Patient Safety Technologies, Inc Form 10-Q November 14, 2011 UNITED STATES

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

### FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011

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 o

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

Large accelerated filer "

Accelerated filer "
Smaller Reporting Company x

Non-accelerated filer " (Do not check if smaller reporting company)

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

The number of outstanding shares of the registrant's common stock, par value \$0.33 per share, as of November 5, 2011 was 34,020,255.

# PATIENT SAFETY TECHNOLOGIES, INC.

# FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2011

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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. 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, 2010 filed on April 14, 2011 and amended on April 29, 2011, including without limitation the following:

- 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 revenues and cash flow from the 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; and
- · any inability to successfully protect our intellectual property portfolio.

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" me 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 Citadel<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, 2011 Unaudited)	]	December 31, 2010
Assets			
Current assets:			
Cash and cash equivalents	\$ 4,957,495	\$	1,896,034
Restricted cash	_	_	223,630
Accounts receivable	1,043,093		772,381
Inventories, net	1,677,100		1,110,832
Prepaid expenses	54,430		104,628
Total current assets	7,732,118		4,107,505
Property and equipment, net	1,111,697		979,833
Goodwill	1,832,027		1,832,027
Patents, net	2,545,377		2,789,083
Other assets	34,233		39,038
Total assets	\$ 13,255,452	\$	9,747,486
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$ 1,704,705	\$	2,605,669
Accrued liabilities	435,978		991,682
Deferred revenue	330,309		1,477,720
Warrant derivative liability	463,838		942,472
Total current liabilities	2,934,830		6,017,543
Commitments and contingencies			
Stockholders' equity:			
Series A preferred stock, \$1.00 par value, cumulative 7% dividend: 1,000,000 shares			
authorized; 10,950 issued and outstanding at September 30, 2011 and December 31,			
2010;			
(Liquidation preference of \$1.1 million at September 30, 2011 and December 31,			
2010)	10,950		10,950
Series B convertible preferred stock, \$1.00 par value, cumulative 7% dividend: 150,000 shares	64,770		61,589
authorized; 64,770 issued and outstanding at September 30, 2011 and 61,589 issued and			

outstanding at December 31, 2010; (Liquidation preference of \$6.5 million at September 30, 2011 and \$6.2 million at December 31, 2010) Common stock, \$0.33 par value: 100,000,000 shares authorized; 34,020,255 shares issued and outstanding at September 30, 2011 and 23,956,063 shares issued and outstanding at December 31, 2010 11,226,684 7,905,501 Additional paid-in capital 57,024,337 52,356,930 Accumulated deficit (58,006,119)(56,605,027) Total stockholders' equity 10,320,622 3,729,943 9,747,486 Total liabilities and stockholders' equity \$ 13,255,452 \$

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

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

	Three Mor Septem	nths Ended lber 30,	Nine Mon Septem	
	2011	2010	2011	2010
Revenues	\$ 2,186,220	\$ 4,122,560	\$ 6,725,646	\$ 10,252,897
Cost of revenue	1,190,879	1,950,573	3,528,110	4,829,821
Gross profit	995,341	2,171,987	3,197,536	5,423,076
Operating expenses:				
Research and development	1,460	35,246	55,220	166,548
Sales and marketing	716,491	518,570	2,049,943	2,341,132
General and administrative	806,544	693,235	2,864,024	4,849,573
Total operating expenses	1,524,495	1,247,051	4,969,187	7,357,253
Operating (loss) income	(529,154)	924,936	(1,771,651)	(1,934,177)
Other income (expense):				
Interest income (expense)	347	3,598	(3,632)	(5,062)
Gain on change in fair value of warrant derivative				
liability	303,222	15,631	527,844	2,685,579
Other income	_		- 227,617	433,958
Total other income	303,569	19,229	751,829	3,114,475
(Loss) income before income taxes:	(225,585)	944,165	(1,019,822)	1,180,298
Income tax (provision) benefit	(2,543)	32,573	(6,316)	
Net (loss) income	(228,128)	976,738	(1,026,138)	1,320,160
Preferred dividends	(125,498)	(14,682)		
Net (loss) income applicable to common shareholders	\$(353,626)	\$962,056		\$ 1,260,383
(Loss) income per common share:				
Basic	\$(0.01)	\$ 0.04	\$ (0.05)	\$ 0.05
Dasic	\$(0.01	φ 0.0 <del>4</del>	\$ (0.03)	φ 0.05
Diluted	\$(0.01)	\$ 0.03	\$ (0.05)	\$ 0.04
Weighted average common shares outstanding:				
Basic	33,782,033	23,456,063	30,606,468	23,456,063
D'1-4-1	22 702 022	22.020.006	20.606.460	25 (50 7()
Diluted	33,782,033	32,039,996	30,606,468	35,659,766

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 Months Ended September 30, 2011 2010

# Operating activities:

Net (loss) income	\$(1,026,138)	\$1,320,160
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	395,412	388,006
Amortization of patents	243,706	243,706
Stock-based compensation	512,953	965,078
Gain on reduction of contingent tax liability	(223,524)	(427,700)
Loss on abandonment of lease	<del>_</del>	151,973
Loss on capital lease write-off	_	3,917
Gain on change in fair value of warrant derivative liability	(527,844)	(2,685,579)
Change in deferred tax liability	_	(97,719)
Changes in operating assets and liabilities:		
Transfer from restricted cash in connection with tax escrow account	223,630	(223,630)
Accounts receivable	(270,712)	226,376
Inventories	(566,268)	(1,164,147)
Prepaid expenses	50,198	(48,459)
Other assets	4,805	(5,554)
Accounts payable	(900,964)	634,086
Accrued liabilities	(282,971)	(101,540)
Deferred revenue	(1,147,411)	(3,652,497)
Net cash used in operating activities	(3,515,128)	(4,473,523)
Investing activities:		
Purchase of property and equipment	(527,276)	(627,888)
Net cash used in investing activities	(527,276)	(627,888)
Financing activities:		
Proceeds from issuance of convertible preferred stock	_	5,000,000
Payments for preferred stock issuance costs	_	(480,010 )
Proceeds from issuance of common stock	7,112,500	
Proceeds from exercise of stock options	375,000	
Capital lease principal payments	_	(15,556)
Payments for common stock issuance costs	(325,241)	
Payments of preferred stock series A dividends	(57,488)	(53,007)
Payments of convertible preferred stock series B dividends	(906)	_
Net cash provided by financing activities	7,103,865	4,451,427
Net increase in cash and cash equivalents	3,061,461	(649,984)
Cash and cash equivalents at beginning of period	1,896,034	3,446,726
Cash and cash equivalents at end of period	\$4,957,495	\$2,796,742
-		

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Supplemental disclosures of cash flow information:		
Cash paid during the period for income taxes	\$6,316	\$16,113
Non-cash investing and financing activities:		
Issuance of convertible preferred stock for accounts payable	<b>\$</b> —	\$1,000,000
Dividends accrued	<b>\$</b> —	\$53,007
Reduction of fixed assets based on write-off of capital lease	<b>\$</b> —	\$62,048
Payment in-kind of Series B preferred dividends	\$317,468	\$6,770
Issuance of common shares previously earned	\$26,674	<b>\$</b> —

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

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

### 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 certain information and disclosures have been condensed or omitted in accordance with accounting principles generally accepted in the United States of America for interim reporting. 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, 2010 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, 2010 (as amended). Results of the three months and nine months ended September 30, 2011 are not necessarily indicative of the results to be expected for the twelve months December 31, 2011.

