

Celsion CORP  
Form 10-Q  
August 08, 2013

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 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: 001-15911

**CELSION CORPORATION**

(Exact name of Registrant as specified in its charter)

**Delaware**

**52-1256615**

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(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification Number)

**997 Lenox Drive, Suite 100**

**Lawrenceville, NJ 08648**

(Address of principal executive offices)

**(609) 896-9100**

(Registrant's telephone number, including area code)

**NA**

(Former name, former address and former fiscal year, if changed since last report)

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 (Check One):

Large accelerated filer

Accelerated filer

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

As of August 7, 2013, the Registrant had 61,160,961 shares of Common Stock, \$.01 par value per share, outstanding.

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**CELSION CORPORATION**  
**QUARTERLY REPORT ON**  
**FORM 10-Q**

**TABLE OF CONTENTS**

**PART I: FINANCIAL INFORMATION**

	<b>Page</b>
Item 1. Financial Statements (Unaudited)	
Balance Sheets	1
Statements of Operations	2
Statements of Comprehensive Income (Loss)	3
Statements of Cash Flows	4
Notes to Financial Statements	5-15
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures about Market Risk	24
Item 4. Controls and Procedures	24

**PART II: OTHER INFORMATION**

Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	34
Item 3. Defaults Upon Senior Securities	34
Item 4. Mine Safety Disclosures	34
Item 5. Other Information	34
Item 6. Exhibits	35
<b>SIGNATURES</b>	<b>36</b>

## Forward-Looking Statements

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q, including, without limitation, any projections of earnings, revenue or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, pre-clinical development, clinical trials, manufacturing and commercialization), any statements concerning proposed drug candidates or other new products or services, any statements regarding future economic conditions or performance, any changes in the course of research and development activities and in clinical trials, any possible changes in cost and timing of development and testing, capital structure, financial condition, working capital needs and other financial items, any changes in approaches to medical treatment, any introduction of new products by others, any possible licenses or acquisitions of other technologies, assets or businesses, any possible actions by customers, suppliers, partners, competitors and regulatory authorities, compliance with listing standards of the NASDAQ Capital Market and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “estimates,” “potential” or “continue,” or the negative of other comparable terminology. Although we believe that our expectations are based on reasonable within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part II, Item 1A “Risk Factors” below and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements, except as required by law or applicable regulations. The discussion of risks and uncertainties set forth in this Quarterly Report on Form 10-Q is not necessarily a complete or exhaustive list of all risks facing us at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is in a state of evolution. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any forward-looking statement.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, the “Company,” “Celsion,” “we,” “us,” and “our” refer to Celsion Corporation, a Delaware corporation.

## Trademarks

The Celsion brand and product names, including but not limited to Celsion® and ThermoDox® , contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.



**PART I: FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****CELSION CORPORATION****BALANCE SHEETS**

	<b>June 30, 2013</b>	<b>December 31,</b>
	<b>(unaudited)</b>	<b>2012</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$6,020,528	\$14,991,488
Investment securities – available for sale, at fair value	42,706,769	8,037,620
Accrued interest receivable on investment securities	206,209	65,925
Advances and deposits for investigator grants	118,240	246,252
Other current assets	520,725	307,699
<b>Total current assets</b>	<b>49,572,471</b>	<b>23,648,984</b>
<b>Property and equipment (at cost, less accumulated depreciation of \$1,074,961 and \$924,961, respectively)</b>	<b>1,022,115</b>	<b>1,114,621</b>
<b>Other assets:</b>		
Deposits, deferred fees and other assets	395,733	567,188
Patent licensing fees, net	24,375	28,125
<b>Total other assets</b>	<b>420,108</b>	<b>595,313</b>
<b>Total assets</b>	<b>\$51,014,694</b>	<b>\$25,358,918</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$1,522,710	\$2,339,768
Accrued liabilities	1,782,967	1,254,979
Notes payable - current portion	1,904,770	1,410,455
Deferred revenue - current portion	500,000	-
<b>Total current liabilities</b>	<b>5,710,447</b>	<b>5,005,202</b>
Common stock warrant liability	4,733,817	4,283,932
Notes payable – non-current portion	2,847,644	3,661,147
Deferred revenue - non-current portion	4,250,000	-
Other non-current liabilities	483,108	446,779
<b>Total liabilities</b>	<b>18,025,016</b>	<b>13,397,060</b>
<b>Stockholders' equity:</b>	<b>-</b>	<b>-</b>

