of customer facilities.

### Cardinal Health Supply Agreement

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

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

In connection with the execution of the new agreement in November 2009, Cardinal Health issued the Forward Order, which was a \$10.0 million stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of that stocking inventory over a 12-month period. Cardinal Health initially paid us \$8.0 million as partial pre-payment of the Forward Order, and agreed to pay \$2.0 million directly to A Plus, to be used to pay for product that A Plus later invoiced us related to the Forward Order. Cardinal Health also agreed to maintain normal ordering patterns and volumes for purchasing our Safety-Sponge® products throughout 2010 and to not use any of the inventory delivered under the Forward Order to meet immediate hospital demand. In late 2010, Cardinal Health requested, and we agreed, to change the product mix of the Forward Order. However, because the products Cardinal Health requested were not immediately available, Cardinal Health agreed to take delivery of the remaining inventory on a modified schedule. As of December 31, 2010 we had delivered approximately \$8.9 million of the \$10 million Forward Order, and we delivered the remaining \$1.1 million of Forward Order inventory in the first half of 2011.

In March 2011, Cardinal Health and the Company signed an amendment to the Supply and Distribution agreement. The Amended Supply and Distribution Agreement revised a number of terms and conditions of the previous agreement, including but not limited to extending the termination date of the agreement from November 19, 2014 to December 31, 2015 and adding certain terms and provisions regarding setting target inventory levels and defining a formula for determining the excess inventory of our products held by Cardinal Health. At that time Cardinal Health agreed to not sell any of the Forward Order inventory until calendar year 2012. We also agreed to a methodology for the amount of the Forward Order inventory Cardinal Health would be able to sell to our customers each month, establishing a more orderly inventory release process that would help to minimize the impact this

inventory release would have on our sales during 2012.

On September 28, 2011, we announced an agreement to implement the Safety-Sponge® System with a large hospital group with over 140 hospitals, with implementations beginning in 2012. Implementation is currently expected to be completed by the end of the fourth quarter of the fiscal year ended 2012. The magnitude of this large implementation compelled us to prioritize our resources in order to scale up for costs associated with the large implementation, including the need to buy more sponge and towel inventory and scanners, as well as hiring and training more staff to support the implementations. As a result of this and other factors, management approached Cardinal Health in late 2011 to discuss the timing of when Cardinal Health would begin to release the Forward Order inventory. Cardinal Health agreed to delay the release of Forward Order inventory until April 1, 2012, to allow both sides additional time to negotiate a possible revision to the previously agreed upon terms, including the release of the Forward Inventory. As of the date this Quarterly Report on Form 10-Q was filed, no final agreement has been reached with Cardinal Health on changing the previously agreed upon terms, including not having set a date for Cardinal to start releasing the Forward Order inventory. Cardinal Health has not initiated any reduction of the Forward Order inventory.

Should Cardinal Health have any excess inventory on the date we mutually agree that Cardinal Health can start releasing Forward Order inventory, and should Cardinal Health begin selling the excess inventory it holds to partially meet customer demand, our reported revenues and cash flows will be negatively affected. The magnitude of this negative impact on our 2012 and 2013 revenue and cash flows will depend on a number of factors, including but not limited to the amount of excess inventory Cardinal Health actually has on hand in 2012, whether the Company chooses to purchase some or all of this excess inventory, and our actual sales growth rates. Actual future sales will depend on a number of factors, including but not limited to actual end-user demand and Cardinal Health's estimates of what inventory levels it needs to meet that demand. Management has no immediate plans to repurchase Cardinal Health's excess inventory. However we will consider this option should an appropriate opportunity arise. While we have not provided any estimates of what we expect future sales growth to be, in order to prevent a significant negative impact to our future revenue by Cardinal Health's release of Forward Order inventory, (i) we would need to experience substantial growth in the number of hospitals using our products, (ii) we would need to buyback any excess inventory from Cardinal Health, or (iii) Cardinal Health would need to decide not to use its excess inventory to partially meet customer demand. If we were to buyback excess inventory from Cardinal Health, this also could have a significant negative impact on our earnings, financial position and our liquidity.