# 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 2011 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 revenue 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, derivative

liabilities, valuation allowance related to deferred tax assets, warranty obligations, provisions for rebates, 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 received 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.

### Income Taxes

The Company currently has net operating loss carryforwards to offset income taxes. The Company has provided for a valuation allowance for all related deferred tax assets as of September 30, 2011.

### **Recent Accounting Pronouncements**

### Newly Adopted Accounting Standards

In December 2010, the Financial Accounting Standard Board ("FASB") issued an update to existing guidance on the calculation of impairment of goodwill. This update modifies Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For these reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. The Company adopted this guidance on January 1, 2011, and will evaluate the impact, if any, on its consolidated financial statements if events occur or circumstances change that would more likely than not reduce the fair value of the Company or its assets below their carrying amounts. No events have occurred since December 31, 2010, that would trigger further impairment testing of the Company's intangible assets with finite lives subject to amortization.

In June 2011, the FASB updated the accounting guidance on alignment of disclosures for GAAP and the International Financial Reporting Standards, or IFRS, by updating Topic 820 entitled "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS", relating to presentation of fair value measurements reported in financial statements. The updated guidance requires companies to align fair value measurement and disclosure requirements between GAAP and IFRS. The updated guidance is effective beginning in our fiscal 2012 year and earlier adoption is not permitted. The adoption of this guidance is not expected to have a material impact on our financial position or results of operations.

Other accounting standards and exposure drafts, such as exposure drafts related to revenue recognition, lease accounting, loss contingencies, comprehensive income and fair value measurements, that have been issued or proposed by the FASB or other standards setting bodies that do not require adoption until a future date, are being evaluated by the Company to determine whether adoption will have a material impact on the Company's consolidated financial statements.

### 3. EARNINGS (LOSS) PER COMMON SHARE

Earnings (loss) per common share is determined by dividing the earnings (loss) applicable to common stockholders by the weighted average number of common shares outstanding. 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 or notes, 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 months ended September 30, 2010, the shares associated with the convertible preferred stock, convertible note, warrants and options that have a value in excess of the average stock price during the nine month period ending September 30, 2010 are included in calculating diluted earnings per share. For the three and nine months ended September 30, 2011, the effects of outstanding options, warrants and the conversion of convertible preferred stock are anti-dilutive, and accordingly shares of common stock underlying these instruments have been excluded from the computation of loss per common share for such periods.

Patient Safety Technologies, Inc.

Notes to Condensed Consolidated Interim Financial Statements

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

	Three Mon Septemb		Nine Mont Septemb	
	2011	2010	2011	2010
Basic	2011	2010	2011	2010
(Loss) income available to common stockholders	\$(353,626)	\$962,056	\$(1,401,092)	\$1,260,383
Weighted average common shares outstanding	33,782,033	23,456,063	30,606,468	23,456,063
(Loss) income per common share	\$(0.01)	\$0.04	\$(0.05)	\$0.05
•			·	
Diluted				
(Loss) income available to common stockholders	\$(353,626)	\$962,056	\$(1,401,092)	\$1,260,383
Plus: Dividends due to assumed conversion of Series				
B preferred stock	—	6,770	_	6,770
(Loss) Income available to common stockholders plus				
assumed conversions	(353,626)	968,826	(1,401,092)	1,267,153
Weighted average common shares outstanding	33,782,033	23,456,063	30,606,468	23,456,063
Assumed issuance of restricted stock		75,000	_	75,000
Assumed exercise of options	_	_	_	1,052,084
Assumed exercise of warrants	_	_	_	2,567,686
Assumed conversion of Series B preferred stock	_	8,008,433	_	8,008,933
Assumed conversion of debt	_	500,000	_	500,000
Common and potential common shares	33,782,033	32,039,996	30,606,468	35,659,766
Diluted (loss) income per common share	\$(0.01)	\$0.03	\$(0.05)	\$0.04
Potentially dilutive securities outstanding at				
period end excluded from diluted computation				
as they were anti-dilutive	18,176,144	8,241,917	18,176,144	8,896,863

# 4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consists of the following:

	As	of
	September	December
	30,	31,
	2011	2010
Computer software and equipment	\$ 1,256,663	\$ 1,100,003
Furniture and equipment	63,672	57,143
Hardware for customer use	1,776,177	1,417,948
Property and equipment, gross	3,096,512	2,575,094
Less: accumulated depreciation	(1,984,815)	(1,595,261)
Property and equipment, net	\$ 1,111,697	\$ 979,833

Patient Safety Technologies, Inc.

Notes to Condensed Consolidated Interim Financial Statements

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. Depreciation expense for the three and nine months ended September 30, 2010 was \$122 thousand and \$388 thousand of which \$77 thousand and \$204 thousand was recorded as hardware cost of revenue, respectively.

### 5. DEFERRED REVENUE

Deferred revenue consists of the following:

		As of	
	Sep	tember	December
		30,	31,
	2	2011	2010
Cardinal Health advance payment on purchase order	\$	-	\$ 1,079,434
Scanner reimbursement revenue	3	330,309	398,286
Total	\$ 3	330,309	\$ 1,477,720

Cardinal Health advance payment on purchase order

In connection with the execution of the Supply and Distribution Agreement in November 2009 between the Company and Cardinal Health, Inc. ("Cardinal Health"), Cardinal Health issued a \$10.0 million stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of stocking inventory over a 12-month period (the "Forward Order"). Cardinal Health paid us \$8.0 million as partial pre-payment of the Forward Order, and agreed to pay \$2.0 million directly to A Plus International ("A Plus"), to pay for product when A Plus invoices the Company. Cardinal Health also agreed to place a second \$5.0 million stocking purchase order prior to the end of the third quarter of 2010, based on whether the Company achieved certain conditions, including a minimum targeted customer sales threshold. Both Cardinal Health and the Company jointly agreed in late 2010 not to go forward with this second stocking purchase order. Cardinal Health also agreed to maintain normal ordering patterns and volumes for purchasing our Safety-Sponge® products throughout 2010 and 2011, and not use any of the inventory delivered under the Forward Order to meet immediate hospital demand. In late 2010 Cardinal Health requested a change to the product mix of the Forward Order. The Company agreed to this change. However, because the products Cardinal Health requested were not immediately available, Cardinal agreed to take delivery of the remaining inventory on a modified schedule. As of June 30, 2011 we had delivered the entire \$10.0 million of the Forward Order. The net effect is the Company recognized \$8.9 million of revenue related to the Forward Order in 2010 and for the three and nine months ended September 30, 2011 the Company recognized \$0 and \$1.1 million, respectively.

In March 2011, the Company and Cardinal Health signed an amendment to the Supply and Distribution agreement (the "Amended 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 what excess inventory is of our products held by Cardinal Health. Cardinal Health has agreed to not sell any of the Forward Order inventory until 2012, and we have agreed to a methodology for how Cardinal Health will sell this inventory to our customers, so there is a more orderly release throughout 2012 that more reasonably minimizes its impact to the Company's revenue and cash flow during 2012. In addition, the Amended Supply and Distribution Agreement gives the Company the right to buy-back at cost any inventory of our products held by Cardinal Health that exceeds 60 days worth of sales. All other terms remain the

same.

### Scanner reimbursement revenue

Beginning with the third quarter of 2009, the Company began to provide its SurgiCounter<sup>TM</sup> scanners and related software to most hospitals at no cost when they adopt its Safety-Sponge® System. Under the distribution agreement with Cardinal Health, Cardinal has agreed to reimburse the Company for a percentage of the scanner costs supplied to certain hospitals. Payments received from Cardinal 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).