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Preferred stock, \$0.01 par value: 100,000 shares authorized; 20,000 and 5,000 shares issued at June 30, 2013 and December 31, 2012 and -0- shares outstanding at June 30, 2013 and December 31, 2012, respectively		
Common stock, \$0.01 par value; 75,000,000 shares authorized; 61,823,340 and 37,967,708 shares issued at June 30, 2013 and December 31, 2012 and 61,160,961 and 37,302,785 shares outstanding at June 30, 2013 and December 31, 2012, respectively	618,233	379,677
Additional paid-in capital	190,963,230	165,276,069
Accumulated other comprehensive loss	(213,841 )	(126,607 )
Accumulated deficit	(155,697,737)	(150,876,770)
Subtotal	35,669,885	14,652,369
Treasury stock, at cost (662,379 and 664,921 shares at June 30, 2013 and December 31, 2012, respectively)	(2,680,207 )	(2,690,511 )
<b>Total stockholders' equity</b>	<b>32,989,678</b>	<b>11,961,858</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$51,014,694</b>	<b>\$25,358,918</b>

See accompanying notes to the financial statements.



## CELSION CORPORATION

## STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2013	2012	June 30, 2013	2012
<b>Licensing revenue</b>	\$ 125,000	\$-	\$ 250,000	\$-
<b>Operating expenses:</b>				
Research and development	2,022,576	4,112,243	5,225,753	8,805,250
General and administrative	1,950,720	1,595,281	3,639,449	3,165,747
<b>Total operating expenses</b>	3,973,296	5,707,524	8,865,202	11,970,997
<b>Loss from operations</b>	(3,848,296 )	(5,707,524 )	(8,615,202 )	(11,970,997 )
<b>Other income (expense):</b>				
Gain (loss) from change in valuation of common stock warrant liability	4,380,120	(447,323 )	8,660,417	(369,723 )
Investment income, net	67,132	62,076	83,695	67,409
Interest expense	(176,211 )	(10,574 )	(357,139 )	(16,275 )
Other expense	(1,861 )	(1,040 )	(1,861 )	(1,040 )
<b>Total other income (expense), net</b>	4,269,180	(396,861 )	8,385,112	(319,629 )
<b>Net income (loss)</b>	420,884	(6,104,385 )	(230,090 )	(12,290,626 )
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	-	-	(4,601,410 )	-
<b>Net income (loss) attributable to common shareholders</b>	\$ 420,884	\$(6,104,385 )	\$(4,831,500 )	\$(12,290,626 )
<b>Net income (loss) attributable to common shareholders per common share</b>				
<b>Basic</b>	\$ 0.01	\$(0.18 )	\$(0.10 )	\$(0.37 )
<b>Diluted</b>	\$-	\$(0.18 )	\$(0.10 )	\$(0.37 )
<b>Weighted average shares outstanding</b>				
<b>Basic</b>	54,391,516	33,236,060	48,631,514	33,211,059
	61,279,766	33,236,060	48,631,514	33,211,059

**Diluted**

**See accompanying notes to the financial statements.**

2

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**CELSION CORPORATION****STATEMENTS OF COMPREHENSIVE INCOME (LOSS)****(Unaudited)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
<b>Other comprehensive loss</b>				
Changes in:				
Realized loss on investment securities recognized in investment income, net	\$ 136,943	\$ 68,616	\$ 190,683	\$ 197,176
Unrealized loss on investment securities	(192,228)	(106,300 )	(277,917)	(236,076 )
Other comprehensive loss	(55,285 )	(37,684 )	(87,234 )	(38,900 )
Net income (loss)	420,884	(6,104,385)	(230,090)	(12,290,626)
<b>Total comprehensive income (loss)</b>	<b>\$ 365,599</b>	<b>\$(6,142,069)</b>	<b>\$(317,324)</b>	<b>\$(12,329,526)</b>

See accompanying notes to the financial statements.

