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**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, 2013.

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 6, 2013
Common Stock, no par value	161,414,862

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**Part I. Financial Information**

**Item 1. Financial Statements**

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

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,404	\$ 258
Restricted cash	250	—
Accounts receivable, net of allowance of \$2 at September 30, 2013 and December 31, 2012, respectively	488	402
Inventories	145	182
Prepaid expenses and other current assets	144	178
Total current assets	2,431	1,020
Equipment, furniture and leasehold improvements, net	50	67
Other assets	4	4
Total assets	<u>2,485</u>	<u>\$ 1,091</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 443	\$ 377
Accrued compensation	41	78
Accrued other	331	368
Deferred revenue	13	317
Total current liabilities	828	1,140
Convertible notes	5,793	8,098
Warrant and option liabilities	6,452	3,800
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Common stock, no par value, unlimited shares authorized, 125,000 shares issued and outstanding; 37,538 unissued and reserved at September 30, 2013; and 32,434 shares issued and outstanding at December 31, 2012	97,263	93,893
Additional paid in capital	—	1,540
Accumulated deficit	(107,586)	(107,114)
Accumulated other comprehensive loss	(265)	(266)
Total stockholders' deficit	<u>(10,588)</u>	<u>(11,947)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,485</u>	<u>\$ 1,091</u>

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

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**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,	
	2013	2012	2013	2012
Revenues	\$ 348	\$ 212	\$ 1,069	\$ 595
Cost of revenues	124	84	438	308
Gross profit	224	128	631	287
Operating expenses:				
Selling, general and administrative	945	674	2,595	1,899
Research and development	549	549	1,661	1,618
Total operating expenses	1,494	1,223	4,256	3,517
Loss from operations	(1,270)	(1,095)	(3,625)	(3,230)
Other income (expense):				
Interest expense	(63)	(137)	(264)	(369)
Foreign currency transaction gains (losses)	16	17	9	2
Financing costs associated with convertible notes	—	(80)	—	(80)
Change in fair value of warrant and option liabilities	1,078	(1,117)	3,192	(3,517)
Change in fair value of convertible notes	1,620	(757)	3,485	(4,218)
Loss on extinguishment of convertible notes	(1,991)	—	(3,274)	—
Other income	1	4	4	24
Total other income (expense)	661	(2,070)	3,152	(8,158)
Net loss	\$ (609)	\$ (3,165)	\$ (473)	\$ (11,388)
Net loss per weighted average share, basic	\$ (0.01)	\$ (0.10)	\$ (0.01)	\$ (0.37)
Weighted average shares outstanding:				
Basic	76,902	30,397	60,923	30,912

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	\$ (609)	\$ (3,165)	\$ (473)	\$ (11,388)
Other comprehensive income (loss)				
Foreign currency translation adjustments	(9)	2	1	(17)
Other comprehensive income (loss)	(9)	2	1	(17)
Comprehensive loss	\$ (618)	\$ (3,163)	\$ (472)	\$ (11,405)

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

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

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	\$ (473)	\$ (11,388)
Depreciation and amortization	39	31
Stock-based compensation expense	158	433
Change in fair value of warrant and liabilities	(3,192)	3,517
Change in fair value of convertible notes	(3,485)	4,218
Financing costs associated with convertible notes	—	80
Loss on extinguishment of convertible notes	3,274	—
Non-cash interest expense	158	215
Change in assets and liabilities:		
Restricted cash	(250)	—
Accounts receivable	(87)	59
Inventories	15	3
Prepaid expenses and other current assets	36	12
Accounts payable	66	82
Deferred revenue	(312)	109
Accrued liabilities	(137)	65
Net cash flows used in operating activities	(4,190)	(2,564)

Cash flows used for investing activities:		
Purchase of equipment, furniture, and leasehold improvements	—	(74)
Net cash flow used for investing activities	—	(74)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	5,079	—
Net proceeds from issuance of convertible notes and warrants	250	920
Net cash provided by financing activities	5,329	920
Effect of exchange rate changes on cash and cash equivalents	7	(144)
Net (decrease) increase in cash and cash equivalents	1,146	(1,862)
Cash and cash equivalents at beginning of period	258	2,585
Cash and cash equivalents at end of period	\$ 1,404	\$ 723
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 112	\$ 154
Supplemental disclosure of non-cash financing activities:		
Cashless exercise of warrants	\$ 2,655	\$ —
Cashless conversion of convertible notes	\$ 883	\$ —

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

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**PLC SYSTEMS INC.**  
NOTES TO CONDENSED CONSOLIDATED UNAUDITED FINANCIAL STATEMENTS  
September 30, 2013

**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 five years, the Company has begun initial commercialization outside the United States of its 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, 2013, the Company incurred a loss from operations of approximately \$3,625,000 and used cash in operations of approximately \$4,190,000. As of September 30, 2013, cash and cash equivalents were \$1,404,000. Management expects that quarterly losses from operations and negative cash flows will continue during 2013. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying 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 from operations during 2013, management is currently investigating ways to raise additional capital that can be completed in the next several months. The Company believes that its existing resources, based on its currently projected financial results, are sufficient to fund operations through the first quarter of 2014. Based upon current and anticipated revenue projections from foreign sales of our RenalGuard product, and the anticipated costs of its U.S. clinical trial, we expect that we will need to raise additional capital during the first quarter of 2014. The Company was able to raise an additional \$1,750,000 of capital in September 2013, and \$4,040,000 in capital in February 2013, through the completion of equity financings. (see Note 9 — *Sale of Common Stock*). Where possible, the Company has taken certain reductions in its discretionary spending. The Company will continue to review its other expense areas to determine whether additional reductions in discretionary spending can be achieved.

**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 GAAP 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. 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, 2012.

The preparation of financial statements in accordance with GAAP 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.

**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, 2013 and December 31, 2012, inventories consisted of the following (in thousands):

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	September 30, 2013	December 31, 2012
Raw materials	\$ 145	\$ 143
Finished goods	—	39
	<u>\$ 145</u>	<u>\$ 182</u>

#### 4. Stock-Based Compensation

##### Stock Option Plans

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.

In June 2013, the Company's shareholders approved the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan allows for an additional 11,382,600 incentive stock options which may be issued to non-employee directors, consultants and others, as well as to employees. Under the 2013 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 2013 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 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 additional 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, 2013, the Company granted options to employees to purchase 5,050,000 shares of the Company's common stock, which vest ratably over a three year period. Certain of these grants were issued to former employees to replace 502,000 options that were cancelled during the three months ended September 30, 2013. These grants were accounted for as modifications of previously issued stock options during the quarter. Additionally, the Company granted 589,000 options to non-employee directors that vest quarterly over a one year period.

During the year ended December 31, 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 purchase 112,500 shares of the Company's common stock to non-employee directors that vest quarterly over one year.

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 nine months ending September 30, 2012.

During the year ended December 31, 2012, the Company issued an aggregate of 2,083,338 shares of restricted common stock to Garden State Securities, Inc. and JFS Investments, Inc. in exchange for certain investor relations and related consulting services provided to the Company. During the nine months ended September 30, 2013, the Company issued an aggregate of 416,668 shares of common stock resulting in \$56,250 of compensation expense. These shares vested immediately but are restricted from being sold for a period of six months from the date of issuance. The contract with Garden State

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Securities, Inc. and JFS Investments, Inc. terminated in February 2013. No further stock issuances will occur under this agreement.

As of September 30, 2013, there were 1,819,000 shares of common stock available to be granted under the 2005 Plan, and 5,743,000 shares of common stock available to be granted under the 2013 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, 2012	5,592	\$ 0.21	3.2	\$ 6,500
Granted	5,639	0.09		
Exercised	—	—		
Cancelled	(502)	0.16		
Forfeited	(643)	0.10		
Expired	—	—		
Outstanding, September 30, 2013	<u>10,086</u>	0.15	6.1	\$ 0
Exercisable, September 30, 2013	<u>5,528</u>	0.20	2.4	\$ 0

##### Stock-Based Compensation Expense

The Company recorded compensation expense related to stock options of \$76,000 and \$102,000 in the three and nine months ended September 30, 2013, respectively, as compared to \$12,000 and \$65,000 in the three and nine months ended September 30, 2012, respectively. The Company also recorded compensation expense of \$0 and \$56,000 related to the issuance of restricted common shares during the three and nine months ended September 30, 2013, respectively, as compared to \$123,000 and \$368,000 in the three and nine

months ended September 30, 2012, respectively. As of September 30, 2013, the Company had \$401,000 of total unrecognized compensation cost related to its unvested options, which is expected to be recognized over a weighted average period of 1.93 years.

