
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012.

OR

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

For the transition period from _____ to _____

Commission File Number: 1-11388

PLC SYSTEMS INC.

(Exact Name of Registrant as Specified in Its Charter)

Yukon Territory, Canada

(State or Other Jurisdiction of
Incorporation or Organization)

04-3153858

(I.R.S. Employer Identification No.)

459 Fortune Boulevard, Milford, Massachusetts

(Address of Principal Executive Offices)

01757

(Zip Code)

Registrant's telephone number, including area code: **(508) 541-8800**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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** **No**

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 8, 2012
Common Stock, no par value	31,809,428

PLC SYSTEMS INC.

Index

<u>Part I.</u>	<u>Financial Information:</u>	
	<u>Item 1.</u>	<u>Financial Statements</u>
		<u>Condensed Consolidated Balance Sheets (unaudited)</u> 3
		<u>Condensed Consolidated Statements of Operations (unaudited)</u> 4
		<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited)</u> 5
		<u>Condensed Consolidated Statements of Cash Flows (unaudited)</u> 6
		<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u> 7
	<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 22
	<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 30
	<u>Item 4.</u>	<u>Controls and Procedures</u> 31
<u>Part II.</u>	<u>Other Information:</u>	
	<u>Item 1A.</u>	<u>Risk Factors</u> 31
	<u>Item 5.</u>	<u>Other Matters</u> 31
	<u>Item 6.</u>	<u>Exhibits</u> 31

Table of Contents

Part I. Financial Information

Item 1. Financial Statements

PLC SYSTEMS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	<u>September 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 723	\$ 2,585
Accounts receivable, net of allowance of \$2 at September 30, 2012 and December 31, 2011, respectively	525	453
Inventories	235	238
Prepaid expenses and other current assets	224	233
Total current assets	<u>1,707</u>	<u>3,509</u>
Equipment, furniture and leasehold improvements, net	79	36
Other assets	4	4
Total assets	<u>\$ 1,790</u>	<u>\$ 3,549</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 231	\$ 149
Accrued compensation	35	63
Accrued other	314	221
Deferred revenue	394	277
Total current liabilities	<u>974</u>	<u>710</u>
Convertible notes	10,176	5,327
Warrant liabilities	5,700	1,600
Commitments and Contingencies (Note 12)		
Stockholders' deficit:		

Common stock, no par value, unlimited shares authorized, 31,809 shares issued and outstanding as of September 30, 2012 and 30,351 shares issued and outstanding as of December 31, 2011	93,893	93,893
Additional paid in capital	1,429	996
Accumulated deficit	(110,115)	(98,727)
Accumulated other comprehensive loss	(267)	(250)
Total stockholders' deficit	(15,060)	(4,088)
Total liabilities and stockholders' deficit	\$ 1,790	\$ 3,549

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

3

[Table of Contents](#)

PLC SYSTEMS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues	\$ 212	\$ 27	\$ 595	\$ 482
Cost of revenues	84	17	308	355
Gross profit	128	10	287	127
Operating expenses:				
Selling, general and administrative	674	591	1,899	1,850
Research and development	549	312	1,618	759
Total operating expenses	1,223	903	3,517	2,609
Gain on the sale of assets	—	—	—	(40)
Loss from continuing operations	(1,095)	(893)	(3,230)	(2,442)
Other income (expense):				
Interest expense	(137)	(116)	(369)	(277)
Foreign currency transaction gain	17	—	2	—
Financing costs associated with convertible notes	(80)	—	(80)	(530)
Change in fair value of warrant liabilities	(1,117)	232	(3,517)	(872)
Change in fair value of convertible notes	(757)	376	(4,218)	(1,840)
Other income	4	—	24	—
Total other (expense) income	(2,070)	492	(8,158)	(3,519)
Net loss from continuing operations before income taxes	(3,165)	(401)	(11,388)	(5,961)
Benefit for income taxes from continuing operations	—	—	—	492
Net loss from continuing operations, net of income taxes	(3,165)	(401)	(11,388)	(5,469)
Discontinued operations:				
Income from discontinued operations, net of income taxes	—	—	—	53
Gain on sale of discontinued operations, net of provision for income taxes of \$492	—	—	—	687
Net income from discontinued operations, net of income taxes	—	—	—	740
Net loss	\$ (3,165)	\$ (401)	\$ (11,388)	\$ (4,729)
Net loss per weighted average share, basic and diluted:				
From loss on continuing operations attributable to common stockholders	\$ (0.10)	\$ (0.01)	\$ (0.37)	\$ (0.18)
From income on discontinued operations	—	—	—	0.00
From gain on sale of discontinued operations	—	—	—	0.02
Net loss attributable to common stockholders per weighted average share, basic and diluted	\$ (0.10)	\$ (0.01)	\$ (0.37)	\$ (0.16)
Weighted average shares outstanding:				
Basic and diluted	30,397	30,351	30,912	30,351

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

4

[Table of Contents](#)

PLC SYSTEMS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	\$ (3,165)	\$ (401)	\$ (11,388)	\$ (4,729)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	2	(14)	(17)	3
Other comprehensive (loss) income	2	(14)	(17)	3
Comprehensive loss	\$ (3,163)	\$ (415)	\$ (11,405)	\$ (4,726)

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

5

[Table of Contents](#)

PLC SYSTEMS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (11,388)	\$ (4,729)
Income from discontinued operations	—	(53)
Gain on sale of discontinued operations, net of taxes	—	(687)
Depreciation and amortization	31	3
Stock-based compensation expense	433	123
Change in fair value of warrant liabilities	3,517	872
Change in fair value of convertible notes	4,218	1,840
Financing costs associated with convertible notes	80	530
Non-cash interest expense	215	158
Deferred income taxes	—	(492)
Change in assets and liabilities:		
Accounts receivable	59	(122)
Inventory	3	108
Prepaid expenses and other assets	12	(86)
Accounts payable	82	(298)
Deferred revenue	109	(98)
Accrued liabilities	65	(41)
Net cash flows used in operating activities	(2,564)	(2,972)
Cash flows used for investing activities:		
Purchase of property and equipment	(74)	4
Net cash used for investing activities	(74)	4
Cash flows from financing activities:		
Net proceeds from issuance of convertible notes and warrants	920	3,605
Net cash provided by financing activities	920	3,605
Discontinued operations:		
Net cash provided by operating activities	—	210
Net cash provided by investing activities	—	1,000
Net cash provided by discontinued operations	—	1,210
Effect of exchange rate changes on cash and cash equivalents	(144)	3
Net (decrease) increase in cash and cash equivalents	(1,862)	1,850
Cash and cash equivalents at beginning of period	2,585	1,324
Cash and cash equivalents at end of period	\$ 723	\$ 3,174
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 154	\$ 122

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

6

[Table of Contents](#)

PLC SYSTEMS INC.

1. Business and Liquidity

PLC Systems Inc. (“PLC” or the “Company”) is a medical device company specializing in innovative technologies for the cardiac and vascular markets. Over the past four years, the Company has begun commercialization outside the United States (the “U.S.”) of its newest product, RenalGuard®, which currently represents the Company’s key strategic growth initiative and primary business focus. The RenalGuard System consists of a proprietary console and accompanying single-use sets and is designed to reduce the potentially toxic effects that contrast media can have on the kidneys when it is administered to patients during certain medical imaging procedures. The Company conducts business operations as one operating segment.

For the nine months ended September 30, 2012, the Company incurred a loss from continuing operations of approximately \$3,230,000, and used cash in operations of \$2,564,000. At September 30, 2012, the Company had an accumulated deficit of \$110,115,000. Management expects that quarterly losses and negative cash flows will continue during 2012 and beyond. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Based upon the current financial condition of the Company and the expectation of continued quarterly losses during 2012, management is currently investigating ways to raise additional capital that can be completed in the next few months. Subsequent to December 31, 2011, the Company reported that it had engaged a financial advisor to assist the Company in this effort. The Company was able to raise an additional \$1,000,000 in capital before issuance costs on July 2, 2012, through the completion of additional financing by the closing on the second tranche of convertible notes with GCP IV LLC (the “Investors” or “Holders”) (see Note 11). The Company will also continue to review its other expense areas to determine whether additional reductions in discretionary spending can be achieved.

The Company also believes that the publication of positive clinical results from two independent investigator-sponsored clinical trials in Italy, which show RenalGuard to be both a safe and effective product for reducing the incidence of Contrast-Induced Nephropathy (“CIN”) in at-risk patients, presents a substantial opportunity for it to increase its sales and achieve profitable results in the next few years, provided, among other factors, the Company is able to raise the additional capital it needs in the near term to sustain its operations and expand its RenalGuard sales and marketing programs and obtain approval by the U.S. Food and Drug Administration (“FDA”) to market RenalGuard in the United States.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. These financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011.

[Table of Contents](#)

The preparation of financial statements in accordance with generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

In the first quarter of 2011, the Company sold the assets related to its TMR business to Novadaq Corp., a subsidiary of Novadaq Technologies Inc., the Company’s then exclusive distributor of TMR in the U.S., for \$1,000,000 plus the relief of approximately \$614,000 in service contract obligations (see Note 10), and issued \$4,000,000 in secured convertible debt (see Note 11).