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

### 6. STOCKHOLDERS' EQUITY

### Common Stock Private Placement

On March 29, 2011 and March 30, 2011, the Company closed a private placement financing raising \$7.1 million through the issuance of 9.48 million shares of the Company's \$0.33 par value common stock at a selling price of \$0.75 per share. The buyers of the common stock (the "Buyers") were accredited investors under Rule 501(a) of Regulation D of the Securities Act of 1933, and included Kinderhook Partners, L.P. ("Kinderhook"), A Plus and certain members of management. Wenchen ("Wayne") Lin, a member of our Board of Directors ("Board") is founder and significant beneficial owner of A Plus. Kinderhook is an investment fund based in Fort Lee, NJ.

In connection with the private placement, the Company also entered into a Registration Rights Agreement with the Buyers, pursuant to which the Company agreed to register shares of the common stock issued, as well as any other shares of common stock held by the Holders on the closing date, along with future common shares for the Holders of the Series B Convertible Preferred Stock (collectively the "Holders"). The required registration statement became effective on August 12, 2011 and the Company has agreed to use commercially reasonable efforts to maintain effectiveness for three years after the registration statement became effective.

Patient Safety Technologies, Inc.

Notes to Condensed Consolidated Interim Financial Statements

### 7. WARRANTS

The following table summarizes warrants to purchase common stock activity for the nine months ended September 30, 2011:

		K	ange of
	Number of	E	xercise
	warrants		Price
			0.75 -
Warrants outstanding December 31, 2010	7,294,919	\$	6.05
Issued	_	_	
			0.75 -
Cancelled/Expired	(2,183,419)	\$	6.05
			0.75 -
Warrants outstanding September 30, 2011	5,111,500	\$	4.00
At September 30, 2011, stock purchase warrants will expire as follows:			

	Range of
# of Warrants	<b>Exercise Price</b>
130,000	\$ 1.25 - 2.00
818,000	\$ 1.40 - 2.00
1,768,292	\$ 0.75 - 1.40*
1,890,000	\$ 1.82 - 4.00
505,208	\$ 1.25
5,111,500	\$ 0.75-4.00
	130,000 818,000 1,768,292 1,890,000 505,208

<sup>\*</sup> Included are certain warrants which contain anti-dilution rights if the Company grants or issues securities for less than exercise price.

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

### 8. FAIR VALUE MEASUREMENTS

### Fair Value Hierarchy

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

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

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

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

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

Financial Instruments Measured at Fair Value on a Recurring Basis

ASC 820 requires disclosure of the level within the fair value hierarchy used by the Company to value financial assets and liabilities that are measured at fair value on a recurring basis. At September 30, 2011, the Company had a total of 511,767 outstanding warrants to purchase common shares of its stock that are classified as warrant derivative liabilities with a fair value of \$464 thousand. The warrants are valued using Level 3 inputs because there are significant unobservable inputs associated with them.

The Company estimates the fair value of these warrants and embedded conversion features using the Monte Carlo simulation option price model. In applying the Monte Carlo simulation model, the Company used the following assumptions to value its derivative liabilities during the nine months ended September 30, 2011:

	For the
	Nine
	Months Ended
	September
	30, 2011
Annual dividend yield	<u> </u>
Expected life (years)	1.63
Risk-free interest rate	0.19%
Expected volatility	90%

The following table reconciles the warrant derivative liability measured at fair on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2011:

December 31, 2010 \$ 991,682

_
_
527,844
\$ 463,838

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

### 9. STOCK OPTION PLANS

The following tables set forth information on the Company's equity compensation plans. All equity compensation plans have been approved by the Company's stockholders.

All options that the Company granted during the nine months ended September 30, 2011 were granted at the per share fair market value on the grant date. Vesting of options differs based on the terms of each option. The Company utilized the Black-Scholes option pricing model and the assumptions used for each period are as follows:

	Nine Months Ended			
	September 30, 2011			
	2011		2010	
Weighted average risk free interest rate	1.70%		1.59%	
Weighted average life (in years)	6.07		4.26	
Weighted average volatility	90.8%		118.6%	
Expected dividend yield	0%		0%	
Weighted average grant-date fair value per share of options granted	\$ 0.72	\$	0.61	

A summary of stock option activity for the nine months ended September 30, 2011 is presented below:

		Weighted					
		Average					
		Weighted Remaining			Aggregate		
		Average Contractual				Intrinsic	
Number of		Exercise Life		Value			
Shares		Price (year		(years)	(1)		
Balance at December 31, 2010 (2)	7,971,949	\$	1.11	7.35	\$	799,169	
Options Granted (3)	380,000	\$	0.97	9.78		-	
Exercised	(500,000)		0.75	-		-	
Forfeited/Cancelled	(1,602,656)	\$	0.91	-		-	
Balance at September 30, 2011	6,249,293	\$	1.19	7.75	\$	2,903,275	
Options exercisable as							
of September 30, 2011	3,302,928	\$	1.43	6.54	\$	1,253,021	
Unvested as of September 30,							
2011	2,946,365	\$	0.92	9.11	\$	1,650,254	

- (1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$1.46 of the Company's Common stock at September 30, 2011.
- (2) Includes 1,500,000 non-qualified options and 950,000 incentive stock options that were issued outside the 2005 and 2009 stock option plans.
- (3) Includes 75,000 non-qualified options that were issued outside the 2005 and 2009 stock option plans.

Patient Safety Technologies, Inc.

Notes to Condensed Consolidated Interim Financial Statements

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. The total grant date fair value of stock options granted during the three and nine months ended September 30, 2010 was \$103 thousand and \$937 thousand, respectively. For the three and nine months ended September 30, 2011 stock based compensation was \$177 thousand and \$513 thousand, respectively. For the three and nine months ended September 30, 2010, stock based compensation was \$161 thousand and \$965 thousand, respectively.

As of September 30, 2011, there was \$2.1 million of unrecognized compensation costs related to outstanding employee stock options. This amount is expected to be recognized over a weighted average period of 3 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

A Plus International, Inc.

During the three and nine months ended September 30, 2011 the Company had purchases of approximately \$1.1 million and \$3.0 million in connection with the manufacture of surgical products by A Plus used in the Safety-Sponge® System. At September 30, 2011, the Company's accounts payable included \$856 thousand owed to A Plus in connection with the purchase of surgical products used in the Safety-Sponge® System.

Please also see discussion under "Common Stock Private Placement" in Note 6 Stockholders Equity and warrant exchange in Note 13 Subsequent Events.

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

### **Major Customers**

During the three and nine months ended September 30, 2011, due to its exclusive distribution agreement with Cardinal Health, the Company had one customer (Cardinal Health) that represented in excess of 99% of total revenue, compared with 97% and 98% for the same respective periods in 2010. At both September 30, 2011 and December 31, 2010, Cardinal Health accounted for approximately 99%, of our accounts receivable.

### Suppliers

The Company relies on a related party third-party exclusive 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

### **Operating Leases**

In September, 2010, the Company entered into a 36 month lease agreement for approximately 5,600 square feet of office space in Irvine, CA which expires December 31, 2013. Monthly lease payments for the remaining lease term of this lease are approximately \$9 thousand. In January 2010, previous management temporarily relocated our headquarters to 5 Caufield Place, Suite 102, Newtown, PA 18940, where they entered into a sublease on December 31, 2009 for 5,670 square feet of office space for approximately \$11 thousand per month. In November 2010, the Company entered into a sub-sublease with a sub lessee to take over the space where they agreed to sub-sublease the space through the remaining term of our sublease or through to April 30, 2013, paying approximately \$8 thousand per month.