**CELSION CORPORATION****STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Six Months Ended</b>	
	<b>June 30, 2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(230,090 )	\$(12,290,626)
Non-cash items included in net loss:		
Depreciation and amortization	153,750	107,910
Change in fair value of common stock warrant liability	(8,660,417 )	369,723
Deferred revenue	(250,000 )	-
Stock-based compensation	734,673	557,021
Treasury shares issued for services and 401(k) matching contribution	20,837	81,617
Change in deferred rent liability	(8,563 )	62,914
Deferred finance charges	62,823	-
Cash received for non-refundable research and development fee	5,000,000	-
Net changes in:		
Accrued interest on short term investments and other current assets	(166,666 )	45,662
Accounts payable	(817,058 )	295,457
Accrued liabilities	572,880	(141,522 )
<b>Net cash used in operating activities:</b>	<b>(3,587,831 )</b>	<b>(10,911,844)</b>
<b>Cash flows from investing activities:</b>		
Purchases of investment securities	(39,804,383)	(11,366,148)
Proceeds from sale and maturity of investment securities	5,048,000	9,440,882
Refund of deposit for letter of credit	50,000	-
Purchases of property and equipment	(57,494 )	(371,215 )
<b>Net cash used in investing activities</b>	<b>(34,763,877)</b>	<b>(2,296,481 )</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of preferred stock, net of issuance costs	13,616,442	-
Proceeds from sale of common stock equity, net of issuance costs	15,640,213	-
Proceeds from exercise of common stock warrants	261,944	-
Proceeds from exercise of options to purchase common stock	181,337	-
Proceeds from note payable	-	4,853,137
Principal payments on notes payable	(319,188 )	(82,556 )
<b>Net cash provided by financing activities</b>	<b>29,380,748</b>	<b>4,770,581</b>
<b>Decrease in cash and cash equivalents</b>	<b>(8,970,960 )</b>	<b>(8,437,744 )</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>14,991,488</b>	<b>20,145,854</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$6,020,528</b>	<b>\$11,708,110</b>

**Supplemental disclosures of cash flow information:**

Interest paid	\$247,899	\$16,275
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**See accompanying notes to the financial statements.**

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 AND 2012**

**Note 1. Business Description**

Celsion Corporation, referred to herein as “Celsion”, “We”, or “the Company,” a Delaware corporation based in Lawrenceville, New Jersey, is an oncology drug development company focused on improving treatment for those suffering with difficult-to-treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. Our lead product ThermoDox®, is being tested in human clinical trials for the treatment of primary liver cancer, recurrent chest wall breast cancer and colorectal liver metastases.

**Note 2. Basis of Presentation**

The accompanying unaudited financial statements of Celsion have been prepared in accordance with generally accepted accounting principles (GAAP) in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited financial statements. Operating results for the three and six month periods ended June 30, 2013 are not necessarily indicative of the results that may be expected for any other interim period(s) or for any full year. For further information, refer to the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on March 18, 2013 and our Amendment No. 1 to the Annual Report on Form 10-K/A filed on April 30, 2013 with the Securities and Exchange Commission.

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company’s financial statements and accompanying notes. Actual results could differ materially from those estimates.

Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. No events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

Certain items in the prior period financial statements have been reclassified to conform to the current period presentation.

### **Note 3. New Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by Financial Accounting Standards Board (FASB) and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

In June 2011, the FASB amended its guidance on the presentation of comprehensive income in financial statements to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items that are recorded in other comprehensive income. This new accounting guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. The provisions of this new guidance are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. In February 2013, the FASB issued *Accounting Standards Update (ASU) No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income*, a new standard to improve the reporting of reclassifications out of accumulated other comprehensive income. The new standard requires the disclosure of significant amounts reclassified from each component of accumulated other comprehensive income and the income statement line items affected by the reclassification. The standard is effective prospectively for interim and annual periods beginning after December 15, 2012. The adoption of this guidance did not have a material effect on the financial statements on January 1, 2013, the date adopted.