The weighted average fair value of options issued, as estimated using the Black-Scholes model, was \$0.08 and \$0.16 during the nine months ended September 30, 2013 and 2012, respectively. The assumptions used were as follows:

	Grants Issued in:	
	2013	2012
Expected life (years)	3.00-6.00	5.00-6.00
Risk free rate	0.73-1.67%	0.19-0.69%
Volatility	195.75-217.52%	204.1-216.2%
Expected dividend yield	None	None
Value of options granted	\$0.07-0.09	\$0.12-0.17

#### *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, 2013 or 2012. At September 30, 2013, 294,461 shares were reserved for future issuance under the Purchase Plan.

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#### **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, 2013, the Company had deferred \$13,000 of revenue related to shipments prior to March 31, 2013 to its distributor in Italy, Artech, because not all revenue recognition criteria were met. The Company expects this revenue to be recognized during the fourth quarter of 2013.

#### **6. Loss per Share**

In the three and nine months ended September 30, 2012, basic loss per share has 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, Rights To Shares Agreement (see Note 9), investor warrants or convertible notes, since their inclusion would be antidilutive.

For the three and nine months ended September 30, 2013, 248,336,287 shares attributable to outstanding warrants, convertible notes, the Rights To Shares Agreements and stock options were excluded from the calculation of diluted earnings per share because the effect would have been antidilutive.

#### **7. Total Comprehensive Income (Loss)**

Total comprehensive loss for the three and nine months ended September 30, 2013 was \$618,000 and \$472,000 as compared to a comprehensive loss of \$3,163,000 and \$11,405,000 in the three and nine months ended September 30, 2012, respectively. Comprehensive income (loss) is comprised of the net income/loss plus the increase/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, 2013 or December 31, 2012.

#### **9. Sale of Common Stock**

##### **September 2013 Financing**

On September 18, 2013 the Company entered into a Securities Purchase Agreement (the "September SPA") with a number of accredited investors, whereby the Company sold an aggregate of 29,166,668 shares of common stock at \$0.06 per share (the "September Purchase Price") and issued warrants to purchase an additional 29,166,668 shares of common stock (the "September Investor Warrants") with gross proceeds to the Company of \$1,750,000. After payment of the placement agent fees and other expenses, the Company received net proceeds of approximately \$1,575,329. As part of the fee for its placement agent services, the Company also issued Palladium Capital Advisors a warrant to purchase 1,485,333 shares of common stock (together with the September Investor Warrants, the "September 2013 Warrants") on the same terms and conditions as the investors under the September SPA. The shares of common stock sold in the offering are subject to certain piggyback registration rights as well as certain other protections, including price protection, as discussed below.

The September SPA provides that for a period of 24 months after the later of (i) September 18, 2013, or (ii) the public announcement of FDA approval for RenalGuard for sale in the United States, and so long as the investors hold the shares purchased pursuant to the September SPA, if the Company issues or sells any shares of common stock or any common stock

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equivalent at a price less than the September Purchase Price (a “Share Dilutive Issuance”), the Company shall issue additional shares of common stock so that total amount paid by the investor to acquire the shares, divided by the number of shares held by the investor pursuant to the September SPA, plus the additional shares issued as a result of a Share Dilutive Issuance, equals the price per share paid in the Share Dilutive Issuance. This provision also extends to any common shares that are issued pursuant to an exercise of the September 2013 Warrants.

In conjunction with the September 2013 SPA, the Company entered into a Right To Shares Agreement with one of the investors. Pursuant to this agreement, in lieu of issuing 16,666,667 of the common shares purchased by the investor, the Company shall be obligated to issue, and the investor has the right to up to 16,666,667 shares of the Company’s common stock. No additional consideration will be paid upon the issuance of the shares and the subscription amount has been paid in full by the investor and is non-refundable. The Company is obligated to deliver the shares to the investor within 3 days of the investor’s request for the share issuance. If the Company fails to deliver the shares within 3 days of the request, under certain circumstances defined in the Right To Shares Agreement, the Company may be obligated to reimburse the investor in cash for losses that the investor incurs as a result of not having access to the shares (the “Buy-In Shares”). As of September 30, 2013, the Company has reserved, but not issued 16,666,667 shares of common stock pursuant to the Right To Shares Agreement.

The September SPA also provides the investors with the option, for a period through June 18, 2014, to purchase on the same terms and with the same rights as the September 2013 SPA up to one-half of the shares of common stock purchased by the purchaser at the initial closing (“September 2013 SPA Option”). The investors would also receive a warrant for every option share exercised with the same terms as the warrants issued in the September SPA. To date, no shares have been purchased under the September 2013 SPA Option. The following is a summary of the September 2013 SPA Option for the:

<u>September 2013 SPA Option</u>	<u>Shares</u>	<u>Exercise Price</u>
Beginning balance at September 18, 2013	14,583,334	\$ 0.06
Ending balance at September 30, 2013	14,583,334	\$ 0.06

The September 2013 Warrants have a term of five-years and are immediately exercisable for an aggregate 30,625,001 shares of common stock purchased at an exercise price of \$0.08 per share. The exercise price of the September 2013 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. The September 2013 Warrants may be exercised on a cashless basis if at any time there is no effective registration statement within 180 days after the closing date of the private placement covering the resale of the shares of common stock underlying the September 2013 Warrants. The September 2013 Warrants contain limitations on the holder’s ability to exercise the September 2013 Warrants in the event such exercise causes the holder to beneficially own in excess of 4.99% of the Company’s issued and outstanding common stock, subject to a discretionary increase in such limitation by the holder to 9.99% upon 61 days’ notice. To date, none of the September 2013 Warrants have been exercised. The following is a summary of the September 2013 Warrants for the nine months ending September 30, 2013:

<u>The September 2013 Warrants</u>	<u>Warrants</u>	<u>Exercise Price</u>
Beginning balance at September 18, 2013	30,625,001	\$ 0.08
Add: Adjustments	—	n/a
Ending balance at September 30, 2013	30,625,001	\$ 0.08

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

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classified as liabilities and reported at fair value.

Upon issuance, the September 2013 Warrants and the September 2013 SPA Option 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. A Monte Carlo simulation was used to estimate the fair value of the September 2013 Warrants and September 2013 SPA Option resulting in grant date fair values of \$1,807,000 and \$1,166,000, respectively (see Note 11 — *Fair Value Measurements*). As of September 30, 2013, the September 2013 Warrants have been marked to fair value resulting in a derivative liability of \$1,574,000. The impact to other income for the change in fair value of the September 2013 Warrants for the three months ended September 30, 2013 was a gain of \$233,000. As of September 30, 2013, the September 2013 SPA Options have been marked to fair value resulting in a derivative liability of \$875,000. The impact to other income for the change in fair value of the September 2013 SPA Option for the three months ended September 30, 2013 was a gain of \$291,000.

The Company also assessed the provisions of the Buy-In Share feature of the Rights To Shares Agreement as an embedded derivative pursuant to ASC 815-15, *Embedded Derivatives*, and has concluded that the feature meets the definition of a derivative and is not clearly and closely related to the Rights To Shares equity host agreement. The Buy-In Shares feature has been bifurcated from the Rights To Shares agreement and accounted for separately. The value of this feature was nominal as of the issuance date and September 30, 2013.

#### *Allocation of SPA Proceeds*



The Company first allocated the proceeds of the September SPA to the fair value of the September 2013 Warrants and September 2013 SPA Option. When the issuance costs were considered, the aggregate fair value of the September 2013 Warrants and September 2013 SPA Option exceeded the net proceeds of the September SPA. The Company first recorded the difference as a reduction of additional paid in capital to the extent available, with the remainder accounted for as a reduction in common stock.

### February 2013 Financing

On February 22, 2013, the Company entered into a Securities Purchase Agreement (the "February SPA") with a number of accredited investors, whereby the Company sold an aggregate of 26,933,333 shares of common stock at \$0.15 per share (the "February Purchase Price") and issued warrants to purchase an additional 26,933,333 shares of common stock (the "February Investor Warrants") with gross proceeds to the Company of \$4,040,000. After payment of the placement agent fees and other expenses, the Company received net proceeds of approximately \$3,504,000. As part of the fee for its placement agent services, the Company also issued Palladium Capital Advisors a warrant to purchase 1,885,333 shares of common stock (together with the Investor Warrant, the "February 2013 Warrants") on the same terms and conditions as the investors under the February SPA. The shares of common stock sold in the offering are subject to certain piggyback registration rights as well as certain other protections, including price protection, as discussed below.