### Contingent Tax Liability

In 2009, during the process of preparing the Company's federal tax returns for prior years, the Company's management found there had been errors in reporting income to the recipients and the respective taxing authorities, related to stock grants made to those certain employees and consultant recipients. In addition, the Company determined that required tax withholding relating to these stock grants had not been made, reported or remitted, as required in fiscal years 2006 and 2007. Due to the Company's failure to properly report this income and withhold/remit required amounts, the Company may be held liable for the amounts that should have been withheld plus related penalties and interest. The Company had estimated its contingent liability based on the estimated required federal and state withholding amounts, the employee and employer portion of social security taxes as well as the possible penalties and interest associated with the error. Although the Company's liability may ultimately be reduced if it can prove that the taxes due on this income were paid on a timely basis by some or all of the recipients, the estimated liability including estimated interest and penalties, accrued by the Company is based on the assumption that it would be liable for the entire amounts due to the uncertainty with respect to whether or not the recipients made such payments.

During the quarter ended June 30, 2011, the Company reduced the tax contingent liability by \$223 thousand as the Company determined that it is improbable that it could be held liable for this amount owed related to the 2006 and 2007 tax years, which resulted in a \$223 thousand gain recorded as other income. The Company had also previously agreed to set aside restricted cash in an escrow account for satisfying any potential liability. Given the tax liability is improbable during the third quarter of 2011 the Company had the \$223 thousand of restricted cash released from the escrow account. As of September 30, 2011, the contingent tax liability was \$0, reflecting that the Company no longer expects to have any liability for the taxes not withheld.

### **Legal Proceedings**

The Company is or may become involved in various litigation matters as a claimant and a defendant. The Company records any amounts recovered in these matters when received. The Company records liabilities for claims against us when the loss is probable and estimable. Amounts recorded, if any, are based on reviews by outside counsel, in-house counsel and management. Actual results could differ from estimates.

On October 15, 2001, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. filed a lawsuit against the Company, Sunshine Wireless, LLC ("Sunshine"), and four other defendants affiliated with Winstar Communications, Inc. This lawsuit alleged that the Winstar defendants conspired to commit fraud and breached their fiduciary duty to the

plaintiffs in connection with the acquisition of the plaintiff's radio production and distribution business. The complaint further alleged that the Company and Sunshine joined the alleged conspiracy. On February 25, 2003, the case against the Company and Sunshine was dismissed. However, on October 19, 2004, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. exercised their right to appeal. On June 1, 2005, the United States Court of Appeals for the Second Circuit affirmed the February 25, 2003 judgment of the district court dismissing the claims against the Company.

On July 28, 2005, Jeffrey A. Leve and Jeffrey Leve Family Partnership, L.P. filed another lawsuit against the Company, Sunshine and four other defendants affiliated with Winstar. That lawsuit attempted to collect a federal default judgment of \$5 million entered against two entities, Winstar Radio Networks, LLC and Winstar Global Media, Inc., by attempting to enforce the judgment against the Company and others under the doctrine of de facto merger. Sunshine was dismissed from the case. The action was tried before a Los Angeles County Superior Court judge, without a jury, in 2008. On August 5, 2009, the Superior Court issued a statement of decision in the Company's favor. On October 8, 2009, the Superior Court entered a complete defense judgment in the Company's favor, and judged plaintiffs' responsible for \$2,708.70 of the Company's court costs. On November 6, 2009, the plaintiffs filed a notice of appeal, appealing the case to the California Court of Appeal. On June 15, 2011, the Court of Appeal of the State of California, Second Appellate District ruled in our favor affirming the trial court's defense judgment. The plaintiffs then filed a petition for review with the California Supreme Court. On August 31, 2011, the California Supreme court denied the plaintiff's petition for review. The Court of Appeal issued remittitur on September 8, 2011, confirming that the Court of Appeal ruling affirming the defense judgment had become final. Accordingly, we believe the lawsuit against the Company is successfully concluded with no liability against the Company.

### 13. SUBSEQUENT EVENTS

Management has evaluated events subsequent to September 30, 2011 through the date that the accompanying financial statements were filed with the Securities and Exchange Commission for transactions and other events which may require adjustment of and/or disclosure in such financial statements. Management has no subsequent events to report except for between October 14, 2011 and November 2, 2011 the Company entered into warrant exchange agreements and amended warrants with three holders of outstanding warrants to purchase the Company's common stock, one of whom included Brian E. Stewart, the Company's President and Chief Executive Officer. The exchanges, which were approved by the Company's Board of Directors with Mr. Stewart abstaining, was effected pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and involved exchanging warrants for 511,767 shares in the aggregate that contained certain anti-dilution features which created derivative liability accounting treatment. As the sole consideration for eliminating these anti-dilution features from these warrants, the warrant holders received, in exchange for their old warrants, new warrants for an additional 51,177 shares in the aggregate (i.e., the total shares subject to the warrants became 562,944 as of the date of the exchanges). The new warrants have an exercise price of \$0.75, and all other terms of the original warrants remained unchanged. The warrant exchange was completed on November 2, 2011.

# 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, 2010 (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 estimate that over 59 million of our Safety-Sponges® have been successfully used in more than 2.8 million surgical procedures. We sell our Safety-Sponge® System to hospitals through our direct sales force and by leveraging the sales and marketing capabilities of our distribution partners. Our proprietary line of surgical sponges and towels are manufactured for us by our exclusive manufacturer, A Plus, a leading China-based manufacturer of disposable medical and surgical supplies. Our sponge and towel products are distributed through Cardinal Health, who provides us sales, marketing and logistics support and the fulfillment of our products to our end user hospitals by both delivering our products directly to our end user hospitals and where appropriate through alternative distributors. Once implemented, the vast majority of our user hospitals use the Safety-Sponge® System across all of their relevant surgical and OB/GYN procedures.

Subsequent to the resignation of our previous President and Chief Executive Officer and four other board members at the end of the second quarter 2010, during the third quarter of 2010 newly appointed management implemented a comprehensive restructuring program focused on a number of initiatives, including the reduction of operating expenses and other initiatives designed to achieve positive operating income and operating cash flow. Restructuring activities included the elimination of certain job positions, lowering executive and employee cash compensation levels, refining and enforcing expense and travel policies, initiating expense measurement systems and increasing accountability across various functional areas. As a result of a number of factors, primarily the continued growth of the Company's revenue from both delivery of Cardinal Health's forward stocking inventory (as discussed in "Cardinal Health Supply Agreement" below) and the increased number of hospitals using the Company's products, combined with the impact on operating expenses from the restructuring initiative, the Company reported positive operating income during the quarter ended September 30, 2010, the first period of positive reported operating income in the history of the Company's ownership of SurgiCount since 2005, and the first reporting period under newly appointed management.

During the third quarter of 2011, the number of institutions using our products surpassed 78 and the Company lost no customers. This compares to approximately 57 institutions using our products at the end of the third quarter of 2010. We generated revenue of \$2.2 million and \$4.1 million during the three months ended September 30, 2011 and 2010, respectively. Our three months ended September 30, 2011 and 2010 revenue included approximately \$0 and \$2.5 million respectively, of revenue from the fulfillment of a \$10.0 million forward stocking order in accordance with the terms of our exclusive distributor arrangement with Cardinal Health ("the Forward Order"). Excluding revenue recognized from the fulfillment of the Forward Order, during the nine months ended September 30, 2011 and 2010 we

generated revenue of approximately \$5.6 million and \$4.4 million, respectively. Under certain circumstances the Forward Order inventory held by Cardinal Health could negatively impact our future 2012 revenue and cash flows. Please refer to our section in this Form 10-Q below in the section called "Factors Affecting Future Results—Cardinal Health Supply Agreement" for more information on the potential impact of the Forward Order.