As a result of its sale in the first quarter of 2011, the operating results of the Company’s TMR business, including those related to the prior periods, have been reclassified from continuing operations to discontinued operations in the accompanying unaudited condensed consolidated financial statements (see Note 9).

3. Inventories

Inventories are stated at the lower of cost (computed on a first-in, first-out method) or market value and include allocations of labor and overhead. As of September 30, 2012 and December 31, 2011, inventories consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	\$ 227	\$ 157

Finished goods	8	81
	<u>\$ 235</u>	<u>\$ 238</u>

4. *Stock-Based Compensation*

Stock Option Plans and Restricted Share Issuance

In May 2005, the Company's shareholders approved the 2005 Stock Incentive Plan (the "2005 Plan"). Incentive stock options are issuable only to employees of the Company, while non-qualified stock options may be issued to non-employee directors, consultants and others, as well as to employees. Under the 2005 Plan, the per share exercise price of incentive stock options may not be less than the fair market value of the common stock on the date the option is granted. The 2005 Plan provides that the Company may not grant non-qualified stock options at an exercise price less than 85% of the fair market value of the Company's common stock.

The Company grants stock options to its non-employee directors. New non-employee directors receive an initial grant of an option to purchase 45,000 shares of the Company's common stock that generally vest in quarterly installments over three years. Once the initial grant has fully vested, non-employee directors (other than the Chairman of the Board) receive an annual grant of an option to purchase 22,500 shares of the Company's common stock that generally will vest in four equal quarterly installments. The Chairman of the Board receives an annual grant of an option to purchase 45,000 shares of the Company's common stock that generally vests in four equal quarterly installments. All such options have an exercise price equal to the fair market value of the Company's common stock on the date of grant.

During the three months ended September 30, 2012, the Company didn't grant any options to employees or non-employee directors.

During the three months ended June 30, 2012, the Company granted options to employees to purchase 355,000 shares of the Company's common stock, which vest ratably over a three year period and granted options to

8

[Table of Contents](#)

purchase 112,500 shares of the Company's common stock to non-employee directors that vest quarterly over one year.

As a result of employee terminations in the first quarter of 2011, options held by terminated employees to purchase a total of 173,000 shares of common stock with an exercise price of \$0.24 per share were cancelled, but were replaced by the Company with new options, all of which were immediately vested, to purchase 173,000 shares of common stock at an exercise price of \$0.24 per share. The Company recorded an additional \$2,000 in stock compensation expense related to these grants during the three months ended March 31, 2011.

During the year ended December 31, 2011, the Company granted options to purchase 565,000 shares of the Company's common stock to employees with performance-based vesting. Management determined that as of June 30, 2012, it was probable that the performance conditions associated with the performance-based vesting were to be met in July 2012 with the closing of the second tranche convertible notes. Therefore, the related expense was recorded in the six months ending June 30, 2012.

During the nine months ended September 30, 2012, the Company issued an aggregate of 1,458,336 shares of restricted common stock (625,000 shares as of the three months ended March 31, 2012, 208,334 shares as of the three months ended June 30, 2012 and 625,002 as of the three months ended September 30, 2012) to Garden State Securities, Inc. and JFS Investments, Inc., respectively, in exchange for certain investor relations and related consulting services to the Company. These shares vest immediately but are restricted from being sold for a period of six months from the date of issuance. The issuance of these shares resulted in \$123,000 and \$368,000 of compensation expense in the three and nine months ended September 30, 2012.

As of September 30, 2012, there were 674,156 shares of common stock available to be granted under the 2005 Plan.

The following is a summary of option activity under all plans (in thousands, except per option data):

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2011	5,602	\$ 0.21		
Granted	468	0.17		
Exercised	—	—		
Expired	(3)	0.55		
Forfeited	(475)	0.24		
Outstanding, September 30, 2012	<u>5,592</u>	<u>0.21</u>	3.42	158,700
Exercisable, September 30, 2012	<u>4,870</u>	<u>0.21</u>	2.54	111,065

Stock-Based Compensation Expense

The Company recorded compensation expense related to stock options of \$12,000 and \$65,000 in the three and nine months ended September 30, 2012, respectively, as compared to \$29,000 and \$123,000 in the three and nine months ended September 30, 2011, respectively. The Company also recorded compensation expense of \$123,000 and \$368,000 related to the issuance of restricted common

shares during the three and nine months ended September 30, 2012, respectively. As of September 30, 2012, the Company had \$76,000 of total unrecognized compensation cost related to its unvested options, which is expected to be recognized over a weighted average period of 1.94 years.

[Table of Contents](#)

The weighted average fair value of options issued, as estimated using the Black-Scholes model, was \$0.16 and \$0.11 during the nine months ended September 30, 2012 and 2011, respectively. The assumptions used were as follows:

	Grants Issued in:	
	2012	2011
Expected life (years)	5.00-6.00	1.00-6.00
Risk free rate	0.19-0.69%	0.27-2.65%
Volatility	204.1-216.2%	107.2-132.1%
Expected dividend yield	None	None
Value of options granted	\$0.12-0.17	\$0.01-0.13

The expected life was calculated using the simplified method. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of the grant for the expected term. Expected volatility is based exclusively on historical volatility data of the Company's common stock. The Company estimates an expected forfeiture rate by analyzing historical forfeiture activity and considering how future forfeitures are expected to differ from historical forfeitures. The Company expects that all outstanding options at September 30, 2012 will fully vest over their requisite service period. Actual results, and future changes in estimates, may differ substantially from the Company's current estimates.

Stock Purchase Plan

The Company has a 2000 Employee Stock Purchase Plan (the "Purchase Plan") for all eligible employees whereby shares of the Company's common stock may be purchased at six-month intervals at 95% of the average of the closing bid and ask prices of the Company's common stock on the last business day of the relevant plan period. Employees may purchase shares having a value not exceeding 10% of their gross compensation during an offering period, subject to certain additional limitations. There was no activity during the three and nine months ended September 30, 2012 or 2011. At September 30, 2012, 294,461 shares were reserved for future issuance under the Purchase Plan.

5. Revenue Recognition

The Company recognizes revenue when the following basic revenue recognition criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the price to the buyer charged for products delivered or services rendered and collectability of the sales price. The Company assesses credit worthiness of customers based upon prior history with the customer and assessment of financial condition. The Company's shipping terms are customarily Free On Board ("FOB") shipping point. The Company records revenue at the time of shipment if all other revenue recognition criteria have been met. As of September 30, 2012 and December 31, 2011, the Company had deferred revenue of \$394,000 and \$277,000, respectively of revenues related to shipments to its distributor in Italy, Artech, because not all revenue recognition criteria were met. During the three and nine months ended September 30, 2012, the Company recognized \$65,000 and \$126,000, respectively, in revenue of previously deferred revenue upon the receipt of cash from the customer.

6. Loss per Share

In the three and nine months ended September 30, 2012 and 2011, basic and diluted loss per share have been computed using only the weighted average number of common shares outstanding during the period without giving effect to any potential future issuances of common stock related to stock option programs, investor warrants

[Table of Contents](#)

or convertible notes, since their inclusion would be anti-dilutive.

For the three and nine months ended September 30, 2012, 50,047,785 and 47,096,392 shares attributable to outstanding warrants, convertible notes and stock options, and for the three and nine months ended September 30, 2011, 46,102,000 shares attributable to outstanding warrants, convertible notes and stock options were excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive.

7. Total Comprehensive Loss

Total comprehensive loss for the three and nine months ended September 30, 2012 was \$3,163,000 and \$11,405,000 as compared to \$415,000 and \$4,726,000 in the three and nine months ended September 30, 2011, respectively. Comprehensive loss is comprised of the

net loss plus the increase or decrease in currency translation adjustment.

8. *Warranty and Preventative Maintenance Costs*

The Company warrants its products against manufacturing defects under normal use and service during the warranty period. The Company evaluates the estimated future unrecoverable costs of warranty and preventative maintenance services for its installed base of products on a quarterly basis and adjusts its warranty reserve accordingly. The Company considers all available evidence, including historical experience and information obtained from supplier audits. There was no warranty liability recorded at September 30, 2012 or December 31, 2011.

9. *Sale of Assets*

In May 2010, the Company sold to a newly-formed corporation affiliated with its principal OEM customer certain of its OEM surgical tube assets, comprised principally of inventory, equipment, intellectual property and certain other intangible assets, as well as all necessary manufacturing documentation needed to perform contract assembly services for general purpose CO2 lasers. The total sale price for these assets was \$225,000, of which approximately \$154,000 was paid at the time of closing, with the balance in a note receivable totaling \$71,000. At the closing of the transaction and as of December 31, 2010, the note receivable was fully reserved. Following the sale, Dr. Robert I. Rudko, who was a director and a stockholder of the Company at the time, acquired a minority interest in the corporation that purchased the OEM assets. In conjunction with this transaction, in the year ended December 31, 2010, the Company recorded an initial gain on sale of assets of \$98,000. In March 2011, Dr. Rudko resigned from the Company's Board of Directors. Also in March 2011, the Company reached an agreement with the acquiring company to settle the note receivable at a reduced amount of \$40,000. This amount was collected in April 2011, and was recorded as a gain when cash was received during the second quarter of 2011.