The February SPA provides that for a period of 24 months after the later of (i) February 22, 2013, or (ii) the public announcement of FDA approval for RenalGuard for sale in the United States, and so long as the investors hold the shares purchased pursuant to the February SPA; in the event that the Company issues or sells any shares of common stock or any common stock equivalent at a price less than the Purchase Price (a "Share Dilutive Issuance"), the Company shall issue additional shares of common stock so that total amount paid by the investor to acquire the shares, divided by the number of shares held by the investor pursuant to the February SPA, plus the additional shares issued as a result of a Share Dilutive Issuance, equals the price per share paid in the Share Dilutive Issuance. This provision also extends to any common shares that are issued pursuant to an exercise of the February 2013 Warrants. As required under the terms of the February SPA, in connection with the September SPA, the Company issued to the investors in the February 2013 Financing an additional 40,400,001 shares of Common Stock due to these anti-dilutive provisions being triggered by the lower purchase price for shares issued in the September SPA.

In conjunction with the February SPA, the Company entered into a Right To Shares Agreement with one of the investors. Pursuant to this agreement, in lieu of issuing 7,000,000 of the common shares purchased by the investor, the Company shall be obligated to issue, and the investor has the right to up to 7,000,000 shares of the Company's common stock. No additional consideration will be paid upon the issuance of the shares and the subscription amount has been paid in full by

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the investor and is non-refundable. The Company is obligated to deliver the shares to the investor within 3 days of the investor's request for the share issuance. If the Company fails to deliver the shares within 3 days of the request, under certain circumstances defined in the Right To Shares Agreement, the Company may be obligated to reimburse the investor in cash for losses that the investor incurs as a result of not having access to the shares (the "Buy-In Shares"). As of September 30, 2013, the Company has reserved, but not issued 19,000,000 shares of common stock pursuant to the Right To Shares Agreement.

The February SPA also provides the investors with the option, for a period through November 21, 2013, to purchase on the same terms and with the same rights as the February 2013 SPA up to one-half of the shares of common stock purchased by the purchaser at the initial closing ("February 2013 SPA Option"). The investors would also receive a warrant for every option share exercised with the same terms as the warrant issued in the February SPA. To date, no shares have been purchased under the February 2013 SPA Option. The following is a summary of the February 2013 SPA Option for the nine months ending September 30, 2013:

<b>February 2013 SPA Option</b>	<b>Shares</b>	<b>Exercise Price</b>
Beginning balance at February 22, 2013	13,466,667	\$ 0.15
Ending balance at September 30, 2013	13,466,667	\$ 0.15

The February 2013 Warrants have a term of five-years and were immediately exercisable for an aggregate 28,818,666 shares of common stock purchased at an exercise price of \$0.20 per share. The exercise price of the 2013 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. Due to the September SPA, certain anti-dilution rights were triggered, resulting in the issuance of an additional 43,228,001 warrants at a price of \$0.08. All previously issued warrants related to the February 2013 financing have been repriced to \$0.08. The February 2013 Warrants may be exercised on a cashless basis if at any time there is no effective registration statement within 180 days after the closing date of the private placement covering the resale of the shares of common stock underlying the February 2013 Warrants. The February 2013 Warrants contain limitations on the holder's ability to exercise the February 2013 Warrant in the event such exercise causes the holder to beneficially own in excess of 4.99% of the Company's issued and outstanding common stock, subject to a discretionary increase in such limitation by the holder to 9.99% upon 61 days' notice. The following is a summary of the February 2013 Warrants for the nine months ending September 30, 2013:

<b>The February 2013 Warrants</b>	<b>Warrants</b>	<b>Exercise Price</b>
Beginning balance at February 22, 2013	28,818,666	\$ 0.20
Add: Anti-dilution adjustment	43,228,001	0.08
Ending balance at September 30, 2013	72,046,667	\$ 0.08

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 February 2013 Warrants and February 2013 SPA Option 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. A Monte Carlo simulation was used to estimate the fair value of the February 2013 Warrants and February 2013 SPA Option resulting in grant date fair values of \$2,759,000 and \$1,211,000, respectively (see Note 11 — *Fair Value Measurements*). As of September 30, 2013, the



February 2013 Warrants have been marked to fair value resulting in a derivative liability of \$3,182,000. The impact to other income for the change in fair value of the February 2013 Warrants for the three and nine months ended September 30, 2013 was a loss of \$1,165,000 and \$423,000 respectively. As of September 30, 2013, the February 2013 SPA Options have been marked to fair value resulting in a derivative liability of \$0. The impact to other income for the change in fair value of the February 2013 SPA Option for the three and nine months ended September 30,

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2013 was a gain of \$404,000 and a gain of \$1,211,000, respectively.

The Company also assessed the provisions of the Buy-In Share feature of the Rights To Shares Agreement as an embedded derivative pursuant to ASC 815-15, *Embedded Derivatives*, and has concluded that the feature meets the definition of a derivative and is not clearly and closely related to the Rights To Shares equity host agreement. The Buy-In Shares feature has been bifurcated from the Rights To Shares agreement and accounted for separately. The value of this feature was nominal as of the issuance date and September 30, 2013.

*Allocation of SPA Proceeds*

The Company first allocated the proceeds of the February SPA to the fair value of the February 2013 Warrants and February 2013 SPA Option. When the issuance costs were considered, the aggregate fair value of the February 2013 Warrants and February 2013 SPA Option exceeded the net proceeds of the February SPA. The Company recorded the difference as a reduction of additional paid in capital.

The SPA requires the Company to use \$1,000,000 of the proceeds received from the February SPA for investor relations. The Company engaged an investor relations firm and made an initial payment of \$500,000 on the date of the February SPA closing. During the quarter ended September 30, 2013 the Company paid an additional \$250,000. The remaining \$250,000 will be paid during the quarter ended December 31, 2013. The Company has recorded the cash held in escrow as restricted cash on the balance sheet. The Company is amortizing the investor relations payments over the one-year estimated period of performance for the investor relations services.

**10. Convertible Notes and Warrants**

*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 "2011 Convertible Notes") and warrants to purchase 40,000,000 shares of common stock at \$0.15 per share (the "2011 Warrants"). Under the terms of the Purchase Agreement, the Company had the opportunity to raise up to an additional \$2,000,000 from the Holders in two separate \$1,000,000 tranches, based upon meeting certain operational milestones within certain periods of time. The deadline for achieving the operational milestones for the first \$1,000,000 tranche expired in February 2012 without the Company achieving such milestones; however, the Investors agreed to waive both the deadline and the achievement of these milestones as a condition for the investment of the first additional \$1,000,000 tranche (the "2012 Convertible Notes") and issuance of warrants to purchase 10,000,000 shares of common stock at \$0.15 per share and 10,000,000 shares of common stock at \$0.25 per share (the "2012 Warrants") which was completed on July 2, 2012. On January 16, 2013 the Company entered into an amendment and waiver to the Purchase Agreement to provide for the issuance of an additional \$250,000 of 5% Senior Secured Convertible Debentures (the "Third Tranche Convertible Notes") maturing on January 16, 2016 and warrants exercisable for a period of five years to purchase up to 2,500,000 shares of common stock at an exercise price of \$0.15 per share (the "Third Tranche Warrants").

The convertible notes and warrants 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 convertible notes also contain non-financial covenants which limit the Company and its subsidiaries from incurring subsequent indebtedness, incurring liens, and amending organizational documents, repurchasing or repaying other debt, paying cash dividends and entering into affiliate transactions.

On February 22, 2013, simultaneous with the closing of the February SPA, the Company entered into an Amendment and Waiver Agreement (the "February Amendment and Waiver Agreement") with the Holder under which the Holder agreed to (a) increase the number of shares exercisable under the 2011 and 2012 Warrants from an aggregate 50,000,000 shares to 81,578,946 shares and to modify both the exercise price and the Volume Weighted Average Price ("VWAP price") of the 2011 and 2012 Warrants to \$0.098 and \$0.155, respectively, (b) return to the Company for forfeiture the remaining warrants previously issued to purchase an aggregate 12,500,000 shares of common stock, (c) extend the due date for the 2012 Convertible Notes from February 22, 2014 to June 30, 2015, (d) until February 22, 2014, without the prior written consent

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from the majority of the investors under the February SPA, forbear from declaring any Event of Default (as defined in the original debenture, and (e) relinquish its right to purchase up to an additional \$750,000 in debentures under the terms of the original Purchase Agreement. The terms of the individual tranches of convertible notes and warrants issued pursuant to this agreement and the impact of the Amendment and Waiver Agreement are discussed below.

On September 18, 2013, simultaneous with the closing of the September SPA, the company entered into an Amendment and Waiver Agreement ("the September Amendment and Waiver Agreement") under which the holders of the term debentures have agreed to (a) extend the payment due date for the interest on the debentures to June 30, 2015, modify the conversion price for the debentures to \$0.06, and set the VWAP Price of the warrants originally issued in 2011 and 2012 to \$0.3705.

2011 Convertible Notes

The September Amendment and Waiver of the Convertible Notes extends the payment due date for the interest on the debentures to

June 30, 2015. 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 \$0.06 per share ("Conversion Price") as per the September 2013 Amendment and Waiver. 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) certain 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.