### 13D Event and Subsequent Restructuring

On April 9, 2010 our current President and Chief Executive Officer, co-founder of our wholly-owned operating subsidiary SurgiCount Medical and co-inventor of our Safety-Sponge® System, Brian E. Stewart, filed a Form 13D with the Securities and Exchange Commission ("SEC") on behalf of himself and certain other stockholders of the Company. The stockholders represented included two of the Company's existing directors and the other co-founder of SurgiCount Medical and co-inventor of the Safety-Sponge® System and collectively represented a sufficient number of shares of the Company's stock outstanding to demand that the Company call a special meeting of stockholders with the express purpose of affecting significant and immediate change by removing five of the then standing directors of the board, including the then President and Chief Executive Officer. As a direct result of this stockholder driven effort, on June 24, 2010, the five designated members of the board of directors resigned and Brian E. Stewart was appointed as President and Chief Executive Officer and as a Director of the Company.

### **Factors Affecting Future Results**

### 130+ Hospital Integrated Delivery Network Agreement

The Company announced on September 28, 2011 that it signed an agreement, effective October 1st 2011, to implement the SurgiCount Safety-Sponge® System in one of the largest hospital operators in the U.S. Though the agreement itself does not call for a minimum number of hospitals, SurgiCount and the operator are actively planning for the implementation of the Safety-Sponge® System across all of the more than 130 hospitals that it operates. Ultimate SurgiCount Safety-Sponge® sales to these more than 130 hospitals will be distributed through Cardinal Health. Including hospitals already using the Safety-Sponge® System, the addition of these incremental hospitals is expected to bring the total number of hospitals using the SurgiCount Safety-Sponge® System to over 200.

### Cardinal Health Supply Agreement

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

In November 2009, we renewed our distribution relationship with Cardinal Health through the execution of a new Supply and Distribution Agreement. This new agreement had a five-year term to 2014 and named Cardinal Heath as the exclusive distributor in the United States, Puerto Rico, and Canada of the current products used in our proprietary Safety-Sponge® System. Though Cardinal Health is our exclusive distributor in these geographical areas, the terms of our agreement with Cardinal Health do not limit the sales of our products to only direct customers of Cardinal Health. Our products are available to every hospital that wishes to purchase them through their existing distribution relationships, whether that is with Cardinal Health or a competitor. In the event an end user hospital customer of ours does not have a distribution relationship with Cardinal Health, Cardinal Health 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 \$10.0 million forward stocking purchase order for products used in our Safety-Sponge® System that called for deliveries of that stocking inventory over a 12-month period (which is the Forward Order described above under Overview section). Cardinal Health 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 pay for product when A Plus invoices the Company for the Forward Order. Cardinal Health also agreed to place a second \$5.0 million forward stocking purchase order prior to the end of the third quarter of 2010, based on whether the Company achieved certain conditions, including a minimum targeted customer sales threshold. Both Cardinal Health and the Company jointly agreed in late 2010 not to go forward with this second forward stocking purchase order. Cardinal Health also agreed to maintain normal ordering patterns and volumes for purchasing our Safety-Sponge® products throughout 2010 and not to use any of the inventory delivered under the Forward Order to meet immediate hospital demand. In late 2010 Cardinal Health requested to change the product mix of the Forward Order. We agreed to this change, however because the products Cardinal Health requested were not immediately available, Cardinal Health agreed to take delivery of the remaining inventory on a modified schedule. As of June 30, 2011, we had fully delivered the entire \$10 million of product under the Forward Order. Accordingly, no revenue from the Forward Order was recognized during the quarter ended September 30, 2011 and we expect no further revenue from the Forward Order in future periods.

In March 2011, we and Cardinal Health signed an amendment to the Supply and Distribution agreement (the "Amended 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 what excess inventory is of our products held by Cardinal Health. Cardinal Health has agreed to not sell any of the Forward Order inventory until 2012, and we have agreed to a methodology for how Cardinal Health will sell this inventory to our customers, so there is a more orderly release throughout 2012 that more reasonably minimizes its impact to the Company's revenue during 2012. In addition, the Amended Supply and Distribution Agreement gives the Company the right to buy-back at cost any inventory of our products held by Cardinal Health that exceeds 60 days worth of sales. All other terms remain the same.

Because of the delivery of \$1.1 million of the Forward Order inventory during the first two quarters of 2011, our reported revenue for the nine months ended September 30, 2011 of \$6.7 million represented more revenue than what we otherwise would have recognized had we filled only orders from Cardinal Health strictly related to filling routine customer demand. During the third quarter of 2011 we recognized \$2.2 million of revenue from the delivery of inventory to Cardinal Health for fulfilling routine customer demand. Our revenue from Cardinal Health is impacted by a number of factors, including but not limited to Cardinal Health's inventory management practices including how much inventory it chooses to maintain throughout its distribution warehouse system and the timing of how it chooses to order product (through recurring standing purchase orders, planned inventory reductions, etc), and its expectations regarding the timing of when new customers will start ordering product.

Should Cardinal Health have any excess inventory on January 1, 2012 and begin selling the excess inventory it holds to partially meet routine customer demand, our reported revenue and cash flows will be negatively affected. The magnitude this negative impact could have on our 2012 revenue and cash flows will depend on a number of factors, including but not limited to, how much excess inventory Cardinal Health actually has on hand in 2012, whether the Company chooses to purchase some or all of this excess inventory at cost, and what our actual revenue growth rates are during 2011 and 2012. Actual revenue during 2011 and 2012 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 the Company will consider this option should an appropriate opportunity arise. While we have not provided any estimates of 2011 or 2012 revenue growth, in order to prevent a significant negative impact to 2012 reported revenue and cash flows, (i) the Company would need to experience substantial growth in the number of hospitals using its products during 2011 and 2012, (ii) the Company would need to buy back any excess inventory from Cardinal Health or (iii) Cardinal Health would need to decide not to use its excess inventory to partially meet routine customer demand. If the Company were to buyback excess inventory from Cardinal Health, it also could have a significant negative impact to our earnings, financial position and liquidity.

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

Our exclusive distribution agreement with Cardinal Health results in all of our revenue coming from orders placed by Cardinal Health. Cardinal Health has discretion in the timing and quantities with the orders they place, subject only to the limits contained in our agreements with them. As a result, our revenue may not necessarily correlate with the actual growth of our underlying customer base. In addition, our revenue can be materially impacted by the size of new customer hospital systems being implemented and the expected timing of those implementations by us and our distribution partners. Size of hospital systems connotes the number of actual hospitals that are a part of the hospital system and the number of surgical procedures that are performed at each hospital. Implementations with our large hospital system customers like the Mayo Clinic in Rochester or the Cleveland Clinic in 2009 had a material impact on our reported revenue and revenue growth for the year 2009. The timing of when these larger hospital system implementations are expected to occur also have a significant impact on our annual reported revenue, as both we and our distribution partners attempt to ensure adequate inventory on hand to accommodate them. The decision process that our distribution partner Cardinal Health uses in determining when to place orders is complex and subject to significant judgment. If those judgments prove incorrect or are inconsistent with our business needs or expectations, our revenue may be materially adversely impacted. For example, some of the factors that go into these judgments include, but are not limited to: (i) the size of some new pending and possible customers, (ii) the distribution agreements new pending and possible hospital customers have with their distribution partners, (iii) the multiple formats our products need to be available in (Single Sterile and Bulk Non Sterile), and (iv) the location of the manufacturing facilities of our China based manufacturing partner and the lead times needed in manufacturing our products. In addition, although growth in the number of customer hospitals is a relevant general indicator of growth in our business and customer acceptance of our products, it is not necessarily proportional to future revenue. Because revenue growth is impacted by a variety of factors, including the number of actual customers represented by the hospitals using our products, the number of procedures such hospitals actually perform, the timing of orders for our products and the other factors can impact our reported customer revenue described in this report and in our Annual Report on Form 10-K for our most recent fiscal year.