10. *Sale of TMR Business to Novadaq/Discontinued Operations*

On November 5, 2010, the Company entered into an agreement to sell its TMR business to Novadaq. This transaction was approved by the Company's shareholders at a special meeting on January 31, 2011 and the transaction closed on February 1, 2011.

Under terms of the agreement, Novadaq acquired substantially all of the Company's assets that were used in the TMR business including all manufacturing rights, substantially all product inventories, and all equipment, intellectual property, regulatory approvals, clinical data and documentation related to TMR, for a purchase price of \$1 million in cash and the assumption of all the Company's obligations under service contracts as of the closing date totaling \$614,000. The total carrying value of the assets sold as of the transaction date was \$385,000. In addition, the Company incurred transaction costs of \$50,000. The Company has recorded a gain on sale of discontinued operations before income taxes of \$1,179,000 in the statement of operations.

[Table of Contents](#)

The operating results of these operations, including those related to the prior periods, have been reclassified from continuing operations to discontinued operations in the accompanying condensed consolidated financial statements.

Revenues and net income attributable to discontinued operations for the nine months ended September 30, 2011 are as follows:

	Nine months ended September 30, (In thousands) 2011
Revenues:	
Product sales	\$ 455
Service fees	68
Total	523
Income from discontinued operations	\$ 53

11. *Convertible Notes and Warrant Liabilities*

Features of the Convertible Notes and Investor Warrants

On February 22, 2011 (the "Original Issue Date"), the Company entered into a Securities Purchase Agreement ("Purchase Agreement") and a 5% Senior Secured Convertible Debenture Agreement (the "Note Agreement") with GCP IV LLC (the "Investors" or "Holders") pursuant to which the Company agreed to issue and sell in a private placement to the Investors an aggregate principal amount of \$4,000,000 of convertible notes due February 22, 2014 (the "Convertible Notes") and warrants to purchase up to 40,000,000 shares of common stock, which expire February 22, 2016 (the "Investor Warrants"). Under the terms of the Purchase Agreement, the Company had the opportunity to raise up to an additional \$2 million from the Holders of the Convertible Notes in two separate \$1 million tranches, based upon meeting certain operational milestones within certain periods of time. The deadline for achieving the operational milestones for the first \$1 million tranche expired in February 2012 without the Company achieving such milestones; however, as discussed below, the Investors agreed to waive both the deadline and the achievement of these milestones as a condition for the investment of the first additional \$1 million tranche ("Second Tranche") which was completed on July 2, 2012. The second additional \$1 million tranche is due to the Company upon achievement of the applicable operational milestones at any time prior to February 22, 2014.

Convertible Notes

The Convertible Notes require payment of interest on the outstanding principal amount, in cash, at the rate of 5% per annum, payable quarterly on January 1, April 1, July 1, and October 1, beginning on the first such date following the Original Issue Date, on each conversion date (for the principal amount then being converted), on each optional redemption date (for the principal amount then being redeemed) and on the maturity date. Interest is calculated on the basis of a 360-day year and accrues daily commencing on the Original Issue Date until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts that may become due in connection with the Convertible Notes, has been made.

The Holders may convert the outstanding principal amount of the Convertible Notes into shares of the Company's common stock at the conversion price of \$0.10 per share ("Conversion Price"). The Conversion Price is subject to adjustment in the event of (a) stock splits, stock dividends, combinations, reclassifications, mergers, consolidations, distributions of assets or evidence of indebtedness, sales or transfers of substantially all assets, share exchanges or similar events, and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the then Conversion Price.

[Table of Contents](#)

At any time after February 2012, and upon entering into a change of control transaction or Fundamental Transaction, as defined in the Debenture Agreement, the Company may deliver a notice to the Holders of its irrevocable election to redeem all of the then outstanding principal of the Convertible Notes for cash in an amount equal to the sum of (a) the greater of (i) the outstanding amount of the Convertible Notes divided by the Conversion Price on the date of the mandatory default amount, as defined in the Purchase Agreement, is either (A) demanded or (B) paid in full, whichever has a lower conversion price, multiplied by the Volume Weighted Average Price ("VWAP") of the date of the mandatory default amount is either (x) demanded or otherwise due or (y) paid in full, whichever has higher VWAP, plus all accrued and unpaid interest, or (ii) 130% of the outstanding principal amount of the Notes, plus 100% of accrued and unpaid interest, and (b) all other amounts, costs, expenses and liquidated damages due under the various agreements covering issuance of the Convertible Notes. Such amount would include the liquidated damages due under the default provision of the Purchase Agreement. As of September 30, 2012, the Company has elected to not deliver such notice.

The Company is required to repay, in cash, any outstanding principal amount of the Convertible Notes on February 22, 2014 and is not permitted, except upon entering into a change of control transaction or fundamental transaction as noted above, to prepay any portion of the principal amount without prior written consent of the Holders.

Investor Warrants

On February 22, 2011, the Company issued warrants for the purchase of up to 40,000,000 shares of common stock at the exercise price of \$0.15 per share and with an expiration date of February 22, 2016 (the "Warrants"). The following is a summary of the Warrants outstanding for the nine months ending September 30, 2012:

	Warrants	Exercise Price
Beginning balance	40,000,000	\$ 0.15
Add: Adjustments (pursuant to warrants agreement)	—	n/a
Less: Exercised	—	n/a
Ending balance	40,000,000	\$ 0.15

The Warrants are exercisable in cash to purchase shares of the Company's common stock (the "Warrant Shares"). The Exercise Price may be paid pursuant to a cashless exercise provision if the Warrant Shares have not been registered within six months after the Warrants are issued. The Exercise Price of the Warrants shall be adjusted in the event of (a) stock splits, stock dividends, combinations, reclassifications, mergers, consolidations, distributions of assets or evidence of indebtedness, sales or transfers of substantially all assets, share exchanges or similar events, and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the then Exercise Price.

In connection with a Fundamental Transaction, as defined in the Purchase Agreement, that is an all-cash transaction, the Company shall have the right to purchase from the Holders all, but not less than all, of the unexercised portion of the Warrants by paying in cash to the Holders an amount equal to 30% of the Exercise Price multiplied by the number of shares of Common Stock for which the Warrants are exercisable immediately prior to such change of control transaction.

Features of the 2012 Second Tranche Amendment

On July 2, 2012, the Company entered into an Amendment and Waiver to Securities Purchase Agreement (the "Amendment and Waiver") to amend our Purchase Agreement with the Investors. Under the Amendment and Waiver agreement the Company has agreed to issue and sell in a private placement to the Investors an aggregate

[Table of Contents](#)

principle amount of \$1,000,000 (the "Second Tranche") of 5% Senior Secured Convertible Debentures of the Company (the "Second Convertible Notes"), warrants to purchase up to 10,000,000 shares of common stock at an initial exercise price of \$0.15 per share (the

“\$0.15 Warrants”) and warrants to purchase up to 10,000,000 shares of common stock at an initial exercise price of \$0.25 per share (the “\$0.25 Warrants” and together with the \$0.15 Warrants, the “2012 Warrants”).

The Second Convertible Notes

The Second Convertible Notes contain the same terms as the original Convertible Notes and requires payment of interest at the rate of 5% per annum, payable quarterly and mature on July 2, 2015. The Second Convertible Notes provide the Investors the option at any time prior to the repayment of the notes to convert any portion of the outstanding Second Tranche balance into fully-paid and non-assessable restricted shares of common stock of the Company at an initial conversion price of \$0.10 per share (the “Conversion Price”).

The Convertible Notes include an adjustment close providing that if the Company issues additional shares of common stock prior to the repayment of the Second Tranche at a price per share less than the effective conversion price of the Second Convertible Notes, the conversion price will, subject to certain exceptions, be reduced to an amount equal to the price per share paid or payable for the common stock of the Company in such subsequent issuance or deemed subsequent issuance. The Conversion price is subject to adjustments in the event of (a) stock splits, stock dividends, combinations, dividends, rights offerings and mergers or sales of assets or similar events and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the then Conversion Price.

The Second Convertible Notes and the Purchase Agreement covering both are secured by a security interest in all assets of the Company and its subsidiaries and all such obligations are guaranteed jointly and severally by the Company’s subsidiaries. The Second Convertible Notes also contain non-financial covenants which limit the Company and its subsidiaries from incurring subsequent indebtedness, incurring liens, amending organizational documents, repurchasing or repaying other debt, paying cash dividends and entering into affiliate transactions.

The Second Convertible Notes may be redeemed at the option of the Company only in connection with a change of control or other fundamental transaction of the Company and subject to the satisfaction of other conditions including, without limitation, that the shares issuable upon conversion of the debentures are freely tradable and that there is no event of default.