The following table presents the changes in each component of accumulated other comprehensive loss for the first six months of 2013.

	<b>Accumulated Other Comprehensive Loss</b>
January 1, 2013	\$ (126,607 )
Other comprehensive loss before reclassifications	(277,917 )
Realized loss reclassified from other accumulated comprehensive loss	190,683
Net other comprehensive loss	(87,234 )
June 30, 2013	\$ (213,841 )

#### **Note 4. Net Loss per Common Share**

Basic earnings per share is calculated based upon the net income (loss) available to common shareholders divided by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated after adjusting the denominator of the basic earnings per share computation for the effects of all dilutive potential common shares outstanding during the period. The dilutive effects of preferred stock, options and, warrants and their equivalents are computed using the treasury stock method.

For the three months ended June 30, 2012 and the six months ended June 30, 2013 and 2012, diluted loss per common share was the same as basic loss per common share as all options and warrants that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. The total number of shares of common stock issuable upon exercise of warrants and equity awards for the periods ended June 30, 2013 and 2012 were 17,908,724 and 15,203,880, respectively.

#### **Note 5. Investment Securities - Available For Sale**

Investment securities available for sale of \$42,706,769 and \$8,037,620 as June 30, 2013 and December 31, 2012, respectively, consist of commercial paper and corporate debt securities. They are valued at fair value, with unrealized gains and losses reported as a separate component of Stockholders' Equity in Accumulated Other Comprehensive Loss.



Investment securities available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term “other than temporary” is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near-term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

A summary of the cost, fair value and bond maturities of the Company’s investment securities is as follows:

	<b>June 30, 2013</b>		<b>December 31, 2012</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Corporate bond maturities</b>				
Within 3 months	\$ 15,106,659	\$ 15,041,480	\$ 3,053,740	\$ 3,002,350
Between 3-12 months	27,813,952	27,665,289	5,110,487	5,035,270
<b>Total</b>	<b>\$42,920,611</b>	<b>\$42,706,769</b>	<b>\$8,164,227</b>	<b>\$8,037,620</b>

The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at June 30, 2013 and December 31, 2012. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

Description of Securities	June 30, 2013		December 31, 2012	
	Fair Value	Gross	Fair	Gross
		Unrealized	Value	Unrealized
		Holding	Value	Holding
	Losses		Gains	
Available for Sale				
Bonds – corporate issuances (all unrealized holding losses are less than 12 months at date of measurement)	\$42,706,769	\$(213,841 )	\$8,037,620	\$(126,607 )

Investment income which includes interest and dividends and gross realized gains and losses on sales of available for sale securities, is summarized as follows:

Description of Securities	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Interest and dividend income	\$204,075	\$130,692	\$274,378	\$264,585
Realized losses	(136,943)	(68,616 )	(190,683)	(197,176)
	\$67,132	\$62,076	\$83,695	\$67,409

#### Note 6. Fair Value of Measurements

FASB Accounting Standards Codification (ASC) Section 820 (formerly SFAS No. 157) "Fair Value Measurements and Disclosures," establishes a three level hierarchy for fair value measurements which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value are as follows:

**Level 1:** Quoted prices (unadjusted) or identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date;

**Level 2:** Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and

**Level 3:** Significant unobservable inputs that reflect a reporting entity's own assumptions that market participants would use in pricing an asset or liability.

The fair values of securities available for sale are determined by obtaining quoted prices on nationally recognized exchanges (Level 1 inputs) or matrix pricing, which is a mathematical technique widely used in the industry to value debt securities without relying exclusively on quoted prices for the specific securities but rather by relying on the securities' relationship to other benchmark quoted securities (Level 2 inputs). The common stock warrant liability has been valued using the Black-Scholes option pricing model, the inputs of which are more fully described in Note 11 to the financial statements.