Reduction in Hardware Revenue – Effect on Revenue and Cost of Revenue.

Prior to the third quarter of 2009, our business model included selling our SurgiCounter<sup>TM</sup> scanners and related software used in our Safety-Sponge® System to most hospitals that adopted our system. Beginning with the third quarter of 2009, we modified our business model and began to provide our SurgiCounter<sup>TM</sup> scanners and related software to all hospitals at no cost when they adopt our Safety-Sponge® System. Because we no longer engage in direct SurgiCounter<sup>TM</sup> scanner sales and generally anticipate only to recognize revenue associated with our SurgiCounter<sup>TM</sup> scanners in connection with reimbursement arrangements we have with Cardinal Health under our agreement with them, SurgiCounter<sup>TM</sup> scanners no longer represent a significant source of revenue for our company. In 2010 and 2009, surgical sponge revenue accounted for 99% and 94% of our revenue, respectively and hardware revenue accounted for 1% and 6%, respectively. In addition to its effect on our revenue, this change also affected our costs of revenue because rather than recognizing the full product cost for all SurgiCounter<sup>TM</sup> scanners at the time of shipment in our cost of revenue, we now recognize only the depreciation expense for those SurgiCounter<sup>TM</sup> scanners provided to hospital clients. This business model change led to an improvement in our gross margin in the year ended December 31, 2009, and further improvement in 2010. However going forward, we anticipate that there will be a negative impact on our gross margins from increased non-cash depreciation expense in our cost of revenue from the growing number of scanners that we give to customers in the field, which will temporarily cause our gross margins to trend lower. We expect that this negative impact on gross margin from scanner depreciation will eventually be offset by sponge and towel revenue growth, which will increase and dilute the negative impact from depreciation.

### Sources of Revenue and Expenses

### Revenue

We generate revenue primarily from the sale of surgical sponges and towels used in our Safety-Sponge® System to our exclusive distributor, Cardinal Health, who then sells directly and through alternative distributors to hospitals that have adopted our Safety-Sponge® System. 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. Generally, the expected term of the customer contracts and the estimated useful life of the scanners are both 3 years. 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. Note that because of the way our revenue cycle works there is typically a lag between the time we begin incurring costs associated with our new customer arrangements subsequent to when we begin generating revenue from such arrangements. 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.

### 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 have historically included a reserve expense for obsolete and slow moving inventory in cost of revenue. In addition, when we provide scanners to hospitals for their use (rather than sell), we include only the depreciation expense of the scanners in cost of revenue (not the full product cost). 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 revenue 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. 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. There was a reclassification starting in 2010 of certain personnel-related expenses to sales and marketing expenses.

### Sales and marketing expenses

Our sales and marketing expenses consist primarily of salaries and related employee benefits, sales commissions and support costs, costs for performing controlled marketing trials of our SurgiCount system to prospective customers, professional service fees, travel, education, trade show and marketing costs.

### General and administrative expenses

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

### Total other income (expense)

Historically our total other income (expense) primarily reflects changes in the fair value of warrants classified as derivative liabilities. Under applicable accounting rules (discussed below under "—Critical Accounting Policies—Warrant Derivative Liability"), we are required to make estimates of the fair value of our warrants each quarter, and to record

the change in fair value each period in our statement of operations. As a result, changes in our stock price from period to period result in other income (when our stock price decreases) or other expense (when our stock price increases) on our income statement.

### Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, 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.

### Warrant Derivative Liability

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

### Goodwill

Our goodwill represents the excess of the purchase price over the estimated fair values of the net tangible and intangible assets of SurgiCount Medical, Inc., which we acquired in February 2005. We review goodwill for impairment at least annually in the fourth quarter, as well as whenever events or changes in circumstances indicate its carrying value may not be recoverable. We are required to perform a two-step impairment test on goodwill. In the first step, we will compare the fair value to its carrying value. If the fair value exceeds the carrying value, then goodwill will not be considered impaired and we are not required to perform further testing. If the carrying value exceeds the fair value, then we must perform the second step of the impairment test in order to determine the implied fair value of goodwill and record an impairment loss equal to the difference. Determining the implied fair value involves the use of significant estimates and assumptions. These estimates and assumptions include revenue growth rates and operating margins used to calculate projected future cash flows, risk-adjusted discount rates, future economic and market conditions and determination of appropriate market comparables. We base our fair value estimates on assumptions we believe to be reasonable but that are unpredictable and inherently uncertain. Actual future results may differ from those estimates. To the extent additional events or changes in circumstances occur, we may conclude that a non-cash goodwill impairment charge against earnings is required, which could have an adverse effect on our financial condition and results of operations.

### **Stock-Based Compensation**

We recognize compensation expense in an amount equal to the estimated grant date fair value of each option grant, or stock award over the estimated period of service and vesting. This estimation of the fair value of each stock-based grant or issuance on the date of grant involves numerous assumptions by management. Although we calculate the fair

value under the Black Scholes option pricing model, which is a standard option pricing model, this model still requires the use of numerous assumptions, including, among others, the expected life (turnover), volatility of the underlying equity security, a risk free interest rate and expected dividends. The model and assumptions also attempt to account for changing employee behavior as the stock price changes and capture the observed pattern of increasing rates of exercise as the stock price increases. The use of different values by management in connection with these assumptions in the Black Scholes option pricing model could produce substantially different results.

# Impairment of Long-Lived Assets

Our management reviews our long-lived assets with finite useful lives for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We recognize an impairment loss when the sum of the future undiscounted net cash flows expected to be realized from the asset is less than its carrying amount. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Considerable judgment is necessary to estimate the fair value of the assets and accordingly, actual results could vary significantly from such estimates. Our most significant estimates and judgments relating to the long-lived asset impairments include the timing and amount of projected future cash flows.

## Accounting for Income Taxes

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

We have measured and recorded uncertain tax positions in accordance with rules that took effect on such date that prescribe a threshold for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Accordingly, we now only recognize (or continue to recognize) tax positions meeting the more-likely-than-not recognition threshold (or that met such threshold on the effective date). Accounting for uncertainties in income tax positions involves significant judgments by management. If actual results differ from management's estimates, we may need to adjust the provision for income taxes.

# **Recent Accounting Pronouncements**

For a discussion regarding recent accounting pronouncements, see Note 2 to our condensed consolidated interim financial statements, appearing elsewhere in this quarterly report on Form 10-Q.