The 2012 Warrants

On July 2, 2012, the Company issued warrants for the purchase of up to 20,000,000 shares of common stock with five year terms. The warrants were issued to allow the Investors to purchase up to 10,000,000 shares of common stock at an initial purchase price of \$0.15 per share and the remaining 10,000,000 shares of common stock at an initial purchase price of \$0.25 per share. The terms of the 2012 Warrants are identical to those of the Warrants, except that the 2012 Warrants are exercisable for a period of five years from the date of issuance and contain different exercise prices. The following is a summary of the 2012 Warrants outstanding for the nine months ending September 30, 2012:

<u>\$0.15 Warrants</u>	<u>Warrants</u>	<u>Exercise Price</u>
Beginning balance at December 31, 2011	—	\$ —
Add: Second Tranche Agreement	10,000,000	0.15
Add: Adjustments (pursuant to warrants agreement)	—	n/a
Less: Exercised	—	n/a
Ending balance at September 30, 2012	10,000,000	\$ 0.15

Table of Contents

<u>\$0.25 Warrants</u>	<u>Warrants</u>	<u>Exercise Price</u>
Beginning balance at December 31, 2011	—	\$ —
Add: Second Tranche Agreement	10,000,000	0.25
Add: Adjustments (pursuant to warrants agreement)	—	n/a
Less: Exercised	—	n/a
Ending balance at September 30, 2012	10,000,000	\$ 0.25

The 2012 Warrants are exercisable in cash to purchase shares of the Company’s common stock. The exercise price may be paid pursuant to a cashless exercise provision if the 2012 Warrants have no effective registration statement registering the shares underlying the warrants by surrendering warrant shares having a value equal to the exercise price of the portion of the warrants being exercised. The exercise price of the 2012 Warrants shall be adjusted in the event of (a) stock splits, stock dividends, combinations, rights offerings, mergers or sales of assets or similar events, and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the exercise price.

The 2012 Warrants provide that the 2012 Warrants may be purchased at the option of the Company only in connection with a change in control of the Company that is an all-cash transaction. The purchase price is 30% of the then effective exercise price of the warrants multiplied by the number of common shares for which the 2012 Warrants are then exercisable. All but not less than all of the 2012 Warrants outstanding are required to be repurchased at such a time.

Fair Value Measurements

The Company measures and reports fair value in accordance with Accounting Standards Codifications (“ASC”) 820 — *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value investments.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value of an asset should reflect its highest and best use by market participants, principal (or most advantageous) markets, and an in-use or an in-exchange valuation premise. The fair value of a liability should reflect the risk of nonperformance, which includes, among other things, the Company’s credit risk.

Valuation techniques are generally classified into three categories: the market approach; the income approach; and the cost approach. The selection and application of one or more of the techniques may require significant judgment and are primarily dependent upon the characteristics of the asset or liability, and the quality and availability of inputs. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820 also provides fair value hierarchy for inputs and resulting measurement as follows:

Level 1

Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2

Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived principally from or corroborated by observable market data for substantially the

[Table of Contents](#)

full term of the assets or liabilities; and

Level 3

Unobservable inputs for the asset or liability that are supported by little or no market activity and that are significant to the fair values.

Fair value measurements are required to be disclosed by the Level within the fair value hierarchy in which the fair value measurements in their entirety fall. Fair value measurements using significant unobservable inputs (in Level 3 measurements) are subject to expanded disclosure requirements including a reconciliation of the beginning and ending balances, separately presenting changes during the period attributable to the following: (i) total gains or losses for the period (realized and unrealized), segregating those gains or losses included in earnings, and a description of where those gains or losses included in earnings are reported in the statement of income.

The following summarizes the Company’s assets and liabilities measured at fair value as of September 30, 2012:

Description	Balance as of September 30, 2012	Fair Value Measurements at Reporting Date Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Convertible notes	\$ 10,176,000	\$ —	\$ —	\$ 10,176,000
Warrant liabilities	\$ 5,700,000	\$ —	\$ —	\$ 5,700,000
Total Liabilities	\$ 15,876,000	\$ —	\$ —	\$ 15,876,000

Accounting for the Convertible Notes, Second Convertible Notes, Investor Warrants and 2012 Warrants

Investor Warrants and 2012 Warrants

In June 2008, the FASB issued ASC 815-40-15 (formerly EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock*), which was effective for the Company in 2009. This issued guidance requires that derivative instruments be evaluated for certain contingencies and anti-dilution provisions that would affect their equity classification as a derivative under ASC 815, *Derivatives and Hedging* (ASC 815) and requires the instruments to be classified as liabilities and reported at fair value.

Upon issuance, the Investor Warrants and 2012 Warrants were not considered indexed to the Company’s own stock and therefore are required to be accounted for as freestanding derivative instruments and classified as a liability. As a result, the Investor Warrants and 2012 Warrants are recorded as a liability at fair value as of September 30, 2012 with changes in fair value recorded in the consolidated

statement of operations.

Convertible Notes and Second Tranche Convertible Notes

The Company has determined that the Convertible Notes and the Second Convertible Notes constitute a hybrid instrument that has the characteristics of a debt host contract containing several embedded derivative features that would require bifurcation and separate accounting as a derivative instrument pursuant to the provisions

16

[Table of Contents](#)

of ASC 815. The Company has identified all of the derivatives associated with the February 22, 2011 financing and the July 2, 2012 additional financing. As permitted under ASC 825-10-10 — *Financial Instruments*, as it relates to the fair value option, the Company has elected, as of February 22, 2011 and including the July 2, 2012 financing, to measure the Convertible Notes in their entirety at fair value with changes in fair value recognized in the Condensed Consolidated Statement of Operations as either a gain or loss until the notes are settled. As such, the Company has appropriately valued the embedded derivatives as a single hybrid contract together with the Convertible Notes and the Second Convertible Notes. This election was made by the Company after determining the aggregate fair value of the Convertible Notes and the Second Convertible Notes to be more meaningful in the context of the Company's financial statements than if separate fair values were assigned to each of the multiple embedded instruments contained in the Convertible Notes and the Second Convertible Notes.

Convertible Notes

Upon issuance of the Convertible Notes, the Company allocated the proceeds received to the Convertible Notes and Investor Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Notes to be \$3,208,000. The Notes were immediately marked to fair value, resulting in a derivative liability in the amount of \$3,680,000. As of September 30, 2012, the Convertible Notes have been marked to fair value resulting in a derivative liability of \$8,240,000. The net charge to other income (expense) was a gain of \$747,000 in the three months ended September 30, 2012 and a loss of \$2,715,000 in the nine months ended September 30, 2012. The debt discount in the amount of \$792,000 (resulting from the allocation of proceeds) is being amortized to interest expense using the effective interest method over the expected term of the Convertible Notes. The Company amortized \$67,000 and \$198,000 for the three and nine months ended September 30, 2012, respectively which is a component of interest expense.

Upon issuance, the Company allocated \$792,000 of the initial proceeds to the Investor Warrants and immediately marked them to fair value resulting in a derivative liability of \$908,000. As of September 30, 2012, the Investor Warrants have been marked to fair value resulting in a derivative liability of \$3,200,000. The charge to other income (expense) for the three and nine months ended September 30, 2012 was income of \$800,000 and expense of \$1,600,000, respectively.

Second Convertible Notes

Upon issuance of the Second Convertible Notes, the Company allocated the proceeds received to the Second Convertible Notes and 2012 Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Second Convertible Notes to be \$417,000. The Second Convertible Notes were immediately marked to fair value, resulting in a derivative liability in the amount of \$2,073,000. As of September 30, 2012, the Second Convertible Notes have been marked to fair value resulting in a derivative liability of \$1,936,000. The net charge to other income (expense) was a loss of \$1,503,000 in the three and nine months ended September 30, 2012, respectively. The debt discount in the amount of \$583,000 (resulting from the allocation of proceeds) is being amortized to interest expense using the effective interest method over the expected term of the Second Convertible Notes. The Company amortized \$17,000 for the three and nine months ended September 30, 2012, respectively which is a component of interest expense.

Upon issuance of the 2012 Warrants, the Company allocated \$583,000 of the initial proceeds to the 2012 Warrants and immediately marked them to fair value resulting in a derivative liability of \$2,900,000. As of September 30, 2012, the 2012 Investor Warrants have been marked to fair value resulting in a derivative liability of \$2,500,000. The charge to other income (expense) for the three and nine months ended September 30, 2012 was expense of \$1,917,000, respectively.