Cash and cash equivalents, other current assets, accounts payable and other accrued liabilities are reflected in the balance sheet at their estimated fair values primarily due to their short-term nature.

The following table presents information about assets and liabilities recorded at fair value on a recurring basis as of June 30, 2013 and December 31, 2012 on the Company's Balance Sheet:

	<b>Total Fair Value on the Balance Sheet</b>	<b>Quoted Prices In Active Markets For Identical Assets /Liabilities (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>Assets:</b>				
As of June 30, 2013				
Short-term investments available for sale Bonds – corporate issuances	\$42,706,769	\$42,706,769	\$ -	\$ -
As of December 31, 2012				
Short-term investments available for sale Bonds – corporate issuances	\$8,037,620	\$8,037,620	\$ -	\$ -
<b>Liabilities:</b>				
As of June 30, 2013				
Common stock warrant liability	\$4,733,817	\$-	\$ -	\$ 4,733,817
As of December 31, 2012				
Common stock warrant liability	\$4,283,932	\$-	\$ -	\$ 4,283,932

There were no transfers of assets or liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during the six month period ended June 30, 2013.

#### **Note 7. Other Accrued Liabilities**

Accrued liabilities at June 30, 2013 and December 31, 2012 include the following:

	<b>June 30,</b>	<b>December</b>
	<b>2013</b>	<b>31,</b>
		<b>2012</b>
Amounts due to contract research organizations and other contractual agreements	\$ 1,196,312	\$ 827,989
Accrued payroll and related benefits	450,790	338,365
Accrued professional fees	56,400	37,400
Accrued interest on notes payable	46,120	-
Other	33,345	51,225
Total	\$ 1,782,967	\$ 1,254,979

**Note 8. Note Payable**

In June 2012, the Company entered into a Loan and Security Agreement (the "Credit Agreement") with Oxford Finance LLC ("Oxford") and Horizon Technology Finance Corporation ("Horizon"). The Credit Agreement provides for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount may be advanced in two tranches of \$5 million each. The first tranche (the "Term A Loan") was made available to the Company on June 27, 2012 and the second tranche (the "Term B Loan") was to be made available, if at all, during the period beginning on the date that the Company achieved positive data in its Phase III clinical trial of RFA and ThermoDox® (the HEAT Study) and ending on March 31, 2013. On January 31, 2013, the Company announced it did not meet the primary endpoint of the HEAT Study, therefore the second tranche was not drawn down.

The Term A Loan is scheduled to mature on October 15, 2015. The obligations under the Credit Agreement are secured by substantially all assets of the Company other than its intellectual property and certain other agreed-upon exclusions.

The Term A Loan bears interest at a fixed rate of 11.75%. However, for the period extending from inception through May 1, 2013 for the Term A Loan, the Company was required to make interest payments only. The Company was also obligated to pay other customary facility fees for a credit facility of this size and type.

The Credit Agreement contains customary covenants, including covenants that limit or restrict the Company's ability to incur liens, incur indebtedness, make certain restricted payments, merge or consolidate and make dispositions of assets. Upon the occurrence of an event of default under the Credit Agreement, the lenders may cease making loans, terminate the Credit Agreement, declare all amounts outstanding to be immediately due and payable and foreclose on or liquidate the Company's assets that comprise the lenders' collateral. The Credit Agreement specifies a number of events of default (some of which are subject to applicable grace or cure periods), including, among other things, non-payment defaults, covenant defaults, a material adverse change in the Company's business, cross-defaults to other materials indebtedness, bankruptcy and insolvency defaults and material judgment defaults. The Company is currently in compliance with all loan covenants.

As a fee in connection with the Credit Agreement, the Company issued warrants to Horizon and Oxford (the "Warrants") to purchase the number of shares of the Company's common stock equal to 3% of each loan amount divided by the exercise price, which was calculated as the average NASDAQ closing price of the Company's common stock for the three days prior to the funding of the loan amount (\$2.92 per share for the Term A Loan). This resulted in 51,370 warrant shares issued in connection with the Term A Loan. The Warrants issued in connection with the Term A Loan are immediately exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019.