#### Hardware Effect on Revenue and Cost of Revenue

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

### Sources of Revenues and Expenses

#### Revenues

We generate revenue 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 revenue from ongoing sales of surgical sponges and other products used in our system. We recognize revenue 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.

#### Cost of revenue

Our cost of revenue 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 revenue. In addition, when we provide (rather than sell) scanners to hospitals for their use, we include the depreciation expense of the scanners in cost of revenue (not the full product cost) over their estimated useful life. We estimate the useful life of the scanners to be three years. However, on rare occasions, if we sell the scanners to hospitals, our cost of revenues includes 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 including sponges & towels, hardware and software. 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. Sales and marketing also includes our initial implementation costs, which consist mostly of contract labor for nurses specialized in operating room procedures who support customer hospital nurses in the field during the implementation of our system, their related travel expenses, and technical service fees. There is typically a delay between the time we begin incurring costs associated with our new customer arrangements and the time we begin generating revenue from such arrangements.

# 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)

Other income (expense) consists mostly of interest income earned or interest expense incurred.

## 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, revenue 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 2 to our condensed consolidated interim financial statements.

# Revenue Recognition

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

# Inventories, net

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

#### 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 first assess qualitative factors to determine if it is necessary to perform the two-step quantitative goodwill impairment test. Under ASU No. 2011-08, we assess qualitative factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying value, including goodwill. In the event we determine that it is more likely than not that our sole reporting unit's fair value is less than its carrying

amount, quantitative testing would be performed comparing recorded values to estimated fair values. As part of our goodwill qualitative testing process, we evaluate various factors to determine whether it is reasonably likely that management's assessment would indicate a material impact on the fair value of our reporting unit. Examples of factors assessed in the qualitative approach are: cash flow forecasts of our reporting unit, the strength of our balance sheet, changes in strategic outlook or organizational structure, industry and market changes and macroeconomic indicators.

# **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.

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.

#### Non-GAAP Financial Measures

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

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

#### **Results of Operations**

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

As of the end of the third quarter of 2012, the number of facilities using our Safety-Sponge® System grew to 265. This compares to 79 facilities using the Safety-Sponge® System at the end of the third quarter of 2011, representing year-over-year growth in our installed customer base of 235%. As of the date of this filing approximately 269 facilities are using the Safety-Sponge® System. Although not necessarily proportional to future revenue, the number of hospitals using our products is a relevant general indicator of our underlying business.

#### Revenue

Total revenue for the three months ended September 30, 2012 was \$5.0 million. This compares with total revenue for the three months ended September 30, 2011 of \$2.2 million, representing year-over-year growth in reported quarterly revenue of 127%. The primary reason for this revenue growth was the large number of new facilities using our Safety-Sponge® System during the third quarter of 2012 as compared to the third quarter of 2011.

#### Cost of revenue

Costs of revenue of \$2.7 million increased by \$1.5 million or 127% for the three months ended September 30, 2012 as compared to cost of revenue of \$1.2 million for the same quarterly period in 2011. This increase was primarily the result of the higher number of facilities purchasing our products. Our cost of revenue in the third quarter of 2012 included a higher amount of non-cash scanner hardware depreciation resulting from the fact that we provide, at no additional cost, scanner hardware to our customer facilities that implement our Safety-Sponge® System, see "Factors effecting Past and Future Results — Reduction in Hardware Revenue". Our cost of revenue as a percentage of revenue was 54% during both the third quarters of 2012 and 2011. Our cost of revenue during the third quarter of 2012 included depreciation and other scanner related costs totaling \$529 thousand, while our third quarter of 2011 cost of revenue included depreciation and scanner related costs of \$132 thousand, representing a 300% increase.