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 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.

Due to the February 2013 Amendment and Waiver agreement, the Company is required to repay, in cash, any outstanding principal amount of the Convertible Notes on June 30, 2015 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.

#### 2011 Warrants

On February 22, 2011, in connection with the issuance of the 2011 Convertible Notes, 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"). On February 22, 2013, as per the terms of the Amendment and Waiver Agreement, the Company canceled the original warrants and re-issued new warrants for the purchase of up to 65,263,156 shares of common stock at an exercise price of \$0.098 per share.

The 2011 Warrants are exercisable by a cashless exercise to purchase shares of the Company's common stock (the "Warrant Shares"). 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) certain 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,

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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.

During the nine months ended September 30, 2013, 47,322,376 of the 2011 Warrants were exercised pursuant to the cashless exercise provisions resulting in the issuance of 19,608,926 shares of common stock.

The following is a summary of the 2011 Warrants outstanding for the nine months ending September 30, 2013:

	<b>2011 Warrants</b>	<b>Exercise Price</b>
Beginning balance — December 31, 2012	40,000,000	\$ 0.15
Less: Canceled	(40,000,000)	0.15
Add: Issued	65,263,156	0.098
Less: Exercised	(47,322,376)	0.098
Ending Balance — September 30, 2013	<u>17,940,780</u>	<u>\$ 0.098</u>

#### 2012 Convertible Notes

The 2012 Convertible Notes contains the same terms as the 2011 Convertible Notes and require payment of interest at the rate of 5% per annum, payable upon the maturation of the debenture and mature on July 2, 2015. The Second Tranche 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 \$0.06 per share (the "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) certain 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 Tranche Convertible Notes may be redeemed at the option of the Company on the same terms as the Convertible Notes 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.

#### 2012 Warrants

On July 2, 2012, in conjunction with the issuance of the 2012 Convertible Notes, 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 2011 Warrants, except that the 2012 Warrants are exercisable for a period of five years from the date of issuance and contain different exercise prices. On February 22, 2013, as per the terms of the Amendment and Waiver Agreement, the Company canceled the original warrants and re-issued new warrants for the purchase of up to 16,315,790 shares of common stock at an initial purchase price of \$0.098. During the nine months ended September 30, 2013, 9,250,535 of the 2012 Warrants were exercised pursuant to the cashless exercise provisions resulting in the issuance of 3,401,809 shares of common stock.

The following is a summary of the 2012 Warrants outstanding at September 30, 2013:

<b>\$0.15 Warrants</b>	<b>Warrants</b>	<b>Exercise Price</b>
Beginning balance at December 31, 2012	10,000,000	\$ 0.15
Less: Canceled	(10,000,000)	0.15
Add: Issued	16,315,790	0.098
Less: Exercised	(9,250,535)	0.098
Ending balance at September 30, 2013	<u>7,065,255</u>	<u>\$ 0.098</u>

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<b>\$0.25 Warrants</b>	<b>Warrants</b>	<b>Exercise Price</b>
Beginning balance at December 31, 2012	10,000,000	\$ 0.25
Less: Canceled	(10,000,000)	0.25
Ending balance at September 30, 2013	<u>—</u>	<u>\$ —</u>

Third Tranche Convertible Notes

The Third Tranche Convertible Notes, which were issued on January 16, 2013, contain the same terms as the 2011 and 2012 Convertible Notes and require payment of interest at the rate of 5% per annum, payable upon the maturation of the debenture on January 16, 2016. The Third Tranche Convertible Notes provide the Investors the option at any time prior to the repayment of the notes to convert any portion of the outstanding Third Tranche balance into fully-paid and non-assessable restricted shares of common stock of the Company at an initial conversion price of \$0.06 per share (the "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) certain 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 Third Tranche Convertible Notes may be redeemed at the option of the Company on the same terms as the 2011 and 2012 Convertible Notes 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.

Third Tranche Warrants

On January 16, 2013, in connection with the Third Tranche Convertible Notes, the Company issued warrants for the purchase of up to 2,500,000 shares of common stock with five year terms. The warrants were issued to allow the Investors to purchase up to 2,500,000 shares of common stock at an initial purchase price of \$0.15 per share. On February 22, 2013, per the terms of the Amendment and Waiver Agreement, the Third Tranche Warrants were canceled. The following is a summary of the 2012 Warrants outstanding for the nine months ending September 30, 2013:

<b>Third Tranche Warrants</b>	<b>Warrants</b>	<b>Exercise Price</b>
Beginning balance at December 31, 2012	—	\$ —
Add: Issued	2,500,000	\$ 0.15
Less: Canceled warrants	(2,500,000)	0.15
Ending balance at September 30, 2013	<u>—</u>	<u>\$ —</u>

***Accounting for the 2011 Convertible Notes, 2012 Convertible Notes, Third Tranche Convertible Notes, 2011 Warrants, 2012 Warrants, and Third Tranche Warrants***

2011 Convertible Notes, 2012 Convertible Notes, and Third Tranche Convertible Notes

The Company has determined that the 2011 Convertible Notes, 2012 Convertible Notes and Third Tranche 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 of ASC 815. The Company has identified all of the derivatives associated with each convertible note. As permitted under ASC 825-10-10 — *Financial Instruments*, as it relates to the fair value option, the Company has elected, as of the original issuance date of each convertible note, to measure the 2011 Convertible Notes, 2012 Convertible Notes, and the Third Tranche Convertible Notes in their entirety at fair value with changes in fair value recognized in the 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

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hybrid contract together with the convertible notes. This election was made by the Company after determining the aggregate fair value of the 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.

Pursuant to the guidance of ASC 815-40-15 (formerly EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*), the 2011 Warrants, 2012 Warrants and Third Tranche Warrants were not considered indexed to the Company's own stock. As a result these instruments have been accounted for as freestanding derivative instruments and classified as a liability recorded at fair value at each reporting period.

The February 2013 Amendment and Waiver Agreement triggered a greater than 10% change in the present value of cash flows of the convertible notes and associated warrants. As a result, the Company has treated the Amendment and Waiver Agreement as a debt extinguishment where the carrying value of the convertible notes and warrants prior to the amendment were removed from the Company's books and the fair value of the amended convertible notes and warrants was recorded. The resulting difference in value was recorded as a \$1,283,000 loss on the extinguishment of debt. The impact to each of the convertible notes and associated warrants is discussed below.

The September 2013 Amendment and Waiver Agreement triggered a greater than 10% change in the present value of cash flows of the convertible notes. As a result, the Company has treated the Amendment and Waiver Agreement as a debt extinguishment where the carrying value of the convertible notes prior to the amendment were removed from the Company's books and the fair value of the amended convertible notes was recorded. The resulting difference in value was recorded as a \$1,991,000 loss on the extinguishment of debt. The impact to each of the convertible note tranches is discussed below.

#### 2011 Convertible Notes and 2011 Warrants

Upon issuance of the 2011 Convertible Notes, the Company allocated the proceeds received to the 2011 Convertible Notes and 2011 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 debt discount in the amount of \$792,000 (resulting from the allocation of proceeds) was being amortized to interest expense using the effective interest method over the expected term of the 2011 Convertible Notes. The carrying value of the 2011 Convertible Notes has been adjusted to fair value each reporting period. During the three and nine months ended September 30, 2012, the Company amortized \$67,000 and \$198,000 of the debt discount and recorded a \$747,000 gain and a \$2,715,000 loss in the adjustment to the fair value of the notes as a component of other income (expense), respectively.

The Company has accounted for the February 2013 Amendment and Waiver Agreement as an extinguishment of debt at February 22, 2013. The fair value of the 2011 Convertible Notes prior to the extinguishment was replaced by the fair value of the amended 2011 Convertible Notes, resulting in a fair value of \$6,070,000 as of February 22, 2013. In connection with the extinguishment of the debt as of February 22, 2013, the Company had amortized \$38,000 of the debt discount and wrote off the remaining debt discount of \$265,000.

The Company has accounted for the September 2013 Amendment and Waiver Agreement as an extinguishment of debt at September 18, 2013. The fair value of the 2011 Convertible Notes prior to the extinguishment was replaced by the fair value of the amended 2011 Convertible Notes, resulting in a fair value of \$4,920,000 as of September 18, 2013. As of September 30, 2013, the 2011 Convertible Notes have been marked to fair value resulting in a derivative liability of \$4,190,000. The impact to other income (expense) for the loss on extinguishment and adjustments to fair value for the three and nine months ended September 30, 2013 was a gain of \$1,227,000 and \$1,475,000 respectively.

During the three and nine months ended September 30, 2013, certain holders of the 2011 Convertible Notes converted \$456,000 and \$756,000, respectively, of convertible note principal into 6,427,000 and 9,427,000 shares of common stock, respectively. The conversions resulted in the reclassification of \$433,000 and \$833,000, respectively, in conversion date fair value of the shares as a component of the common stock balance in stockholders' equity within the balance sheet.