The Company valued the Warrants using the Black-Scholes option pricing model and recorded \$73,654 as deferred financing fees. In calculating the value of the warrants, the Company assumed a volatility rate of 74.3%, risk free interest rate of 1.10%, an expected life of 3.5 years, a stock price of \$2.80 (closing price on date of the Warrant) and no expected forfeitures nor dividends.

In connection with the Credit Agreement, the Company incurred cash and other expenses of \$291,369 which were recorded as deferred financing fees. These deferred financing fees are being amortized as interest expense over the life of the loan. For the first six months of 2013, \$63,120 in deferred financing fees was amortized as interest expense. Also, the Company paid \$243,380 in interest expense on the Credit Agreement during this same period.

Following is a schedule of future principal payments due on the Credit Agreement:

### **Credit**

**Agreement**

For the year ending June 30:

2014	\$ 1,862,558
2015	2,093,588
2016	754,056
	\$ 4,710,202

In November 2011, the Company financed \$144,448 of lab equipment through a capital lease. This lease obligation has thirty monthly payments of \$5,651 through February 2014. During the first six months of 2013, the Company made principal and interest payments totaling \$33,909. The outstanding lease obligation is \$42,212 as of June 30, 2013.

**Note 9. Stockholders' Equity**

During the first six months of 2013, we received approximately \$0.4 million of gross proceeds from the exercise of warrants and stock options to purchase approximately 137,032 shares of the Company's common stock.

Controlled Equity Offering

On February 1, 2013, the Company entered into a Controlled Equity Offering SM Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which Celsion may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to \$25.0 million (the "ATM Shares") pursuant to the Company's previously filed and effective Registration Statement on Form S-3. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the our common stock or to or through a market maker. From February 1, 2013 through February 25, 2013, the Company sold and issued an aggregate of 5,381,670 shares of common stock under the ATM Agreement, receiving approximately \$6.8 million in net proceeds.

The Company is not obligated to sell any ATM Shares under the ATM Agreement. Subject to the terms and conditions of the ATM Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell ATM Shares from time to time based upon the Company's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. In addition, pursuant to the terms and conditions of the ATM Agreement and subject to the instructions of the Company, Cantor may sell ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The ATM Agreement will terminate upon the earlier of (i) the sale of ATM Shares under the ATM Agreement having an aggregate offering price of \$25.0 million and (ii) the termination of the ATM Agreement by Cantor or the Company. The ATM Agreement may be terminated by Cantor or the Company at any time upon 10 days' notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company pays Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of ATM Shares and has agreed to provide Cantor with customary indemnification and contribution rights. The Company also reimbursed Cantor for legal fees and disbursements, of \$50,000, in connection with entering into the ATM Agreement. In connection with the preferred stock offering in February 2013 discussed below, the Company agreed to not sell any ATM Shares for a period of one year from February 26, 2013. In connection with the common stock offering below, the Company agreed to not sell any ATM Shares for an extended period of one year from June 3, 2013.

#### February 2013 Preferred Stock Offering

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 15,000.00422 shares of its Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock, for an aggregate purchase price of approximately \$15.0 million (the February 2013 Preferred Stock Offering). The closing of the February 2013 Preferred Stock Offering occurred on February 26, 2013, in which the Company received approximately \$15.0 million in gross proceeds. Subject to certain ownership limitations, shares of Series A 0% convertible preferred stock are convertible, at the option of the holder thereof, into an aggregate of up to 12,072,438 shares of common stock, and the warrants are exercisable to purchase an aggregate of up to 6,036,219 shares of common stock. Each warrant has an exercise price of \$1.18 per share, equal to the closing bid price of common stock on February 21, 2013. The warrants are immediately exercisable and expire five years after its issuance.

Upon issuance, we estimated the fair value of the warrants issued in the February 2013 Preferred Stock Offering to be approximately \$5.4 million using the Black-Scholes pricing model. Also, upon issuance, we recognized approximately \$4.6 million as a one-time, non-cash deemed dividend related to the beneficial conversion feature connected to the preferred stock in the Preferred Stock Offering.