17

[Table of Contents](#)

A summary of changes in the Convertible Notes and Investor Warrants is as follows:

	Fair Value of Convertible Notes	Fair Value of Warrant Liabilities	Fair Value of Second Convertible Notes	Fair Value of 2012 Warrant Liabilities	Total
Allocation of initial proceeds	\$ 3,208,000	\$ 792,000	\$ —	\$ —	\$ 4,000,000
Initial fair value adjustment	\$ 469,000	\$ 116,000	\$ —	\$ —	\$ 585,000
February 22, 2011	\$ 3,677,000	\$ 908,000	\$ —	\$ —	\$ 4,585,000
Amortization of debt discount	\$ 158,000	\$ —	\$ —	\$ —	\$ 158,000
Fair value adjustment	\$ 1,371,000	\$ 756,000	\$ —	\$ —	\$ 2,127,000
Balance September 30, 2011	\$ 5,206,000	\$ 1,664,000	\$ —	\$ —	\$ 6,870,000

Balance December 31, 2011	\$ 5,327,000	\$ 1,600,000	\$ —	\$ —	\$ 6,927,000
Allocation of initial proceeds	\$ —	\$ —	\$ 417,000	\$ 583,000	\$ 1,000,000
Initial fair value adjustment	\$ —	\$ —	\$ 1,656,000	\$ 2,317,000	\$ 3,973,000
July 2, 2012	\$ 5,327,000	\$ 1,600,000	\$ 2,073,000	\$ 2,900,000	\$ 11,900,000
Amortization of debt discount	\$ 198,000	\$ —	\$ 17,000	\$ —	\$ 215,000
Fair value adjustment	\$ 2,715,000	\$ 1,600,000	\$ (154,000)	\$ (400,000)	\$ 3,761,000
Balance September 30, 2012	\$ 8,240,000	\$ 3,200,000	\$ 1,936,000	\$ 2,500,000	\$ 15,876,000

The Company records the fair value of Convertible Notes, Second Convertible Notes, Investor Warrants and 2012 Warrants as a long term liability.

Financing Costs

Financing costs include costs associated with obtaining the February 22, 2011 financing. Financing costs totaling \$530,000 were recorded in other income (expense) in the nine months ending September 30, 2011, \$135,000 of which were recorded in prepaid expenses and other current assets at December 31, 2010 and expensed upon closing of the transaction.

The Company incurred financing costs associated with obtaining the July 2, 2012 financing which totaled \$80,000 and were recorded in other income (expense) in the three and nine months ending September 30, 2012.

Valuation — Methodology and Significant Inputs Assumptions

Fair values for the Company's derivatives and financial instruments are estimated by utilizing valuation models that consider current and expected stock prices, volatility, dividends, market interest rates, forward yield curves and discount rates. Such amounts and the recognition of such amounts are subject to significant estimates that may change in the future. The methods and significant inputs and assumptions utilized in estimating the fair value of the Warrant Liabilities, 2012 Warrant Liabilities, Convertible Notes and Second Convertible Notes are discussed below. Each of the measurements is considered a Level 3 measurement as a result of at least one unobservable input.

Warrant Liabilities

A Black-Scholes-Merton option-pricing model, with dilution effects, was utilized to estimate the fair value of the Warrant Liabilities as of February 22, 2011, September 30, 2011, December 31, 2011 and September 30, 2012. This model is widely used in estimating value of European options dependent upon a non dividend-paying stock and fixed inputs. This model is subject to the significant assumptions discussed below and requires the following key inputs with respect to the Company and/or instrument:

Table of Contents

<u>Input</u>	<u>February 22, 2011</u>	<u>September 30, 2011</u>	<u>December 31, 2011</u>	<u>September 30, 2012</u>
Stock Price	\$ 0.0755	\$ 0.12	\$ 0.1075	\$ 0.19
Exercise Price	\$ 0.15	\$ 0.15	\$ 0.15	\$ 0.15
Expected Life (in years)	5.00	4.40	4.15	3.40
Stock Volatility	90%	95%	95%	100%
Risk-Free Rate	2.16%	0.80%	0.63%	0.37%
Dividend Rate	0%	0%	0%	0%
Outstanding Shares of Common Stock	30,351,092	30,351,092	30,351,092	31,809,428

2012 Warrant Liabilities

\$0.15 Warrants

A Black-Scholes-Merton option-pricing model, with dilution effects, was utilized to estimate the fair value of the \$0.15 Warrants as of July, 2, 2012 and September 30, 2012. This model is subject to the significant assumptions discussed below and requires the following key inputs with respect to the Company and/or instrument:

<u>Input</u>	<u>July 2, 2012</u>	<u>September 30, 2012</u>
Stock Price	\$ 0.20	\$ 0.19
Exercise Price	\$ 0.15	\$ 0.15
Expected Life (in years)	5.00	4.76
Stock Volatility	110.00%	100.00%
Risk-Free Rate	0.67%	0.58%
Dividend Rate	0%	0%
Outstanding Shares of Common Stock	30,976,092	31,809,428

\$0.25 Warrants

A Black-Scholes-Merton option-pricing model, with dilution effects, was utilized to estimate the fair value of the \$0.25 Warrants as of July, 2, 2012 and September 2012. This model is subject to the significant assumptions discussed below and requires the following key inputs with respect to the Company and/or instrument:

Input	September 30,	
	July 2, 2012	2012
Stock Price	\$ 0.20	\$ 0.19
Exercise Price	\$ 0.25	\$ 0.25
Expected Life (in years)	5.00	4.76
Stock Volatility	110.00%	100.00%
Risk-Free Rate	0.67%	0.58%
Dividend Rate	0%	0%
Outstanding Shares of Common Stock	30,976,092	31,809,428

Convertible Notes

A binomial lattice model was utilized to estimate the fair value of the Convertible Notes. The binomial model considers the key features of the Convertible Notes, as noted above, and is subject to the significant assumptions discussed below. First, a discrete simulation of the Company's stock price, without effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Second, a discrete simulation of the Company's stock price, with effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Third, based upon the simulated

Table of Contents

stock price with dilution effect, an analysis of the higher position of a conversion position, redemption position, or holding position (i.e. fair value of the respective future nodes value discounted using the applicable discount rate) was conducted relative to each node until a final fair value of the instrument is conducted at the node representing the measurement date. This model requires the following key inputs with respect to the Company and/or instrument:

Input	February 22,	September 30,	December 31,	September 30,
	2011	2011	2011	2012
Stock Price	\$ 0.0755	\$ 0.1200	\$ 0.1075	\$ 0.19
Exercise Price	\$ 0.10	\$ 0.10	\$ 0.10	\$ 0.10
Expected remaining term (in years)	3.00	2.40	2.15	1.40
Stock Volatility	95%	100%	100%	105%
Risk-Free Rate	1.22%	0.32%	0.27%	0.19%
Dividend Rate	0%	0%	0%	0%
Outstanding Shares of Common Stock	30,351,092	30,351,092	30,351,092	31,809,428
Effective discount rate	20.3%	16.4%	13.2%	9.90%
Probability of forced redemption	20%	20%	20%	20%

Second Tranche Convertible Notes

A binomial lattice model was utilized to estimate the fair value of the Second Tranche Convertible Notes. The binomial model considers the key features of the Second Tranche Convertible Notes, as noted above, and is subject to the significant assumptions discussed below. First, a discrete simulation of the Company's stock price, without effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Second, a discrete simulation of the Company's stock price, with effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Third, based upon the simulated stock price with dilution effect, an analysis of the higher position of a conversion position, redemption position, or holding position (i.e. fair value of the respective future nodes value discounted using the applicable discount rate) was conducted relative to each node until a final fair value of the instrument is conducted at the node representing the measurement date. This model requires the following key inputs with respect to the Company and/or instrument:

Input	September 30,	
	July 2, 2012	2012
Stock Price	\$ 0.20	\$ 0.19
Exercise Price	\$ 0.10	\$ 0.10
Expected remaining term (in years)	3.00	2.75
Stock Volatility	100%	95%
Risk-Free Rate	0.39%	0.29%
Dividend Rate	0%	0%
Outstanding Shares of Common Stock	30,976,092	31,809,428
Effective discount rate	10.00%	10.00%
Probability of forced redemption	20.00%	20.00%

The following are significant assumptions utilized in developing the inputs of both the Convertible Notes and the Second Convertible Notes:

- The Company's common stock shares are traded on the OTC Bulletin Board and, accordingly, the stock price input is based

upon bid prices as of the valuation dates due to the extremely thin trading volume, broker-driven market (vs. exchange market) and the wide bid/ask spread as of the valuation

[Table of Contents](#)

date;

- The expected future stock prices of the Company's stock were modeled to include the effect of dilution upon conversion of the instruments to shares of common stock;
- Stock volatility was estimated by considering (i) the annualized monthly volatility of the Company's stock price during the historical period preceding the respective valuation dates and measured over a period corresponding to the remaining life of the instruments (monthly data set is more relevant given the extremely thin trading volume of the Company's common stock) and (ii) the annualized daily volatility of comparable companies' stock price during the historical period preceding the respective valuation dates and measured over a period corresponding to the remaining life of the instrument. Historic prices of the Company and comparable companies' common stock were used to estimate volatility as the Company did not have traded options as of the valuation dates;
- Based upon the Company's historical operations and management's expectations for the foreseeable future, the Company's stock was assumed to be a non-dividend-paying stock;
- The risk-free interest rate is based on the U.S. Treasury Yield curve in effect as on the valuation date for the expected term;
- With respect to the Convertible Notes and the Second Convertible Notes, the Company is expected to pay all accrued interest due to the Holders on each Interest Payment Date;
- With respect to the Convertible Notes and Second Convertible Notes, based upon management's expectations for a change of control or fundamental transaction to occur prior to the maturity date of the Convertible Notes and the Second Convertible Notes, a low probability of a forced redemption;
- Upon a change of control redemption, the change of control redemption amount shall equal to the sum of:
 - I. the greater of:
 - (i) the outstanding amount of the debt divided by the Conversion Price on the date of the mandatory default amount is either (A) demanded or (B) paid in full, whichever has a lower conversion price, multiplied by the VWAP of the date of the mandatory default amount is either (x) demanded or otherwise due or (y) paid in full, whichever has higher VWAP, plus all accrued and unpaid interest, or
 - (ii) 130% of the outstanding principal amount of the debt, plus 100% of accrued and unpaid interest, and
 - II. all other amounts, costs, expenses and liquidated damages due under the various agreements covering issuance of the debt.