# Gross profit

Gross profit totaled \$2.3 million for the three months ended September 30, 2012, an increase of \$1.3 million, or 128%, compared to gross profit of \$1.0 million for the third quarter of 2011. Our gross profit for the quarter ended September 30, 2012 as compared to the quarter ended September 30, 2011 was negatively impacted by higher amounts of non-cash depreciation expense (primarily associated with the relatively larger amount of scanning equipment we provided to support a higher number of new customers) offset by higher relative pricing on our products to new customers. Gross profit as a percent of revenue was 46% during both the quarter ended September 30, 2012 and 2011.

## Operating expenses

Operating expenses totaled \$2.4 million for the quarter ended September 30, 2012, an increase of \$0.9 million, or 59%, compared to operating expenses of \$1.5 million during the same quarterly period in 2011. This increase was primarily due to higher one-time costs associated with the 50 successful customer implementations during the third quarter 2012 as compared to 2 implementations during the third quarter of 2011. Total one-time implementation costs in the third quarter of 2012 were approximately \$0.6 million, as compared to approximately \$0.1 million during the third quarter of 2011. One-time expenses associated with implementing new customer facilities included utilizing clinical and IT contractors to provide project management and on-site customer support throughout the implementation process, along with their related travel, lodging and other costs. During the third quarter of 2012, we continued implementing the large hospital group comprised of over 140 hospital facilities, and estimate that

approximately 95% of their facilities have been implemented.

#### Research and development expenses

Research and development expenses totaled \$111 thousand for the quarter ended September 30, 2012, an increase of \$110 thousand compared to \$1.4 thousand during the same quarterly period in 2011. The year-over-year increase in research and development expenses reflects management's growing investment in resources for improving and expanding our product offering.

#### Sales and marketing expenses

Sales and marketing expenses totaled \$1.4 million for the quarter ended September 30, 2012, an increase of \$634 thousand, or 89%, compared to \$716 thousand during the same period in 2011. The increase in sales and marketing expenses during the third quarter of 2012 as compared to the prior year's third quarter was primarily due to one-time implementation expenses of approximately \$610 thousand for supporting new facility implementations as described above in Operating Expenses.

#### General and administrative expenses

General and administrative ("G&A") expenses totaled \$1.0 million for the quarter ended September 30, 2012, representing an increase of \$150 thousand, or 19%, compared to G&A expenses of \$0.8 million during the same quarterly period in 2011. The increase in G&A expenses during the third quarter 2012 as compared the third quarter of 2011 was due primarily to the addition of employees to support our growing customer base and expanded operations.

#### Total other income (expense)

We reported other expense of \$35 thousand for the quarter ended September 30, 2012, as compared to other income of \$304 thousand for the quarter ended September 30, 2011. During the third quarter 2011 we had a gain of \$303 thousand related to the mark to market adjustment of a warrant derivative liability, which was extinguished in Q4 2011, and as such, we have not had similar adjustments during 2012.

#### Net loss

We had a net loss of \$0.3 million applicable to common stockholders for the three months ended September 30, 2012 compared to a net loss of \$0.4 million for the same quarterly period in 2011 based upon the explanations described above. Additionally, during the quarter ended September 30, 2011 our net loss of \$0.4 million included the benefit of a non-cash gain on the change in the fair value of a warrant derivative liability of \$0.3 million. There was no such non-cash gain during the quarter ended September 30, 2012.

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

#### Revenue

Total revenue for the nine months ended September 30, 2012 was \$12.5 million, which compares to total revenue for the nine months ended September 30, 2011 of \$6.7 million, representing year over year growth in reported revenue of 86%. For the nine months ended September 30, 2011, revenue of \$6.7 million included approximately \$1.1 million of revenue for filling a \$10 million Forward Order to our exclusive distributor, Cardinal Health. The Forward Order was completed in Q2 2011, so there was no revenue earned from the Forward Order during 2012. When excluding the effect of the Forward Order revenue on the reported third quarter 2011 revenue, the nine months ended September 30, 2012 year-over-year revenue growth would have been 121%. The primary reason for the increased revenue growth is the larger number of new customer implementations we have had throughout 2012, having grown by 166 hospital facilities during the nine months ended September 30, 2012.