As a result of the February 2013 Amendment and Waiver Agreement the carrying value of the 2011 Warrants was adjusted at February 22, 2013 to reflect the revised terms. As of September 30, 2013, the 2011 Warrants have been marked to fair value resulting in a derivative liability of \$538,000. The impact to other income (expense) for the change in fair value of

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the 2011 Warrants for the three and nine months ended September 30, 2013 was a gain of \$857,000 and a loss of \$955,000 respectively.

During the three and nine months ended September 30, 2013, certain holders of the 2011 Warrants exercised warrants to purchase 18,236,853 and 47,322,376, respectively, shares of common stock pursuant to the cashless exercise provisions resulting in the issuance of 8,913,000 and 19,609,000, respectively, shares of the Company's common stock. The cashless exercise resulted in the reclassification of \$652,000 and \$2,405,000, respectively, in the exercise date fair value of the 2011 Warrants exercised as a component of the common stock balance within stockholders' equity in the balance sheet.

#### 2012 Convertible Notes and 2012 Warrants

Upon issuance of the 2012 Convertible Notes, the Company allocated the proceeds received to the Second Tranche 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 Tranche Convertible Notes to be \$417,000. The debt discount in the amount of \$583,000 (resulting from the allocation of proceeds) was being amortized to interest expense using the effective interest method over the expected term of the 2012 Convertible Notes. The carrying value of the 2012 Convertible Notes has been adjusted to fair value each reporting period. During the three and nine months ended September 30, 2012 the Company amortized \$17,000 of the debt discount and recorded a loss of \$1,502,000 in fair value adjustment as a component of other income (expense), respectively.

The Company has accounted for the February 2013 Amendment and Waiver Agreement as an extinguishment of debt at February 22, 2013. The fair value of the 2012 Convertible Notes prior to the extinguishment was replaced by the fair value of the amended 2012 Convertible Notes, resulting in a fair value of \$1,516,000 as of February 22, 2013.

The Company has accounted for the September 2013 Amendment and Waiver Agreement as an extinguishment of debt at September 18, 2013. The fair value of the 2012 Convertible Notes prior to the extinguishment was replaced by the fair value of the amended 2012 Convertible Notes, resulting in a fair value of \$1,390,000 as of September 18, 2013. As of September 30, 2013, the 2012 Convertible Notes have been marked to fair value resulting in a derivative liability of \$1,290,000. The impact to other income (expense) for the loss on extinguishment and adjustments to fair value was a loss of \$110,000 and a gain of \$353,000 for the three and nine months ended

September 30, 2013, respectively.

As a result of the February 2013 Amendment and Waiver Agreement the carrying value of the 2012 Warrants was adjusted at February 22, 2013 to reflect the revised terms. As of September 30, 2013, the 2012 Warrants have been marked to fair value resulting in a derivative liability of \$283,000. The impact to other income (expense) for the three and nine months ended September 30, 2013 was a gain of \$458,000 and \$1,279,000 respectively.

During the three months ended September 30, 2013, certain holders of the 2012 Warrants exercised warrants to purchase 9,250,535 shares of common stock pursuant to the cashless exercise provisions resulting in the issuance of 3,401,809 shares of the Company's common stock. The cashless exercise resulted in the reclassification of \$238,000 in the exercise date fair value of the 2012 Warrants exercised as a component of common stock in stockholders' equity.

#### Third Tranche Convertible Notes and Third Tranche Warrants

Upon issuance of the Third Tranche Convertible Notes in January 2013, the Company allocated the proceeds received to the Third Tranche Convertible Notes and Third Tranche Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Third Tranche Convertible Notes to be \$142,000. The Third Tranche Convertible Notes were immediately marked to fair value, resulting in a derivative liability in the amount of \$394,000. The debt discount in the amount of \$108,000 (resulting from the allocation of proceeds) was being amortized to interest expense using the effective interest method over the expected term of the Convertible Notes.

The Company has accounted for the February 2013 Amendment and Waiver Agreement as an extinguishment of debt at February 22, 2013. The fair value of the Third Tranche Convertible Notes prior to the extinguishment was replaced by the fair value of the amended Third Tranche Convertible Notes, resulting in a fair value of \$386,000 as of February 22, 2013.

The Company has accounted for the September 2013 Amendment and Waiver Agreement as an extinguishment of

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debt at September 18, 2013. The fair value of the Third Tranche Convertible Notes prior to the extinguishment was replaced by the fair value of the amended Third Tranche Convertible Notes, resulting in a fair value of \$361,000 as of September 18, 2013. As of September 30, 2013, the Third Tranche Convertible Notes have been marked to fair value resulting in a derivative liability of \$313,000. The impact to other income (expense) for the loss on extinguishment and adjustments to fair value was a loss of \$18,000 and a gain of \$83,000 for the three and nine months ended September 30, 2013, respectively.

Upon issuance of the Third Tranche Warrants, the Company allocated \$108,000 of the initial proceeds to the Third Tranche Warrants and immediately marked them to fair value resulting in a derivative liability of \$300,000. As of September 30, 2013, the Third Tranche Warrants have been canceled as per the terms of the February 2013 Amendment and Waiver Agreement. The impact to other income (expense) for the three and nine months ended September 30, 2013 was a gain of \$0 and \$108,000, respectively.

#### 11. *Fair Value Measurements*

The following summarizes the Company's assets and liabilities measured at fair value as of December 31, 2012:

Description	Balance as of December 31, 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)
<b>Liabilities</b>				
Convertible notes	\$ 8,098,000	\$ —	\$ —	\$ 8,098,000
Warrant liabilities	\$ 3,800,000	\$ —	\$ —	\$ 3,800,000
Total Liabilities	\$ 11,898,000	\$ —	\$ —	\$ 11,898,000

The following summarizes the Company's assets and liabilities measured at fair value as of September 30, 2013:

Description	Balance as of September 30, 2013	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)
<b>Liabilities</b>				
Convertible notes	\$ 5,793,000	\$ —	\$ —	\$ 5,793,000
Warrant liabilities	\$ 6,452,000	\$ —	\$ —	\$ 6,452,000
Total Liabilities	\$ 12,245,000	\$ —	\$ —	\$ 12,245,000

A summary of changes in the Convertible Notes, Second Tranche Convertible Notes, Third Tranche Convertible Notes, Investor Warrants, 2012 Warrants, Third Tranche Warrants, and the 2013 Warrants and Additional 2013 Warrants as of September 30, 2012, December 31, 2012, February 22, 2013, September 18, 2013 and September 30, 2013 is as follows:

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	Fair Value of 2011 Convertible Notes	Fair Value of 2011 Warrant Liabilities	Fair Value of 2012 Convertible Notes	Fair Value of 2012 Warrant Liabilities	Fair Value of Third Tranche Convertible Notes	Fair Value of Third Tranche Warrant Liabilities	February 2013 Warrants	February 2013 SPA Option	September 2013 Warrants	September 2013 SPA Options	Total
<b>Balance December 31, 2011</b>	\$ 5,327,000	\$ 1,600,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 6,927,000
Amortization of debt discount	\$ 198,000	\$ —	\$ 17,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 215,000
Allocation of initial proceeds	\$ —	\$ —	\$ 417,000	\$ 583,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 1,000,000
Fair value adjustment	\$ 2,715,000	\$ 1,600,000	\$ 1,502,000	\$ 1,917,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 7,734,000
<b>Balance September 30, 2012</b>	\$ 8,240,000	\$ 3,200,000	\$ 1,936,000	\$ 2,500,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 15,876,000
<b>Balance December 31, 2012</b>	\$ 6,510,000	\$ 2,000,000	\$ 1,588,000	\$ 1,800,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 11,898,000
Allocation of initial proceeds	\$ —	\$ —	\$ —	\$ —	\$ 142,000	\$ 108,000	\$ —	\$ —	\$ —	\$ —	\$ 250,000
Initial fair value adjustment	\$ —	\$ —	\$ —	\$ —	\$ 252,000	\$ 192,000	\$ —	\$ —	\$ —	\$ —	\$ 444,000
<b>January 16, 2013</b>	\$ 6,510,000	\$ 2,000,000	\$ 1,588,000	\$ 1,800,000	\$ 394,000	\$ 300,000	\$ —	\$ —	\$ —	\$ —	\$ 12,592,000
Amortization of debt discount	\$ 38,000	\$ —	\$ 55,000	\$ —	\$ 2,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 95,000
Fair value adjustment	\$ (370,000)	\$ —	\$ (72,000)	\$ —	\$ (8,000)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (450,000)
Carrying value of old debt at modification	\$ (6,178,000)	\$ —	\$ (1,571,000)	\$ —	\$ (388,000)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (8,137,000)
Fair value of new debt at modification	\$ 6,070,000	\$ —	\$ 1,516,000	\$ —	\$ 386,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 7,972,000
Modification of warrants	\$ —	\$ 1,916,000	\$ —	\$ 632,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 2,548,000
Cancellation/retirement of warrants	\$ —	\$ —	\$ —	\$ (800,000)	\$ —	\$ (300,000)	\$ —	\$ —	\$ —	\$ —	\$ (1,100,000)
Fair value of instruments at issuance	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 2,759,000	\$ 1,211,000	\$ —	\$ —	\$ 3,970,000
<b>February 22, 2013</b>	\$ 6,070,000	\$ 3,916,000	\$ 1,516,000	\$ 1,632,000	\$ 386,000	\$ —	\$ 2,759,000	\$ 1,211,000	\$ —	\$ —	\$ 17,490,000
Fair value adjustment	\$ (2,041,000)	\$ (716,000)	\$ (536,000)	\$ (970,000)	\$ (136,000)	\$ —	\$ (742,000)	\$ (807,000)	\$ —	\$ —	\$ (5,948,000)
Carrying value of old debt at modification	\$ (3,450,000)	\$ —	\$ (980,000)	\$ —	\$ (250,000)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (4,680,000)
Fair value of new debt at modification	\$ 4,920,000	\$ —	\$ 1,390,000	\$ —	\$ 361,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 6,671,000
Conversion of debentures and warrants	\$ (579,000)	\$ (2,152,000)	\$ —	\$ (238,000)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (2,969,000)
Fair value of instruments at issuance	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 1,807,000	\$ 1,166,000	\$ 2,973,000
<b>September 18, 2013</b>	\$ 4,920,000	\$ 1,048,000	\$ 1,390,000	\$ 424,000	\$ 361,000	\$ —	\$ 2,017,000	\$ 404,000	\$ 1,807,000	\$ 1,166,000	\$ 13,537,000
Conversion of debentures and warrants	\$ (304,000)	\$ (265,000)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (569,000)
Fair value adjustment	\$ (426,000)	\$ (245,000)	\$ (100,000)	\$ (141,000)	\$ (48,000)	\$ —	\$ 1,165,000	\$ (404,000)	\$ (233,000)	\$ (291,000)	\$ (723,000)
<b>September 30, 2013</b>	\$ 4,190,000	\$ 538,000	\$ 1,290,000	\$ 283,000	\$ 313,000	\$ —	\$ 3,182,000	\$ —	\$ 1,574,000	\$ 875,000	\$ 12,245,000

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**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, 2013 SPA Options and Convertible Notes as of the December 31, 2012 balance sheet date, February 22, 2013 Amendment and Waiver Agreement date, September 18, 2013 Amendment and Waiver agreement, and the September 30, 2013 balance sheet date are discussed below. Each of the measurements is considered a Level 3 measurement as a result of at least one significant unobservable input.

**2011 Warrants**



A Black-Scholes-Merton option-pricing model, with dilution effects, was utilized to estimate the fair value of the 2011 Warrants as of December 31, 2012, February 22, 2013, and September 30, 2013. This model is widely used in estimating value of European options dependent upon a non-paying dividend 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:

Input	December 31,		February 22,		September 30,	
	2012		2013		2013	
Stock Price	\$	0.15	\$	0.14	\$	0.065
Exercise Price	\$	0.15	\$	0.15	\$	0.098
Expected Life (in years)		3.15		3.00		2.40
Stock Volatility		100%		100%		100%
Risk-Free Rate		0.39%		0.40%		0.24%
Dividend Rate		0%		0%		0%
Outstanding Shares of Common Stock		32,434,430		59,576,097		160,666,475

### 2012 Warrants

#### \$0.15 Warrants

A Black-Scholes-Merton option-pricing model, with dilution effects, was also utilized to estimate the fair value of the \$0.15 Warrants as of December 31, 2012, February 22, 2013, and September 30, 2013.

Input	December 31,		February 22,		September 30,	
	2012		2013		2013	
Stock Price	\$	0.15	\$	0.14	\$	0.065
Exercise Price	\$	0.15	\$	0.15	\$	0.0098
Expected Life (in years)		4.50		4.38		3.76
Stock Volatility		100%		100%		100%
Risk-Free Rate		0.63%		0.70%		0.92%
Dividend Rate		0%		0%		0%
Outstanding Shares of Common Stock		32,434,430		59,576,097		160,666,475

#### \$0.25 Warrants

A Black-Scholes-Merton option-pricing model, with dilution effects, was also utilized to estimate the fair value of the \$0.25 Warrants as December 31, 2012. These warrants were canceled on February 22, 2013.

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Input	December 31, 2012	
Stock Price	\$	0.15
Exercise Price	\$	0.25
Expected Life (in years)		4.50
Stock Volatility		100%
Risk-Free Rate		0.63%
Dividend Rate		0%
Outstanding Shares of Common Stock		32,434,430

### Third Tranche Warrants

A Black-Scholes-Merton option-pricing model, with dilution effects, was also utilized to estimate the fair value of the Third Tranche Warrants as of January 16, 2013. These warrants were canceled on February 22, 2013.

Input	January 16, 2013	
Stock Price	\$	0.15
Exercise Price	\$	0.15
Expected Life (in years)		5
Stock Volatility		110%
Risk-Free Rate		0.75%
Dividend Rate		0%
Outstanding Shares of Common Stock		32,434,430

### February 2013 Warrants

A Monte Carlo simulation mode was utilized to estimate the fair value of the February 2013 warrants as of February 22, 2013 and September 30, 2013.

Input	February 22,		September 30,	
	2013		2013	
Stock Price	\$	0.12	\$	0.058
Exercise Price	\$	0.20	\$	0.08
Expected Life (in years)		5		4.40
Stock Volatility		110%		110%
Risk-Free Rate		0.84%		1.16%
Number of Steps		100,000		100,000
Outstanding Shares of Common Stock		59,576,097		160,666,475

### **February 2013 SPA Option**

The February 2013 SPA option, upon exercise, allows the investor to purchase one share of common stock and one common stock warrant. The option was valued using multiple valuation models, including a Black-Scholes-Merton option-pricing model, with dilution effects, to estimate the fair value of the option to purchase the common share, and a Monte Carlo simulation to determine the estimated fair value of the warrant that would be issued at the time of exercise. These models were used to estimate the fair value of the option at February 22, 2013 and September 30, 2013.

A Black-Scholes-Merton option-pricing model, with dilution effects, was also utilized to estimate the fair value of the February 2013 SPA Option as of February 22, 2013 and September 30, 2013.

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<b>Input</b>	<b>February 22, 2013</b>	<b>September 30, 2013</b>
Stock Price	\$ 0.14	\$ 0.065
Exercise Price	\$ 0.15	\$ 0.015
Expected Life (in years)	0.75	0.142
Stock Volatility	110 %	110 %
Risk-Free Rate	0.15 %	0.03 %
Dividend Rate	0 %	0 %
Outstanding Shares of Common Stock	73,042,764	160,666,475

A Monte Carlo simulation model was also utilized to estimate the fair value of the February 2013 SPA Option as of February 22, 2013 and September 30, 2013.

<b>Input</b>	<b>February 22, 2013</b>	<b>September 30, 2013</b>
Stock Price (simulated)	\$ 0.10	\$ 0.065
Exercise Price	\$ 0.20	\$ 0.20
Expected Life (in years)	5.00	0.142
Stock Volatility	110 %	110 %
Risk-Free Rate	1.158 %	1.475 %
Number of Steps	10,000	10,000

### **September 2013 Warrants**

A Monte Carlo simulation mode was utilized to estimate the fair value of the September 2013 warrants as of September 18, 2013 and September 30, 2013.

<b>Input</b>	<b>September 18, 2013</b>	<b>September 30, 2013</b>
Stock Price	\$ 0.071	\$ 0.062
Exercise Price	\$ 0.08	\$ 0.08
Expected Life (in years)	5	4.97
Stock Volatility	110 %	110 %
Risk-Free Rate	1.43 %	1.38 %
Number of Steps	100,000	100,000

### **September 2013 SPA Option**

The September 2013 SPA option, upon exercise, allows the investor to purchase one share of common stock and one common stock warrant. The option was valued using multiple valuation models, including a Black-Scholes-Merton option-pricing model, with dilution effects, to estimate the fair value of the option to purchase the common share, and a Monte Carlo simulation to determine the estimated fair value of the warrant that would be issued at the time of exercise. These models were used to estimate the fair value of the option at September 18, 2013 and September 30, 2013.

A Black-Scholes-Merton option-pricing model, with dilution effects, was also utilized to estimate the fair value of the September 2013 SPA Option as of September 18, 2013 and September 30, 2013.