Additionally, it is assumed that no amounts are due pursuant to clause (II) above in any period and that the stock price at each respective node represents a reasonable approximation of the VWAP requirements.

The changes in fair value between reporting periods are related to the changes in the price of the Company's common stock as of the measurement dates, the volatility of the Company's common stock during the remaining term of the instrument, changes in the conversion price and effective discount rate.

[Table of Contents](#)

12. Commitments

Lease Commitments

In June 2011, the Company entered into a three year facility lease for office space at a new location in Milford, Massachusetts, beginning August 2011. In addition to the minimum lease payments, the new lease agreement requires payment of the Company's pro-rata share of property taxes and building operating expenses.

Under the new lease, future minimum lease payments are estimated to be as follows (in thousands):

<u>Year</u>	<u>Future Minimum Lease Payments</u>
2012	10

2013	41
2014	<u>30</u>
Total	<u>\$ 81</u>

The Company manufactures its RenalGuard consoles and sterile disposable kits using two separate outside contract manufacturers. The contracts with these manufacturers do not contain minimum purchase requirements or any future commitments. Purchases are made upon request to the manufacturer.

During the year ended December 31, 2011, the Company hired a clinical research organization (“CRO”) to assist with managing its clinical trial. The contract with the CRO does not contain minimum purchase requirements or any future commitments, and payments are made once services are provided.

13. Subsequent Event

The Company has evaluated all events or transactions through the date of this filing. During this period, the Company did not have any material subsequent events that impacted its condensed consolidated financial statements or disclosures.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a medical device company specializing in innovative technologies for the cardiac and vascular markets. Our key strategic growth initiative is RenalGuard.

RenalGuard is designed to reduce the potentially toxic effects that contrast media can have on the kidneys when administered to at-risk patients during certain medical imaging procedures. It is believed that allowing contrast media to dwell in the kidneys of certain higher risk patients can lead to contrast induced nephropathy (CIN), a potentially deadly form of acute kidney injury. By inducing and maintaining a high urine flow rate before, during and after these medical imaging procedures, we believe the incidence rates of CIN in at-risk patients can be reduced. RenalGuard facilitates this increased urine clearance automatically, enabling the body to more rapidly void the contrast media, thereby reducing its overall resident time and potential toxic effects in the kidney. RenalGuard may have additional applications in ancillary therapeutic areas, such as chemotherapy, where protecting the kidneys from toxic agents is beneficial, but PLC is primarily focusing on CIN prevention currently.

The RenalGuard System consists of a proprietary console and accompanying single-use sets. RenalGuard operates by first collecting and measuring patient urine outputs and then in real-time precisely matching these urine outputs with a prescribed replacement fluid by means of intravenous infusion. With its automated matched fluid replacement capability, RenalGuard is intended to promote and maintain high urine outputs and minimize the risk

[Table of Contents](#)

to patients of over- or under-hydration during image-guided catheterization procedures where contrast media are routinely administered.

We obtained a CE Mark for RenalGuard in December 2007 and began our initial commercialization efforts in the EU in Italy in April 2008. We are now marketing RenalGuard in Europe and several additional countries around the world. In the U.S. we must first successfully complete a pivotal clinical study assessing the safety and effectiveness of RenalGuard in reducing the rates of CIN in at-risk patients and obtain FDA pre-market approval in order to market and sell RenalGuard. We began this U.S. pivotal study in late 2011.

Our distributor of RenalGuard in Italy, Artech, accounted for 46% of our total revenues and 56% of our RenalGuard revenues in the year ended December 31, 2011. Sales made to Artech during the nine months ended September 30, 2012 and 2011 were \$130,000 and \$209,000, respectively. Artech’s business infrastructure was heavily damaged due to an earthquake which occurred in Italy during the second quarter of 2012. This is not expected to have any significant impact to the distribution efforts made by Artech over the remainder of 2012.

With the sale of our TMR business to Novadaq in February 2011, as discussed in Note 10 to these Unaudited Condensed Consolidated Financial Statements, our ability to increase revenues depends solely upon higher sales of our RenalGuard products into international markets. This dependency on international RenalGuard revenue growth will continue until such time, if ever, that we may obtain FDA pre-market approval and are permitted to begin selling RenalGuard in the U.S.

Our management reviews a number of key performance indicators to assist in determining how to allocate resources and run our day-to-day operations. These indicators include (1) actual prior quarterly sales trends, (2) projected sales for the next four quarters, (3) research and development progress as measured against internal project plan objectives, (4) budget to actual financial expenditure results, (5) inventory levels (both our own and our distributors’), and (6) short term and long term projected cash flows of the business.

Critical Accounting Policies and Estimates

Our financial statements are based upon the application of significant accounting policies, many of which require us to make significant estimates and assumptions (see Note 2 to the Condensed Consolidated Unaudited Financial Statements). We believe that the following are some of the more material judgment areas in the application of our accounting policies that currently affect our financial

condition and results of operations.

Inventories

Inventories are stated at the lower of cost (computed on a first-in, first-out method) or market value and include allocations of labor and overhead. We regularly review slow-moving and excess inventories, and writes down inventories to net realizable value if the ultimate expected proceeds from the disposals of excess inventory are less than the carrying cost of the inventory.

Accounts Receivable

Accounts receivable are stated at the amount we expect to collect from the outstanding balances. We continuously monitor collections from customers, and we maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues that we have identified. Historically, we have not experienced significant losses related to our accounts receivable. Collateral is not generally required. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances might be required.

[Table of Contents](#)

Valuation of Convertible Notes, Second Convertible Notes, Warrant Liabilities and 2012 Warrant Liabilities

The valuation of our convertible notes, our second convertible notes, our warrant liabilities and our 2012 warrant liabilities as derivative instruments utilizes certain estimates and judgments that affect the fair value of the instruments. Fair values are estimated by utilizing valuation models that consider current and expected stock prices, volatility, dividends, forward yield curves and discount rates. Such amounts and the recognition of such amounts are subject to significant estimates that may change in the future.

Warranty and Preventative Maintenance Costs

We warranty our products against manufacturing defects under normal use and service during the warranty period. We obtain similar warranties from a majority of our suppliers.

We evaluate the estimated future unrecoverable costs of warranty and preventative maintenance services for our installed base of products on a quarterly basis and adjust our warranty reserve accordingly. We consider all available evidence, including historical experience and information obtained from supplier audits.

Revenue Recognition

We recognize revenue when the following basic revenue recognition criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the price to the buyer charged for products delivered or services rendered and collectability of the sales price. We assess credit worthiness of customers based upon prior history with the customer and assessment of financial condition. Our shipping terms are customarily Free On Board ("FOB") shipping point. We record revenue at the time of shipment, if all other revenue recognition criteria have been met.