#### Cost of revenue

Costs of revenue of \$7.1 million increased by \$3.5 million or 102% for the nine months ended September 30, 2012 as compared to cost of revenue of \$3.5 million for the same period in 2011. This increase was primarily the result of higher number of facilities purchasing our products. Our cost of revenue for the nine months ended September 30, 2012 included a higher amount of non-cash depreciation expense from providing the scanner hardware at no cost to our new customer facilities (see "Factors effecting Past and Future Results — Reduction in Hardware Revenue"). Our cost of revenue as a percentage of revenue increased to 57% during the nine months ended September 30, 2012 as compared to 52% during the same period in 2011. This increase was attributable mostly to higher non-cash depreciation expense and other equipment costs that totaled \$1.2 million in our cost of revenue during the nine months ended September 2012, as compared to similar costs during the same period in 2011 of \$423 thousand. This 190% increase in depreciation and equipment costs reflected the large amounts of hardware purchased in order to support 166 new hospital customer implementations occurring in the nine months ended September 30, 2012.

#### Gross profit

Gross profit totaled \$5.4 million for the nine months ended September 30, 2012, an increase of \$2.2 million, or 68%, compared to gross profit of \$3.2 million during the same period in 2011. Our gross profit for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was negatively impacted by higher amounts of non-cash depreciation expense (primarily associated with the relatively larger amount of scanning equipment we provided to support a higher number of new customers) offset by higher relative pricing on our products to new customers. Gross profit as a percent of revenue was 43% during the nine months ended September 30, 2012 and 48% during the same period in 2011.

### Operating expenses

Operating expenses totaled \$7.3 million for the nine months ended September 30, 2012, an increase of \$2.4 million, or 48%, compared to \$5.0 million of operating expenses during the same period in 2011. The increase in operating expenses was primarily due to higher one-time costs associated with a significantly larger number of new customer implementations during the first three quarters of 2012 as compared to the same period of 2011. During the nine months ended September 30, 2012 we successfully implemented 166 new customer facilities, the most new customer facilities we have ever implemented during a nine-month time period in our history. This compares to 9 new customer facilities implemented during the first nine months of 2011. Total one-time implementation costs in the nine months ended September 30, 2012 were approximately \$1.7 million, as compared to approximately \$0.3 million during the nine months ended September 30, 2011. One-time expenses associated with implementing new customer facilities included utilizing per diem clinical and IT personnel for upfront planning and staffing clinical and technical on-site support during the implementation process, associated travel and lodging expenses and other directly related implementation expenses. Additionally, during the third quarter of 2012, we continued the implementation of a new large hospital system customer comprised of over 140 hospital facilities, for which we originally initiated implementations in the first quarter of 2012. The relatively fast pace with which we have been implementing these new facilities is resulting in significantly higher implementation costs than we would otherwise normally have expected to incur.

# Research and development expenses

Research and development expenses totaled \$400 thousand for the nine months ended September 30, 2012, an increase of \$345 thousand, or 626%, compared to \$55 thousand during the same period in 2011. The year-over-year increase in research and development spending was primarily due to expanded investment in resources dedicated to improving and expanding our product offering.

# Sales and marketing expenses

Sales and marketing expenses totaled \$3.7 million for the nine months ended September 30, 2012, an increase of \$1.7 million, or 82%, compared to \$2.0 million during the same period in 2011. The increase in sales and marketing expenses during the first nine months of 2012 as compared to the same period in 2011 was due primarily to the significantly higher one-time implementation expenses to support new facility implementations during this period as described above in Operating expenses.

# General and administrative expenses

General and administrative ("G&A") expenses totaled \$3.2 million for the nine months ended September 30, 2012, representing an increase of \$336 thousand, or 12%, compared to G&A expenses of \$2.9 million during the same period in 2011. The slight increase in G&A expenses during the nine months ended September 30, 2012 as compared

the same period in 2011 was due primarily to the addition of employees to support our growing customer base and expanded operations.