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<b>Input</b>	<b>September 18, 2013</b>	<b>September 30, 2013</b>
Stock Price	\$ 0.075	\$ 0.065
Exercise Price	\$ 0.06	\$ 0.06
Expected Life (in years)	0.748	0.715
Stock Volatility	110 %	110 %
Risk-Free Rate	0.07 %	0.07 %
Dividend Rate	0 %	0 %
Outstanding Shares of Common Stock	143,997,066	160,666,475

A Monte Carlo simulation model was also utilized to estimate the fair value of the 2013 SPA Option as of September 18, 2013 and September 30, 2013.

Input	September 18,		September 30,	
	2013		2013	
Stock Price (simulated)	\$	0.075	\$	0.065
Exercise Price	\$	0.06	\$	0.06
Expected Life (in years)		.7480		0.715
Stock Volatility		110 %		110 %
Risk-Free Rate		0.07 %		0.07 %
Number of Steps		10,000		10,000

### 2011 Convertible Notes

A binomial lattice model was utilized to estimate the fair value of the Convertible Notes as of December 31, 2012, February 22, 2012, September 18, 2013 and September 30, 2013. 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 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	December 31,		February 22,		September 18,		September 30,	
	2012		2013		2013		2013	
Stock Price	\$	0.15	\$	0.14	\$	0.075	\$	0.065
Strike Price	\$	0.10	\$	0.10	\$	0.06	\$	0.06
Expected remaining term (in years)		1.15		2.35		1.78		1.75
Stock Volatility		105 %		100 %		100 %		100 %
Risk-Free Rate		0.17 %		0.32 %		0.38 %		0.27 %
Dividend Rate		0 %		0 %		0 %		0 %
Outstanding Shares of Common Stock		32,434,430		59,576,097		143,997,066		160,666,475
Effective discount rate		13.1 %		13.2 %		16.4 %		16.4 %
Probability of forced redemption		20 %		20 %		20 %		20 %

### 2012 Convertible Notes

A binomial lattice model was also utilized to estimate the fair value of the 2012 Convertible Notes as of December 31, 2012, February 22, 2012 and September 30, 2013. This model requires the following key inputs with respect to the Company and/or instrument:

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Input	December 31,		February 22,		September 18,		September 30,	
	2012		2013		2013		2013	
Stock Price	\$	0.15	\$	0.14	\$	0.075	\$	0.065
Exercise Price	\$	0.10	\$	0.10	\$	0.06	\$	0.06
Expected remaining term (in years)		2.50		2.35		1.79		1.75
Stock Volatility		100 %		100 %		100 %		100 %
Risk-Free Rate		0.31 %		0.32 %		0.38 %		0.26 %
Dividend Rate		0 %		0 %		0 %		0 %
Outstanding Shares of Common Stock		32,434,430		59,576,097		143,997,066		160,666,475
Effective discount rate		13.2 %		13.2 %		16.4 %		16.4 %
Probability of forced redemption		20 %		20 %		20 %		20 %

### Third Tranche Convertible Notes

A binomial lattice model was also utilized to estimate the fair value of the Tranche Three Convertible Notes as of January 16, 2012, February 22, 2012 and September 30, 2013. This model requires the following key inputs with respect to the Company and/or instrument:

Input	January 16,		February 22,		September 18,		September 30,	
	2013		2013		2013		2013	
Stock Price	\$	0.15	\$	0.14	\$	0.075	\$	0.065
Exercise Price	\$	0.10	\$	0.10	\$	0.06	\$	0.06
Expected remaining term (in years)		3		2.90		2.33		2.30
Stock Volatility		100 %		100 %		100 %		100 %
Risk-Free Rate		0.36 %		0.39 %		0.56 %		0.42 %
Dividend Rate		0 %		0 %		0 %		0 %
Outstanding Shares of Common Stock		32,434,430		59,576,097		143,997,066		160,666,475
Effective discount rate		13.2 %		13.2 %		13.3 %		13.3 %
Probability of forced redemption		20 %		20 %		20 %		20 %

The following are significant assumptions utilized in developing the inputs:

- 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 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 of the valuation date for the expected term;
- With respect to the 2011 Convertible Notes, 2012 Convertible Notes and Third Tranche Convertible Notes, the

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Company is expected to pay all accrued interest due to the Holders on each Interest Payment Date;

- With respect to the 2011 Convertible Notes, 2012 Convertible Notes and Third Tranche Convertible Notes, based upon management's expectations for a change of control or fundamental transaction to occur prior to the maturity date of the 2011 Convertible Notes, 2012 Convertible Notes and Third Tranche 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.

**12. Commitments**

*Lease Commitments*

The Company leases its corporate office under an operating lease agreement that expires in August 2014. In addition to the minimum lease payments, the agreement requires payment of the Company's pro-rata share of property taxes and building operating expenses.

As of September 30, 2013, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments	
2013	\$	11
2014		30
Total	\$	41

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 Events**

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.

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## 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 our newest marketable product, RenalGuard.

RenalGuard 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. It is believed that allowing contrast media to dwell in the kidneys of certain higher risk patients can lead to 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 toxic effects in the kidney.

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 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 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 RenalGuard. The first patient was enrolled in the U.S. pivotal study in January 2012.

Our distributor of RenalGuard in Italy, Artech, accounted for 78% and 68% of our total revenues in the three and nine months ended September 30, 2013, respectively, and 32% and 22% of our total revenues in the three and nine months ended September 30, 2012, respectively. ACIST, our distributor in Germany and France, accounted for 18% and 12% of our total revenues in the three and nine months ended September 30, 2013 and 4% and 9% of our revenues in the three months ended September 30, 2012.

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.

For the three and nine months ended September 30, 2013, we incurred net losses from operations of approximately \$1,270,000 and \$3,625,000, respectively, and used cash in operations of approximately \$4,190,000. As of September 30, 2013, cash and cash equivalents were \$1,404,000. Management expects that quarterly losses from operations and negative cash flows will continue during 2013. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared assuming that we 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 we be unable to continue as a going concern.

### 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 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.

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#### ***Inventories***

Inventories are stated at the average cost (computed on a first-in, first-out method) of market value and include allocations of labor and overhead. We regularly review slow-moving and excess inventories, and write 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.

#### ***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 RenalGuard consoles and single-use sets on a quarterly basis and adjust our warranty reserve accordingly. We consider all available evidence, including historical experience and information obtained from supplier audits. Historically, we have not experienced significant costs related to warranty and preventative maintenance.

#### ***Valuation of Convertible Notes, Warrant and Option Liabilities***

The valuation of our convertible notes, warrant and option 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.

### 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 generally record product revenue, including sales of RenalGuard consoles and single-use sets at the time of shipment, if all other revenue recognition criteria have been met. As of September 30, 2013 and 2012, we had deferred revenue balances of \$13,000 and \$394,000, respectively, related to shipments to our distributor in Italy, Artech, because not all revenue recognition criteria were met. During the quarter ended September 30, 2013, we recognized \$40,000 in revenue of previously deferred revenue upon the receipt of cash.

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### Results of Operations

Results for the three and nine months ended September 30, 2013 and 2012 were as follows:

	Three Months Ended		Increase (decrease)		Nine Months Ended		Increase (decrease)	
	September 30,		over 2012		September 30,		over 2012	
	2013	2012	\$	%	2013	2012	\$	%
	\$	\$	\$	%	\$	\$	\$	%
	(dollars in thousands)							
Total revenues	348	212	136	64	1,069	595	474	80
Total cost of revenues	124	84	40	48	438	308	130	42
Gross profit	224	128	96	75	631	287	344	120
Selling, general & administrative expenses	945	674	271	40	2,595	1,899	696	37
Research and development expenses	549	549	—	—	1,661	1,618	43	3
Total operating expenses	1,494	1,223	271	22	4,256	3,517	739	21
Loss from operations	(1,270)	(1,095)	(175)	16	(3,625)	(3,230)	(395)	12
Interest expense	(63)	(137)	74	54	(264)	(369)	105	(28)
Interest income	—	—	—	—	—	—	—	—
Foreign currency transaction gains	16	17	(1)	(6)	9	2	7	350
Financing costs associated with convertible notes	—	(80)	80	100	—	(80)	80	100
Change in fair value of warrant liabilities	1,078	(1,117)	2,195	(197)	3,192	(3,517)	6,709	(191)
Change in fair value of convertible notes	1,620	(757)	2,377	(314)	3,485	(4,218)	7,703	(183)
Other expense	1	4	(3)	(75)	4	24	(20)	100
Loss on extinguishment of convertible notes	(1,991)	—	(1,991)	100	(3,274)	—	(3,274)	100
Total other income (expense)	661	(2,070)	2,731	(132)	3,152	(8,158)	11,310	(139)
Net loss	(609)	(3,165)	2,556	(81)	(473)	(11,388)	10,915	(96)

### Product Sales

Revenues increased \$136,000 and \$474,000 or 64% and 80% in the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012, respectively. RenalGuard Console sales decreased \$65,000 and \$135,000 or 38% and 32% in the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012, respectively, due to a lower volume of RenalGuard consoles sold to international distributors. RenalGuard single use set revenues increased \$204,000 and \$605,000 or 479% and 341% in the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012, respectively, due to a higher volume of RenalGuard single-use sets sold to international distributors. As of September 30, 2013 and 2012, we had deferred revenue balances of \$13,000 and \$394,000, respectively, related to shipments to our distributor in Italy, Artech, because not all revenue recognition criteria were met. During the quarter ended September 30, 2013, we recognized \$40,000 in revenue of previously deferred revenue upon the receipt of cash.