[Table of Contents](#)

Results of Operations

Results for the three and nine months ended September 30, 2012 and 2011 were as follows:

	Three Months Ended		Increase (decrease)		Nine Months Ended		Increase (decrease)	
	September 30,		over 2011		September 30,		over 2011	
	2012	2011	\$	%	2012	2011	\$	%
	\$	\$	\$	%	\$	\$	\$	%
	(dollars in thousands)							
Total revenues	212	27	185	685	595	482	113	23
Total cost of revenues	84	17	67	394	308	355	(47)	(13)
Gross profit	128	10	118	1,180	287	127	160	126
Selling, general & administrative expenses	674	591	83	14	1,899	1,850	49	3
Research & development expenses	549	312	237	76	1,618	759	859	113
Total operating expenses	1,223	903	320	35	3,517	2,609	908	35
Gain on the sale of assets	—	—	—	—	—	(40)	40	100
Loss from continuing operations	(1,095)	(893)	(202)	23	(3,230)	(2,442)	(788)	(32)
Interest expense	(137)	(116)	(21)	18	(369)	(277)	(92)	(33)
Foreign currency transaction gains	17	—	17	100	2	—	2	100
Financing costs associated with convertible notes	(80)	—	(80)	(100)	(80)	(530)	450	85
Change in fair value of warrant liabilities	(1,117)	232	(1,349)	(581)	(3,517)	(872)	(2,645)	303
Change in fair value of convertible notes	(757)	376	(1,133)	(301)	(4,218)	(1,840)	(2,378)	(129)
Other income	4	—	4	100	24	—	24	100
Total other (expense) income	(2,070)	492	(2,562)	(521)	(8,158)	(3,519)	(4,639)	(132)
Net loss from continuing operations before income taxes	(3,165)	(401)	(2,764)	689	(11,388)	(5,961)	(5,427)	(91)

Benefit for income taxes from continuing operations	—	—	—	—	—	492	(492)	(100)
Net loss from continuing operations, net of income taxes	(3,165)	(401)	(2,764)	689	(11,388)	(5,469)	(5,919)	(108)
Income from discontinued operations, net of income taxes	—	—	—	—	—	53	(53)	(100)
Gain on sale of discontinued operations, net provision for income taxes of \$492	—	—	—	—	—	687	(687)	(100)
Net income from discontinued operations, net of income taxes	—	—	—	—	—	740	(740)	(100)
Net Loss	(3,165)	(401)	(2,764)	689	(11,388)	(4,729)	(6,659)	(141)

Revenues

Revenues increased \$185,000 and \$113,000, or 685% and 23%, in the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011, respectively. RenalGuard console sales increased \$149,000 and \$215,000 in the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011, respectively, due to a higher volume of RenalGuard consoles sold to international distributors. RenalGuard single use set revenues increased \$36,000 and \$20,000 in the three and nine months ended September 30, 2012 as compared to the three and nine months ended

25

[Table of Contents](#)

September 30, 2011, respectively. OEM revenues decreased \$120,000 for the nine months ended September 30, 2012, as compared to the nine months ended September 30, 2011 as the business was sold during 2011.

Gross Profit

Gross profit was \$128,000 and \$287,000 in the three and nine months ended September 30, 2012, as compared with a gross profit of \$10,000 and \$127,000 in the three and nine months ended September 30, 2011, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenditures increased 14% and 3% in the three and nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. The increase in selling, general and administrative expenditures for the three and nine month comparative period is a result of additional stock based compensation expense incurred during the three and nine months ended September 30, 2012 due to an increase in restricted common stock issued in that period as compared to the same period in 2011. This increase is offset by a decrease in selling, general and administrative expenditures for the three and nine month comparative period due to lower compensation-related expenses due to their being fewer individuals working at the organization in 2012 compared to the same period in 2011.

Research and Development Expenses

Research and development expenditures increased 76% and 113% in the three and nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. Costs for the RenalGuard U.S. clinical trials are recorded as research and development expenses, and we began enrolling patients in January 2012 for these trials. Virtually all our research and development expenses relate to these trials.

As we continue our U.S clinical trial for our RenalGuard program, we expect our research and development expenses to significantly increase for the remainder of 2012, compared to the same period in 2011.

Other Income (Expense)

In February 2011, the Company entered into a Securities Purchase Agreement and a 5% Senior Secured Convertible Debenture Agreement as described in Note 11 of the Unaudited Condensed Consolidated Financial Statements. In July 2012, the Company entered into an Amendment to the Securities Purchase Agreement and 5% Senior Secured Convertible Debenture Agreement as described in Note 11 of the Unaudited Condensed Consolidated Financial Statements. As a result of these two transactions, interest expense on the Convertible Notes and Second Convertible Notes of \$137,000 and \$369,000 in the three and nine months ended September 30, 2012, respectively and \$116,000 and \$277,000 in the three and nine months ended September 30, 2011, respectively, was recorded. In addition, financing costs associated with Second Convertible Notes of \$80,000 were recorded in the three and nine months ended September 30, 2012 and financing costs associated with the convertible note of \$530,000 were recorded in the nine months ended September 30, 2011.

The Company recorded other expense of \$1,117,000 and \$3,517,000 in the three and nine months ended September 30, 2012 as compared to other income of \$232,000 and other expense of \$872,000 in the three and nine months ended September 30, 2011, respectively as a result of a fair value adjustment related to the Warrant Liabilities as well as the additional expense for the fair value adjustment for the 2012 Warrants entered into in July 2012. The Company recorded other expense of \$757,000 and \$4,218,000 in the three and nine months ended September 30, 2012 as compared to other income of \$376,000 and other expense of \$1,840,000 in the three and nine months ended September 30, 2011, respectively, as a result of a fair value adjustment related to the Convertible Notes as well as the additional expense and fair value adjustment for the Second Tranche Convertible Notes entered into in July 2012.

26

[Table of Contents](#)

Discontinued Operations

In February 2011, we sold the TMR business to Novadaq as disclosed in Note 10 to our Unaudited Condensed Consolidated Financial Statements.

Novadaq acquired substantially all of the Company's assets that were used in the TMR business including all manufacturing rights, substantially all product inventories, and all equipment, intellectual property, regulatory approvals, clinical data and documentation related to TMR, for a purchase price of \$1 million in cash and the assumption of all the Company's obligations under service contracts as of the closing date totaling \$614,000. The total carrying value of the assets sold as of the transaction date was \$385,000. In addition, the Company incurred transaction costs of \$50,000. The Company recorded a gain on sale of discontinued operations before income taxes of \$1,179,000 during the nine months ended September 30, 2011.

Net Loss

In the three and nine months ended September 30, 2012, our net loss increased \$2,764,000 and \$6,659,000, respectively, compared to the net loss reported for the three and nine months ended September 30, 2011, due to the Second Convertible Notes valuation, the 2012 Warrant Liabilities valuation, the increase in the valuation of our Warrant Liabilities and Convertible Notes as well as increased research and development costs related to our ongoing RenalGuard U.S. clinical trial and limited revenues relative to overhead costs.

Liquidity and Capital Resources

We compete in the highly regulated and competitive medical device market place where products can take significant time to develop, gain regulatory approval and then introduce to distributors and end users. We have incurred recurring quarterly operating losses over the past few years as we have worked to bring our RenalGuard System through development and initial commercialization efforts outside the United States. We expect such operating losses will continue until such time, if ever, that RenalGuard product sales increase sufficiently to generate profitable results.

Cash and cash equivalents totaled \$723,000 as of September 30, 2012, a decrease of \$1,862,000 from \$2,585,000 recorded as of December 31, 2011. We have historically funded our working capital requirements through cash received from public and private offerings of our common stock and to a lesser extent, through our sales of products and services. We believe that our existing resources, based on our currently projected financial results, are sufficient to fund operations through the first quarter of 2013. Based upon current and anticipated revenue projections from foreign sales of our RenalGuard product, and the anticipated costs of our U.S. clinical trial, we expect that we will need to raise additional capital during the remainder of 2012. Under the terms of the Securities Purchase Agreement, we had the opportunity to raise up to an additional \$2 million from the Holders of the Convertible Notes in two separate \$1 million tranches, based upon meeting certain operational milestones within certain periods of time. The deadline for achieving the operational milestones for the first \$1 million tranche expired in February 2012 without our achieving such milestones; however, as discussed below, the Investors agreed to waive both the deadline and the achievement of these milestones as a condition for the investment of the first additional \$1 million and invested such funds in July 2012. The second \$1 million tranche is available to us upon achievement of the applicable operational milestones at any time prior to February 22, 2014.

On July 2, 2012 we entered into an Amendment and Waiver to Securities Purchase Agreement to amend our Securities Purchase Agreement to provide for the issuance of (i) an additional \$1,000,000 of 5% Senior Secured Convertible Debentures maturing on July 2, 2015, (ii) warrants exercisable for a period of five years to purchase up to 10,000,000 shares of common stock at an exercise price of \$0.15 per share and (iii) warrants exercisable for a period of five years to purchase up to 10,000,000 shares of common stock at an exercise price of \$0.25 per share. See Note 11 to our Unaudited Condensed Consolidated Financial Statements for additional disclosure surrounding

[Table of Contents](#)

this amendment.

Our plan is to seek additional capital through the sale of equity and/or debt securities to fund operations. However, there can be no assurance that such capital will be available at all, or if available, that the terms of such financing will not be dilutive to our existing stockholders. The Holders of the Convertible Notes and the Second Convertible Notes have a right to participate in up to 50% of any subsequent financing. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of the company by our stockholders would be diluted. In addition, any debt securities would have rights, preferences and privileges senior to our common stock and we may sell equity or other convertible debt financing securities that would have rights, preferences and privileges senior to our common stock.

If we are unable to generate adequate cash flows or obtain sufficient additional funding when needed, we may have to take certain actions including, but not limited to, cutting back our operations, selling some or all of our assets, licensing potentially valuable technologies to third parties, and/or ceasing some or all of our operations.

Cash flows used in operating activities in the nine months ended September 30, 2012 were \$2,564,000 due to our net loss and unfavorable working capital changes, partially offset by non cash activity including 1) the change in fair value of convertible notes and warrant liabilities 2) non-cash interest expense; 3) depreciation expense; 4) stock-based compensation expense; and 5) financing costs associated with convertible notes. The effect of exchange rate changes was a \$144,000 decrease in cash.