#### Total other income (expense)

We reported other expense of \$32 thousand for the nine months ended September 30, 2012, a decrease of \$784 thousand of income compared to other income of \$752 thousand for the nine months ended September 30, 2011. During the nine months ended September 30, 2011, we had recognized a gain of \$227 thousand related to the reduction of a contingent tax liability, and also recognized a gain of \$527 thousand from recording a mark to market adjustment for changes in the fair value of a warrant derivative liability. The warrant derivative liability was extinguished in Q4 2011, and as such, we have not had similar adjustments during 2012.

#### Net loss

We had a net loss of \$2.4 million applicable to common stockholders for the nine months ended September 30, 2012 compared to a net loss of \$1.4 million for the same period in 2011 based upon the reasons described above. Additionally, during the nine months ended September 30, 2011 our net loss of \$1.4 million included the benefits of non-cash gains on the change in the fair value of a warrant derivative liability of \$0.5 million and \$0.2 million for a gain on the reduction of a contingent tax liability. There were no such non-cash gains during the nine months ended September 30, 2012.

## Financial Condition, Liquidity and Capital Resources

We had cash and cash equivalents of \$5.5 million at September 30, 2012 compared to \$3.7 million at December 31, 2011. As of September 30, 2012, we had total current assets of \$11.2 million and total current liabilities of \$6.4 million resulting in a positive working capital of \$4.7 million, which compared to \$4.0 million in positive working capital as of December 31, 2011. Current liabilities as of September 30, 2012 include deferred revenue of \$0.8 million relating to hardware reimbursement payments from Cardinal Health, which is a non-cash liability. Excluding this non-cash liability, our current liabilities would have been \$5.6 million as of September 30, 2012, giving us an adjusted positive working capital of \$5.6 million.

We believe our sources of liquidity are sufficient to satisfy our anticipated cash requirements through the next 12 months as we expect the business to generate improved cash flow from operations as result of our growing installed base of customer facilities. We may seek financing to fund future growth for periods beyond the next 12 months, through future offerings of equity or debt, or through agreements with strategic partners to help fund our growth and the development of future products and technologies. However, we can offer no assurances that we will be able to obtain additional financing or agreements with strategic partners on acceptable terms, if at all. Management continually evaluates our liquidity needs and whether to increase capital resources. See Item 1A "Risk Factors" in our Annual Report on Form 10-K (as amended) for the year ended December 31, 2011 for additional information on factors that could impact our future liquidity and capital resources.

## Operating activities

We had positive net cash flow from operating activities of \$2.2 million during the nine months ended September 30, 2012. Our net loss of \$2.0 million for the nine months ended September 30, 2012 included non-cash charges in the form of stock-based compensation, amortization of intangible assets and depreciation totaling \$2.1 million during the nine months ended September 30, 2012.

Cash provided by working capital and other assets during the nine months ended September 30, 2012 was \$2.1 million. Working capital is comprised primarily of accounts receivable, inventory, other assets, deferred revenue and other liabilities. Accounts receivable increased by \$345 thousand or 26% during the nine months ended September 30, 2012, as compared to fiscal year end 2011, reflecting our increased non-Forward Order revenue. Inventory increased by \$1.2 million or 43% during the nine months ended September 30, 2012, as compared to fiscal year end 2011, due to our new business growth and increased levels of safety stocks. Accounts payable increased by \$2.2 million or 78%, representing mostly the additional inventory of both sponges and hardware ordered for supporting our new business growth. Our increase in accounts payable also reflects extended payment terms that went into effect with certain key vendors helping to support our rapid new customer growth during the first nine months of 2012.

Deferred revenue of \$1.9 million as of September 30, 2012 represents a significant component of our working capital, having increased by \$1.3 million or 250% during the nine months ended September 30, 2012, as compared to fiscal year end 2011. This increase in deferred revenue was a result of the large increase in implementations during the first three quarters of 2012 and Cardinal Health's agreement in certain situations to reimburse half of our hardware costs that are typically provided to our customers for use at no cost.