### **Results of Operations**

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010

During the third quarter of 2011, the number of hospitals using our products surpassed 78 hospitals, and the Company lost no customers. This compares to approximately 57 hospitals using our products at the end of the third quarter of 2010. 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, 2011 was \$2.2 million. This compared with total revenue for the three months ended September 30, 2010 of \$4.1 million a decrease of 47%, which consisted of approximately \$2.5 million of revenue from filling a \$10 million Forward Order to our exclusive distributor, Cardinal Health (see Factors Affecting Future Results – Cardinal Health Supply Agreement). Excluding the effect of the Forward Order, revenue for the three months ended September 30, 2010 would have been \$1.6 million. Accordingly, excluding the effect of the Forward Order, revenues for the three months ended September 30, 2011 were 38% higher than revenues in the comparable 2010 period. This increase in revenue (excluding the effect of the Forward Order) reflected a 37% growth experienced in the number of new customer hospitals as compared to the number of hospitals we had as customers at the end of third quarter 2010.

Our revenue of \$2.2 million to Cardinal Health during the third quarter 2011 did not include any revenue from the Forward Order, as we completed filling the last of this \$10 million Forward Order in the second quarter of 2011. In addition, our third quarter 2011 revenue of \$2.2 million did not include an outstanding sales backorder at the quarter-end of approximately \$500 thousand, which we anticipate fulfilling in the fourth quarter of 2011. Although the backorder revenue cannot be recognized in the third quarter, because the backorder relates to an order placed in the third quarter, management believes the combined amount of this backorder, together with the \$2.2 million of third quarter non-Forward Order revenue is a reasonable approximation of underlying customer demand for our surgical sponges and towels. At the same time, while the additional \$500 thousand of backorder revenue is expected to be recognized in the fourth quarter, management regards such backorder as being reflective of third quarter customer demand. As discussed in the section "Factors Effecting Future Revenue", historically there have been a number of factors within Cardinal Health's control that have affected our level of non-Forward Order revenue to Cardinal Health, resulting in making it difficult to measure customer demand levels. On September 29, 2011 we announced the contract signing of a 130 hospital Integrated Delivery Network ("IDN") whose implementations will be starting in the fourth quarter 2011 and throughout 2012.

#### Cost of revenue

Cost of revenue of \$1.2 million decreased by \$0.8 million or 39% for the three months ended September 30, 2011 as compared to cost of revenue of \$2.0 million for the same period in 2010. This decrease was mostly the impact from having Forward Order revenue of \$2.5 million during the third quarter of 2010, and \$0 Forward Order revenue in the third quarter 2011. In addition, our cost of revenue in the third quarter of 2011 was impacted by a growing amount of scanner hardware non-cash depreciation resulting from no longer primarily selling the hardware used with our Safety-Sponge® System (see "Factors Effecting Future Results — Reduction in Hardware Revenue"). Our cost of revenue as a percentage of revenue increased to 54% during the third quarter 2011 as compared to 47% in the third quarter 2010. This increase in cost of revenue was primarily attributable to higher non-cash depreciation expense included in our cost of revenue in the third quarter of 2011, as compared to the third quarter of 2010, reflecting larger amounts of hardware purchased by the Company to support new hospital implementations. Our cost of revenue during the third quarter 2011 included depreciation expense and other related equipment costs totaling \$132 thousand, while our third

quarter 2010 cost of revenue included depreciation and other related equipment costs totaling \$77 thousand, a 71% increase.

## Gross profit

Gross profit totaled \$1.0 million for the three months ended September 30, 2011, a decrease of \$1.2 million, or 54%, compared to gross profit of \$2.2 million during the third quarter of 2010. The primary reason for the year over year decrease was not having any Forward Order revenue to Cardinal Health during the third quarter 2011, while Forward Order revenue during the quarter ended September 30, 2010 generated gross profit of \$1.3 million. In addition, our gross profit for the quarter ended September 30, 2011 as compared to the quarter ended September 30, 2010 was negatively impacted by higher non-cash depreciation expense from growth in the number of scanners given to customers, along with the impact of A Plus increasing our costs for sponges and towels effective in January 2011.

### Operating expenses

Operating expenses totaled \$1.5 million for the quarter ended September 30, 2011, an increase of \$277 thousand, or 22%, compared to \$1.2 million of operating expenses during the same period in 2010. The increases were due to organizational growth to support our expanding business.

# Research and development expenses

Research and development expenses totaled \$1 thousand for the quarter ended September 30, 2011, a decrease of \$34 thousand, or 96%, compared to \$35 thousand during the same period in 2010. The decrease year over year primarily reflected current management's restructuring activities that were initiated during the third quarter of 2010.

## Sales and marketing expenses

Sales and marketing expenses totaled \$716 thousand for the quarter ended September 30, 2011, an increase of \$198 thousand, or 38%, compared to \$519 thousand during the same period in 2010. The increase in sales and marketing expenses during the third quarter of 2011 as compared to the prior year quarter was mostly due to growth in resources used to support our expanding business, including customer service support and field clinical support costs. Field clinical support costs include compensation and related travel expenses for having specialized Registered Nurses ("OR-RN's") support clinical trial demonstrations of our products, as well as implementation training. The number of clinical trials to facilitate sales of our Safety-Sponge® System grew considerably during the third quarter 2011.

## General and administrative expenses

General and administrative ("G&A") expenses totaled \$806 thousand for the quarter ended September 30, 2011, representing an increase of \$113 thousand, or 16%, compared to G&A expenses of \$693 thousand during the same period in 2010. The increased G&A expenses in the third quarter 2011 as compared the third quarter of 2010 was due to adding headcount resources to support our expanding business and public company compliance expenses.

### Total other income (expense)

We reported other income of \$304 thousand for the quarter ended September 30, 2011, compared to other income of \$19 thousand for the quarter ended September 30, 2010. The largest change between the third quarter of 2011 and the third quarter of 2010 was the mark to market adjustment for the change in fair value of our warrant derivative liability. During the quarter ended September 30, 2011, the mark to market adjustment for our warrant derivative liability resulted in a gain of \$303 thousand, while the change for the quarter ended September 30, 2010 was a gain of \$16 thousand, resulting in an increase of \$288 thousand. As discussed above under "Critical Accounting Policies", certain warrants issued during past financings are required to be recorded as "derivative liabilities" and not as equity. Each reporting period we record increases and decreases in the estimated fair value of these warrants based on fluctuations in the price of our common stock and the number of warrants outstanding. When our stock price increases, it increases the liability resulting in the Company recording "other losses", while when there are decreases in our stock price it causes the liability to decrease resulting in the Company recording "other income". During the third quarter of 2011 the number of these "derivative liability" warrants outstanding decreased significantly, resulting in having a gain or "other income" of \$304 thousand.

#### **Provision for Income Taxes**

We had a \$3 thousand tax expense for the three months ended September 30, 2011, compared to a \$33 thousand tax benefit during the same three month period in 2010.

## Net income (loss)

We had a net loss of \$354 thousand applicable to common shareholders for the three months ended September 30, 2011 compared to a net income of \$962 thousand for the same period in 2010 for the reasons described above.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

#### Revenue

Total revenue for the nine months ended September 30, 2011 was \$6.7 million, which included \$1.1 million of product shipped to Cardinal Health under the Forward Order representing the final shipments under this stocking

arrangement with Cardinal Health (see "Factors Affecting Future Results —Cardinal Health Supply Agreement"). Total revenue during the nine months ended September 30, 2011 excluding the Forward Order revenue was \$5.6 million, an increase of 27% as compared to \$4.4 million during the same nine month period in 2010. This increase in non-Forward Order revenue reflected a 37% growth experienced in the number of new customer hospitals as compared to the number of hospitals we had as customers at the end of third quarter 2010. In addition, our exclusive distributor, Cardinal Health, began ordering product during the second and third quarter of 2011, at a level that management believes more closely aligns with routine customer demand. Revenue for surgical sponges and towels during the nine months ended September 30, 2011 accounted for 99% of revenue, while revenue from hardware accounted for only 1%, reflecting our change in strategy implemented during 2010 of providing scanners to customers at zero cost instead of selling scanners to them.