Forward-Looking Statements

This quarterly report on Form 10-Q 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 (the "Exchange Act"). Statements containing terms such as "believes", "plans", "expects", "anticipates", "intends", "estimates" and similar expressions reflect uncertainty and are forward-looking statements. Forward-looking statements are based upon current plans and expectations and involve known and unknown important risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such important factors and uncertainties include, but are not limited to:

- We expect to incur significant net losses in future quarters;
- We received a 'going concern' opinion in our consolidated financial statements indicating that our cash balance as of December 31, 2011, combined with recurring net losses and negative cash flows from operations, raises substantial doubt about our ability to continue as a going concern for the next 12 months. As noted above, we are investigating ways to raise additional capital to continue our operations.
- Our quarterly operating results have varied in the past and are expected to continue to vary significantly in the future, causing volatility in our stock price;
- With the sale of our TMR business in February 2011, our future prospects are solely dependent upon the successful commercialization of RenalGuard. To date we have recorded only a limited amount of sales of RenalGuard, principally to a single customer in one country, Italy. Sales of RenalGuard alone are currently insufficient, and may never grow to be sufficient, to sustain our ongoing operations;
- Our ability to effectively market RenalGuard outside the U.S. is largely dependent on the reception of the results of the MYTHOS and REMEDIAL II investigator-sponsored clinical trials. We have no assurance that the results from these two trials will be viewed as clinically meaningful or that they will lead to increased sales of RenalGuard;

[Table of Contents](#)

- We may never be successful in establishing a broad distribution channel for RenalGuard outside the U.S., and any distribution channel we may establish may never generate sufficient sales for us to attain profitability;
- If we are required to change our pricing models to compete successfully, our margins and operating results may be adversely affected;
- We commenced our U.S. pivotal clinical trial in late 2011 to study RenalGuard, which is necessary to obtain FDA pre-market approval to market RenalGuard in the U.S. This study will take us a significant amount of time and money to complete and will require us to raise additional capital. We can provide no assurance that we will be able to complete this study or, if we are able to complete it, that RenalGuard will be shown to be safe or effective in preventing CIN, or that the degree of any positive safety and efficacy results will be sufficient to either obtain FDA approval or otherwise successfully market our product. Furthermore, the completion of a U.S. pivotal clinical trial is dependent upon many factors, some of which are not entirely within our control, including, but not limited to, our ability to successfully recruit investigators, the availability of patients meeting the inclusion criteria of our clinical study, the competition for these particular study patients amongst other clinical trials being conducted by other companies at these same study sites, the ability of the sites participating in our study to successfully enroll patients in our trial, and proper data gathering on the part of the investigating sites. Should a U.S. pivotal clinical trial take longer than we expect, our competitive position relative to existing preventative measures, or relative to new devices, drugs or therapies that may be developed, could be seriously harmed and our ability to successfully fund the completion of the trial and bring RenalGuard to market may be adversely affected;
- Our RenalGuard System has only had limited testing in a clinical setting in the U.S. and we may need to modify it substantially in the future for it to be commercially acceptable in the broader market;
- Any potential future modifications required to make RenalGuard commercially acceptable for the broader market may result in substantial additional costs and/or market introduction delays;
- Rapid technological change in the medical device industry could make our products obsolete and requires substantial research and development expenditures and responsiveness to customer needs. We expect to continue to face substantial competition from different treatment modalities and if we do not compete effectively with these alternatives, our market share may never grow and could decline;
- An inability to obtain third party reimbursement for RenalGuard could materially affect future demand for our product. We know of no existing Medicare coverage or other third party reimbursement that currently would be available in the U.S. to either hospitals or physicians that would help defray the additional cost that would result from the future purchase and/or use of our RenalGuard System. We also can provide no assurance that we will ever be able to obtain Medicare coverage or other third party reimbursement for the use of RenalGuard, which could materially and adversely affect the potential future demand for our product;
- Securing patent protection over our intellectual property ideas in the field of CIN prevention is, we believe, critical to our plans to successfully differentiate and market our RenalGuard System and grow our future revenues. However, we can provide no assurance as to how strong our issued patents will prove to be. Furthermore we can provide no assurance that we will be successful in securing any additional patent protection for our intellectual property ideas in this field or that our efforts to obtain patent protection will not prove more difficult, and therefore more costly, than we are otherwise expecting. Finally, even if we are successful in securing patent protection for some of our pending patent applications, or for additional intellectual property ideas in this field, we cannot predict when in the future any such potential patents may be issued, how strong such additional patent protection will prove to be, or whether these patents will be issued in a timely enough fashion to afford us any commercially meaningful advantage in marketing our RenalGuard System against other potentially competitive devices;
- We are exposed to risks associated with outsourcing activities, which could result in supply shortages that could affect our ability to meet customer needs;
- If we deliver systems with defects, our credibility may be harmed, sales and market and regulatory approvals acceptance of our systems may decrease and we may incur liabilities associated with those defects;

[Table of Contents](#)

- If we require additional capital in the future, it may not be available, or if available, may not be on terms acceptable to us;
- We are exposed to various risks related to the regulatory environment for medical devices. Compliance with medical device health and safety regulations may be very costly, and the failure to comply could result in liabilities, fines and cessation of our business;
- Our share price will fluctuate based upon a number of factors including, but not limited to:
 - actual or anticipated fluctuations in our results of operations;
 - changes in estimates of our future results of operations by us or securities analysts;
 - announcements of technological innovations or new products or services by us or our competitors;
 - changes affecting the medical device industry;
 - announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
 - additions or departures of key technical or management personnel;
 - issuances of debt or equity securities;
 - significant lawsuits, including patent or stockholder litigation;
 - changes in the market valuations of similar companies;
 - sales of our common stock by us or our stockholders in the future;
 - dilution caused by the conversion of convertible debt currently outstanding or which may be issued to our current secured lender and its assignees as well as the exercise of warrants issued to this lender, as well as by the exercise of employee stock options or the issuance of shares on the vesting of restricted stock units;
 - trading volume of our common stock; and
 - other events or factors that may directly or indirectly affect the value or perceived value of our business and/or prospects, including the risk factors identified in our SEC filings.
- We have pledged all of our assets to our secured debt holders. We are not currently permitted, nor do we currently intend, to pay any cash dividends on our common stock in the foreseeable future and therefore our shareholders may not be able to receive a return on their shares unless they sell them at an amount greater than the price paid for such shares;
- Our secured debt holders may be able to exert significant control over the company through restrictive covenants contained in such debt agreements or through the conversion to our equity securities of the convertible debt and warrants issued and/or issuable to these debt holders;
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our stock plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall;
- U.S. broker-dealers may be discouraged from effecting transactions in shares of our common stock because it may be considered a “penny stock” and thus be subject to the penny stock rules; and
- Our ability to recruit and retain management and other qualified personnel is crucial to our ability to develop, market, sell and support our products.

Off-Balance Sheet Arrangements

None.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Pursuant to Item 305(e) of Regulation S-K, we are not required to provide this information because we are a smaller reporting company.

[Table of Contents](#)

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management

recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon the evaluation of our disclosure controls and procedures as of September 30, 2012, our chief executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1A. Risk Factors

Pursuant to the instructions to Item 1A. of Form 10-Q, we are not required to provide this information because we are a smaller reporting company.

Item 5. Other Matters

None

Item 6. Exhibits

Exhibit Number	Description of Document
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from PLC Systems Inc. Quarterly Report on Form 10-Q for the quarter ended

31

[Table of Contents](#)

September 30, 2012, formatted in XBRL (Extensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, (iv) Condensed Consolidated Statements of Comprehensive Income and (v) Notes to Condensed Consolidated Financial Statements.

32

[Table of Contents](#)

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.

PLC SYSTEMS INC.

Date: November 14, 2012

By: /s/ Mark R. Tauscher
Mark R. Tauscher
President and Chief Executive Officer
(Principal Executive Officer)

33

[Table of Contents](#)

EXHIBIT INDEX

Exhibit Number	Description of Document
31.1+	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101+	The following materials from PLC Systems Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, (iv) Condensed Consolidated Statements of Comprehensive Income and (v) Notes to Condensed Consolidated Financial Statements.

+ Exhibits marked with a plus sign (“+”) are filed herewith.

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark R. Tauscher, certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of PLC Systems Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 14, 2012

/s/ Mark R. Tauscher

Mark R. Tauscher
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory W. Mann, certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of PLC Systems Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 14, 2012

/s/ Gregory W. Mann

Gregory W. Mann
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of PLC Systems Inc. (the "Company") for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark R. Tauscher, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2012

By: /s/ Mark R. Tauscher
Mark R. Tauscher
President and Chief Executive Officer
(Principal Executive Officer)

In connection with the quarterly report on Form 10-Q of PLC Systems Inc. (the "Company") for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gregory W. Mann, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2012

By: /s/ Gregory W. Mann
Gregory W. Mann
Chief Financial Officer
(Principal Financial Officer)