Assumptions used in the valuation of the warrants issued in the February 2013 Preferred Stock Offering are as follows:

Risk-free interest rate	0.78	%
Expected volatility	102.23	%
Expected life (in years)	5.0	
Expected forfeiture rate	0.0	%
Expected dividend yield	0.00	%

As of June 30, 2013, all 12,072,438 shares of common stock in the aggregate were issued upon conversion of all 15,000.00422 shares of the Series A 0% convertible preferred stock.

*The Common Stock Offering*

On May 30, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 6,264,492 shares of its common stock for an aggregate purchase price of approximately \$9.8 million (the “Common Stock Offering”). The closing of the Common Stock Offering occurred on June 3, 2013. The issuance of common stock in the Common Stock Offering was made pursuant to the Company’s previously filed and effective Registration Statement on Form S-3 (File No. 333-183286), the base prospectus dated September 14, 2012 filed as part of such Registration Statement, and the prospectus supplement filed with the Securities and Exchange Commission on June 3, 2013. The Securities Purchase Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

Prior to the closing of the Common Stock Offering, there were an insufficient number of authorized shares to complete the transaction. The Common Stock Offering institutional investors also held warrants to purchase previously reserved and registered shares of common stock of the Company which were issued in conjunction with previous offerings. Concurrent with the closing of the Common Stock Offering, the institutional investors agreed to waive their rights to exercise these warrants to purchase 6,294,674 shares of common stock of the Company (the “Waived Warrants”) until the Company has obtained stockholders’ approval to increase the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. At the Company’s 2013 Annual Meeting of Stockholders held on July 19, 2013, the Company’s stockholders voted to approve the proposal to grant discretionary authority to the Board of Directors to amend the Certificate of Incorporation of the Company, as amended, to effect, at any time on or prior to the date of the 2014 Annual Meeting of Stockholders, a reverse stock split at an exchange ratio within the specified range and to set the number of authorized shares effective immediately after the reverse stock split at 75 million share.

Prior to the closing of the Common Stock Offering, the warrants described above were originally recorded as equity at the fair value on the date of issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity’s Own Equity*, the Waived Warrants are required to be liability classified immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to satisfy the terms of the warrants. Therefore, the Company has reclassified the fair value the Waived Warrants totaling approximately \$9.1 million from equity to a liability as of June 3, 2013. The Waived Warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings (see Note 11). Following is a summary list of the Waived Warrants:

<b>Shares of common stock associated with the Waived Warrants</b>	<b>Expiration Date of Waived Warrants</b>	<b>Strike Price</b>	<b>Per Share Fair Value on June 3, 2013</b>
5,955,736	2/26/2018	\$ 1.18	\$ 1.4670
140,593	7/25/2016	\$ 4.22	\$ 0.9791
56,827	7/6/2016	\$ 3.13	\$ 1.0693
141,518	11/25/2017	\$ 2.77	\$ 1.2353

Assumptions used in the valuation of the Waived Warrants associated with the Common Stock Offering are as follows:

Risk-free interest rate	0.50 - 1.03 %
Expected volatility	102.86- 110.88 %

Expected life (in years)	3.1	-	4.7
Expected forfeiture rate	0.0		%
Expected dividend yield	0.00		%