#### Cost of revenue

Cost of revenue for the nine months ended September 30, 2011 of \$3.5 million decreased \$1.3 million or 27%, as compared to cost of revenue of \$4.8 million during the same nine month period in 2010. This decrease in cost of revenue was due to lower cost of revenue related to Forward Order revenue during the nine months ended September 30, 2011. This decrease reflected the fact that the final \$1.1 million of sales to Cardinal Health under the \$10 million Forward Order arrangement occurred during the six months ended June 30, 2011, and most of this forward stocking order had been filled throughout 2010, leaving only \$460 thousand of cost of revenue related to product to be shipped during 2011. The cost of revenue related to non-Forward Order revenue was \$3.1 million during the nine months ended September 30, 2011, which was an increase of \$923 thousand compared to the \$1.9 million cost of revenue for similar revenue during the same nine month period in 2010, reflecting growth in our non-Forward Order revenue as described above.

### Gross profit

Gross profit of \$3.2 million for the nine months ended September 30, 2011 decreased by \$2.2 million, or 41%, compared to \$5.4 million during the same nine month period in 2010. The primary reason for this decrease in gross profit was the significant decrease in Forward Order related revenue, where only \$1.1 million of Forward Order revenue was recognized during the nine months ended September 30, 2011 compared to \$5.9 million of similar revenue during the same nine month period in 2010. In addition, there was higher non-cash depreciation expense included in our cost of revenue during the nine months ended September 30, 2011 as compared to the same nine months of 2010, which reflected a larger amount of hardware purchased by the Company to support new hospital implementations. Gross profit on Forward Order revenue for the nine months ended September 30, 2011 of \$0.6 million was \$2.5 million or 80% lower than the \$3.1 million of gross profit recognized on Forward Order revenue during the same nine month period in 2010. This decrease in gross profit related to Forward Order revenue that was filled primarily during 2010, with the final remaining \$1.1 million of shipments filled in early 2011. Total gross margin was 48% for the nine months ended September 30, 2011, compared to 53% for the same nine month period in 2010, which was primarily attributed to increased non-cash scanner depreciation expense from giving scanners to customers at no cost, as well the impact of a cost increase on our purchases of sponges and towels by our exclusive manufacturer, A Plus, that became effective January 1, 2011. This cost increase mostly reflected the higher cost of cotton and to a lesser extent, changes in the U.S. dollar exchange rate with the Chinese Yuan.

# Operating expenses

We had total operating expenses which included research and development, sales and marketing and G&A expenses, of \$5.0 million for the nine months ended September 30, 2011, a decrease of \$2.4 million, or 32%, compared to \$7.4 million for the same nine month period in 2010. This decrease in operating expense was due to the comprehensive restructuring implemented by current management during the third quarter of 2010, which was focused on a number of initiatives to reduce operating expenses and achieve operating income and positive cash flow. Restructuring activities included the elimination of certain job positions, lowering executive and employee cash compensation levels, refining and enforcing expense and travel policies and initiating expense controls and increased accountability across all functional areas.

### Financial Condition, Liquidity and Capital Resources

We had cash and cash equivalents of \$5.0 million at September 30, 2011 compared to \$1.9 million at December 31, 2010. As of September 30, 2011 we had total current assets of \$7.7 million and total current liabilities of \$2.9 million resulting in a positive working capital of \$4.8 million. Excluding the warrant derivative liability of \$0.5 million and the deferred revenue of \$0.3 million relating to hardware reimbursement payments from Cardinal Health, which are both noncash based liabilities, we had total adjusted current liabilities of \$2.1 million as of September 2011, giving us an adjusted positive working capital of \$5.6 million. We believe our sources of funding are sufficient to satisfy our anticipated cash requirements through at least the next 12 months. Although management does not have any plans to do so, we may seek additional financing to fund future growth for periods beyond the next 12 months, through future offerings of equity or 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 funding 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 for additional information that could impact our future liquidity and capital resources.

On March 29, 2011 and March 30, 2011, we closed a private placement financing raising \$7.1 million in gross proceeds through the issuance of 9.48 million shares of our \$0.33 par value common stock at a selling price of \$0.75 per share. The proceeds from the offering have been, and will continue to be used for general corporate purposes,

including paying down existing company liabilities and to invest in new initiatives to increase market penetration of our Safety-Sponge® System to hospitals throughout the U.S. and world-wide.

## Operating activities

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.

We used \$4.5 million of net cash from operating activities in the nine months ended September 30, 2010. Non-cash adjustments to reconcile net income to net cash used in operating activities of \$1.5 million plus changes in operating assets and liabilities of \$4.3 million for the nine months ended September 30, 2010. These significant non-cash adjustments primarily reflect adjustments to reflect the change in fair value of our warrant derivative liability, deferred revenue adjustments relating to shipments to Cardinal Health, and increased inventory balances. In 2011, we reclassified restricted cash transfers from being reported as financing activities to operating activities within our Condensed Consolidated Statement of Cash flows.

### Investing activities

We used \$527 thousand of net cash in investing activities during the nine months ended September 30, 2011, primarily for the purchase of scanners and related hardware used in our Safety-Sponge® System.

We used \$628 thousand of net cash in investing activities during the nine months ended September 30, 2010, primarily for the purchase of scanners and related hardware used in our Safety Sponge® System.

## Financing activities

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.

We generated \$4.5 million of net cash from financing activities in the nine months ended September 30, 2010, primarily from the net proceeds of the \$6.0 million issuance of Series B Convertible Preferred Stock in June 2010 (\$5.0 million in cash proceeds and \$1.0 million in reductions of our accounts payable), offset with the write-off of capital lease obligations following the closure of the Newtown, PA office, and the payment of preferred stock dividends.

### **Off-Balance Sheet Arrangements**

As of September 30, 2011, we had no off-balance sheet arrangements.

#### Commitments and Contingencies

As of September 30, 2011, 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 the design and operation 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, 2011. 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 this paragraph that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### PART II - OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

In Jeffrey A. Leve et al. v. Patient Safety Technologies, Inc et al., on August 31, 2011, the California Supreme court denied the plaintiff's petition for review. The Court of Appeal issued remittitur on September 8, 2011, confirming that the Court of Appeal ruling affirming the defense judgment had become final. Accordingly, the lawsuit against the Company is successfully concluded with no liability against the Company.

## ITEM 1A. RISK FACTORS

We are not aware of any material changes to the risk factors in Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2010.

# ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. (REMOVED AND RESERVED)

ITEM 5. OTHER INFORMATION

None.

### ITEM 6. EXHIBITS

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)*
32.1*	Certification of Chief Executive Officer and Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code*
EX-101.INS**	XBRL Instance document
EX-101.SCH**	XBRL Taxonomy Extension Schema Document
EX-101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB**	XBRL Taxonomy Extension Label Linkbase Document

EX-101.PRE\*\* XBRL Taxonomy Extension Presentation Linkbase Document

- \* Filed herewith.
- \*\* Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to the Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

## **SIGNATURES**

Pursuant to the requirements 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 14, 2011 By: /s/ Brian E. Stewart

Brian E. Stewart, President and

Chief

**Executive Officer** 

Date: November 14, 2011 By: /s/ David Dreyer

David Dreyer, Executive Vice

President,

Chief Financial Officer, and

Secretary