### Gross Profit

Gross profit was \$224,000 and \$631,000 or 64% and 59% of total revenues, in the three and nine months ended September 30, 2013, as compared with gross profit of \$128,000 and \$287,000, or 60% and 48% of total revenues, in the three and nine months ended September 30, 2012, respectively. Gross margin generated from the low volume of RenalGuard revenues was sufficient to offset the fixed manufacturing costs incurred during the three and nine months ended September 30, 2013.

### Selling, General and Administrative Expenses

Selling, general and administrative expenditures increased 40% and 37% in the three and nine months ended September 30, 2013 as



compared to the three and nine months ended September 30, 2012, respectively. The increase was due to higher investor relations expense during the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012.

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***Research and Development Expenses***

Research and development expenditures increased 0% and 3% in the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012, respectively, due to RenalGuard U.S. clinical trial costs.

As we continue our U.S. clinical trial for our RenalGuard program, we expect our Research and development expenses to significantly increase in 2013.

***Other Income (Expense)***

In February 2011, we entered into a Securities Purchase Agreement and a 5% Senior Secured Convertible Debenture Agreement as described in the Condensed Consolidated Financial Statements. In July 2012, we entered into an Amendment to the Securities Purchase Agreement and 5% Senior Secured Convertible Debenture Agreement as described in Note 10 of the Condensed Consolidated Financial Statements. In January 2013, we entered into an Amendment to the Securities Purchase Agreement and 5% Senior Secured Convertible Debenture Agreement as described in Note 10 of the Condensed Consolidated Financial Statements. As a result of these three transactions, interest expense on the Convertible Notes, Second Tranche Convertible Notes, and Third Tranche Convertible Notes of \$63,000 and \$264,000 in the three and nine months ended September 30, 2013, and \$137,000 and \$369,000 in the three and nine months ended September 30, 2012, was recorded.

We recorded other income of \$1,078,000 and \$3,192,000 in the three and nine months ended September 30, 2013 as compared to other expense of \$1,117,000 and \$3,517,000 in the three and nine months ended September 30, 2012, respectively, as a result of a fair value adjustments related to our Warrant and Option Liabilities. We recorded other income of \$1,620,000 and \$3,485,000 in the three and nine months ended September 30, 2013 as compared to other expense of \$757,000 and \$4,218,000 in the three and nine months ended September 30, 2012, respectively, as a result of fair value adjustments related to the Convertible Notes. We also recorded other expense of \$1,991,000 and \$3,274,000 in the three and nine months ended September 30, 2013, related to the modification of convertible notes and warrants.

***Net Loss***

In the three and nine months ended September 30, 2013, we recorded net losses of \$609,000 and \$473,000, respectively, as compared to net losses of \$3,165,000 and \$11,388,000 for the three and nine months ended September 30, 2012, respectively.

**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.

Under the terms of the Securities Purchase Agreement entered into in February 2011, 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, 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. On February 22, 2013 we entered into a Securities Purchase Agreement with a number of accredited investors which revised certain terms of this Securities Purchase Agreement, including the cancellation of remaining milestone investments. See Note 10 to our condensed consolidated financial statements for additional disclosure surrounding this amendment.

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

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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. On February 22, 2013 we entered into a Securities Purchase Agreement with a number of accredited investors which revised certain terms of this Securities Purchase Agreement, including the cancellation of the \$0.25 warrants and a repricing of the \$0.15 Warrants. See Note 10 to our condensed consolidated financial statements for additional disclosure surrounding this amendment.

On January 16, 2013 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 \$250,000 of 5% Senior Secured Convertible Debentures maturing on January 16, 2016 (ii) warrants exercisable for a period of five years to purchase up to 2,500,000 shares of common stock at an exercise price of \$0.15 per share. On February 22, 2013 we entered into the February Securities Purchase Agreement with a number of accredited investors which revised certain terms of this Securities Purchase Agreement. See Note 10 to our condensed consolidated financial statements for additional disclosure surrounding this amendment.

Under the February Securities Purchase Agreement, we sold an aggregate of 26,933,333 shares of common stock and the February 2013 Warrants to purchase an additional 26,933,333 shares of common stock with gross proceeds of \$4,040,000 to these accredited investors. We utilized the proceeds of the private placement for general working capital purposes, to pay for investor relations services, for

payment of fees to Palladium Capital, LLC, the exclusive placement agent, and for legal, blue sky and related expenses. After payment of the placement agent fees and these other expenses, we received net proceeds of approximately \$2.5 million. See Note 9 to our condensed consolidated financial statements for additional disclosure surrounding this agreement.

On September 18, 2013, we entered into a Securities Purchase Agreement with a number of accredited investors, whereby we sold an aggregate of 29,166,667 shares of common stock and warrants to purchase an additional 29,166,667 shares of common stock (the "Warrants") with gross proceeds of \$1,750,000 to these accredited investors. We intend to utilize the proceeds of the private placement for general working capital purposes, to pay for investor relations services, for payment of fees to Palladium Capital, LLC, the exclusive placement agent, and for legal, blue sky and related expenses. After payment of the placement agent fees and these other expenses, we received net proceeds of approximately \$1.5 million. See Note 9 to our condensed consolidated financial statements for additional disclosure surrounding this agreement.

Cash and cash equivalents totaled \$1,404,000 as of September 30, 2013, an increase of \$1,146,000 from \$258,000 as recorded as of December 31, 2012. We also had restricted cash of \$250,000 as of September 30, 2013 as required per the terms of the Securities Purchase Agreement we entered into on February 22, 2013. These funds are reserved for investor relations awareness and related activities. 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 2014. 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 first quarter of 2014.

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 holders of the Common Stock and the Warrants issued in the February 2013 and September 2013 Securities Purchase Agreements have certain rights to participate in 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 which 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, 2013 were \$4,190,000 due to our net income, 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; 5) modification of convertible notes

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and warrants; and 6) retirement of warrants. Cash flows from financing activities in the nine months ended September 30, 2013 were \$5,329,000 from the issuance of 56,100,000 shares of common stock with net proceeds of \$5,079,000 and convertible notes with proceeds of \$250,000. The effect of exchange rate changes was a \$7,000 increase 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 and Section 21E of the Exchange Act. Statements containing terms such as "believes", "plans", "expects", "anticipates", "intends", "estimates" and similar expressions contain uncertainty and are forward-looking statements. Forward-looking statements are based on 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 have received a 'going concern' opinion in our consolidated financial statements indicating that our cash balance as of December 31, 2012, 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 will 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;
- 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 2012 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 in the future. 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 United States 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

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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;
- 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 this prospectus.
- We have pledged all of our assets to our secured debtholders. 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 debtholders 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 debtholders;
- Certain of our holders of common stock and warrants may be able to exert significant control over the company through restrictive covenants contained in such purchase agreements or through the conversion to our equity securities of the warrants issued and/or issuable to these holders of common stock as well as certain antidilution protection rights;
- 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

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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 they may be considered

- penny stocks 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.

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2013. 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 (the “SEC’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, 2013, our chief executive officer and chief 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, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### *Management’s Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. The term “internal control over financial reporting” is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company’s principal executive and principal financial officers and effected by the company’s board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

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- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of September 30, 2013. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on this assessment, our management has concluded that, as of September 30, 2013, our internal control over financial reporting was effective based on those criteria.

This quarterly report on Form 10-Q does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Pursuant to Item 308(b) of Regulation S-K, we are not required to provide such an attestation report because we are a smaller reporting company.

## **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 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
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, 2013, 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, and (iv) Notes to Condensed Consolidated Financial Statements.

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**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, 2013

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

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
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, 2013, 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, and (iv) Notes to Condensed Consolidated Financial Statements.

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

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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.
- 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, 2013

/s/ Mark R. Tauscher

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

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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.
- 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, 2013

/s/ Gregory W. Mann

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

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**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, 2013 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, 2013

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, 2013 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, 2013

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

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