We used \$3.5 million of net cash from operating activities during the nine months ended September 30, 2011. Our net income included non-cash charges in the form of stock-based compensation, amortization of intangible assets, mark to market adjustment of our warrant derivative liability, gain on contingent tax liability and depreciation. These non-cash charges totaled \$0.4 million during the nine months ended September 30, 2011.

Cash used in working capital and other assets during the nine months ended September 31, 2011 was \$2.9 million. Working capital is comprised primarily of accounts receivable, inventory, other assets, deferred revenue and other liabilities. Accounts receivable increased by \$270 thousand or 35% during the nine months ended September 30, 2011 reflecting timing of sales and our increased non-Forward Order revenue. Inventory increased by \$566 thousand or 51% during the nine months ended September 30, 2011 due to our business growth and safety stocks required. Accounts payable decreased by \$901 thousand or 36%, which included payments totaling \$2.1 million to our contract manufacturer, A Plus, to pay for past due amounts owed to them from previous periods, which we paid immediately upon receiving proceeds from our private placement that closed on March 29, 2011 and March 30, 2011. Deferred revenue decreased by \$1.1 million or 23% during the nine months ended September 30, 2011 relating to our final shipments to Cardinal Health in filling the Forward Order.

# Investing activities

We used \$4.3 million of net cash in investing activities during the nine months ended September 30, 2012, almost entirely for the purchase of scanners and related hardware used for implementing our Safety-Sponge® System at new customer facilities. This compares to using \$527 thousand of net cash in investing activities during the nine months ended September 30, 2011, which were also primarily for the purchase of scanners and related hardware for implementing our Safety Sponge® System at new customers.

# Financing activities

During the nine months ended September 30, 2012, we generated \$3.8 million of net cash from financing activities primarily from the net proceeds from closing a \$3.5 million private placement in May 2012, along with \$470 thousand of proceeds received from the exercise of employee stock options, offset by the payment of preferred stock dividends and other stock issuance costs.

We generated \$7.1 million of net cash from financing activities in the nine months ended September 30, 2011, primarily from the net proceeds of our \$7.1 million private placement and exercise of employee stock options, offset by the payment of preferred stock dividends and other stock issuance costs.

**Off-Balance Sheet Arrangements** 

As of September 30, 2012, we had no off-balance sheet arrangements.

Commitments and Contingencies

As of September 30, 2012, other than our office leases and employment agreements with key executive officers, we had no material commitments other than the liabilities reflected in our condensed consolidated interim financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As of the end of the period covered by this Report, we conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2012.

During the most recently completed fiscal quarter, there was no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended) identified in the evaluation described in the preceding paragraph that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### PART II – OTHER INFORMATION

# ITEMLEGAL PROCEEDINGS

1.

32.1\*

On June 12, 2012, the Company filed a complaint in the United States District Court for the Central District of California (Case No. SACV12-00937 DOC) alleging infringement of United States Patent No. 5,931,824 entitled "Identification and Accountability System for Surgical Sponges" by ClearCount Medical Solutions, Inc. (the "Complaint"). The Complaint seeks damages and injunctive relief relating to ClearCount's allegedly infringing sales

# of its SmartSponge System and SmartSponge Flex Products. ITEMRISK FACTORS 1A. Not applicable. ITEMUNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS 2. None. ITEMDEFAULTS UPON SENIOR SECURITIES 3. None. ITEMMINE SAFETY DISCLOSURES 4. None. ITEMOTHER INFORMATION 5. None. **ITEMEXHIBITS** 6. Exhibit Number Description 31.1\* Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a)\* 31.2\* Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a)\*

Certification of Chief Executive Officer and Chief Financial Officer required by Rule 13a-14(b) or

Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code\*

101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

## **SIGNATURES**

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

PATIENT SAFETY TECHNOLOGIES,

INC.

Date: November 5, 2012 By: /s/ Brian E. Stewart

Brian E. Stewart, President and Chief

**Executive Officer** 

Date: November 5, 2012 By: /s/ David C. Dreyer

David C. Dreyer, Executive Vice

President,

Chief Financial Officer, and Secretary