### January 2011 Preferred Stock Offering

The Company is currently reassessing the application of ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity* as it relates to the 8% Series A Redeemable Convertible Preferred Stock Offering completed in January 2011 (the January 2011 Preferred Offering). The Company received gross proceeds from the January 2011 Preferred Offering of approximately \$5.1 million in which it sold 5,000 shares of 8% redeemable convertible preferred stock with a stated value of \$1,000 per share, each share convertible into 416.6667 shares of common stock, and warrants to purchase up to approximately 2.1 million shares of common stock. All 5,000 shares of preferred stock sold in the January 2011 Preferred Offering were converted into the stated number of common stock shares as of August 2011. ASC 815-40 requires the Company to value the preferred stock and common stock warrants, any resulting beneficial conversion feature(s) resulting from the valuation of these securities and to determine and record the value of each of these securities or conversion feature as debt or equity based on the interpretation and application of ASC 815-40. In a draft report to the Company's independent registered public accounting firm, the Public Company Accounting Oversight Board has indicated that it believes the Company has not accounted for the January 2011 Preferred Offering properly. The Company believes it had properly accounted for the transaction in all material respects but is currently reviewing the accounting treatment in light of the report. The Company believes that any resulting adjustment, reclassification, or restatement of our financial statements, if necessary, would be isolated to 2011, would be non-cash in nature, would have no effect on the cash proceeds received or the stock or warrants issued in the Preferred Offering, would result in no additional cash interest or dividends being paid, and would not have any financial impact on the Company's 2012 or 2013 financial statements.

## **Note 10. Stock Based Compensation**

### Stock Options Plans

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. Generally, the terms of these plans require that the exercise price of the options may not be less than the fair market value of Celsion's common stock on the date the options are granted. Options granted generally vest over various time frames or upon milestone accomplishments. The Company's options generally expire ten years from the date of the grant.

In 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the "2007 Plan") under which 1,000,000 shares were authorized for issuance. The purpose of the 2007 Plan is to promote the long-term growth and profitability of the Company by providing incentives to improve stockholder value and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2007 Plan permits the granting of equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted

stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. At the Annual Meetings of Stockholders of Celsion held on June 25, 2010 and June 7, 2012, the stockholders approved amendments to the Plan. The only material difference between the original Plan and the amended Plan was the number of shares of common stock available for issuance under the amended Plan which was increased by 1,000,000 to a total of 2,000,000 shares in 2010 and by 2,250,000 to a total of 4,250,000 shares in 2012.

Prior to the adoption of the 2007 Plan, the Company adopted two stock plans for directors, officers and employees (one in 2001 and another in 2004) under which 666,667 shares were reserved for future issuance under each of these plans. As these plans have been superseded by the 2007 Plan, any options previously granted which expire, forfeit, or cancel under these plans will be rolled into the 2007 Plan.

The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options, which have different characteristics from Celsion's stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate.

The Company used the following assumptions for determining the fair value of options granted under the Black-Scholes option pricing model:

	<b>Six Months Ended June 30,</b>			
	<b>2013</b>		<b>2012</b>	
Risk-free interest rate	0.85 -	1.19 %	1.60 -	2.97 %
Expected volatility	83.41 -	97.83 %	80.8 -	82.3 %
Expected life (in years)	5.25 -	6.0	5.00 -	6.30
Expected forfeiture rate	5.0 -	7.5 %	0.0 -	7.5 %
Expected dividend yield	0.0%		0.0%	

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk free interest rate is derived from values assigned to U.S. Treasury bonds as published in the Wall Street Journal in effect at the time of grant. The model incorporates exercise, pre-vesting and post-vesting forfeiture assumptions based on analysis of historical data. The expected life of the fiscal 2013 and 2012 grants was generated using the simplified method.

A summary of the Company's stock option and restricted stock awards for the three month period ended June 30, 2013 is as follows:

<b>Equity Awards</b>	<b>Stock Options</b>		<b>Restricted Stock Awards</b>		<b>Weighted Average</b>
	<b>Options</b>	<b>Weighted</b>	<b>Non-vested</b>	<b>Weighted</b>	
	<b>Outstanding</b>	<b>Average</b>	<b>Restricted</b>	<b>Average</b>	<b>Contractual</b>
		<b>Exercise</b>	<b>Stock</b>		<b>Terms of</b>

		<b>Price</b>	<b>Outstanding</b>	<b>Grant Date</b>	<b>Equity Awards</b>
				<b>Fair Value</b>	<b>(in years)</b>
Equity awards outstanding at December 31, 2012	3,264,880	\$ 3.25	19,334	\$ 3.20	
Equity awards granted	845,000	\$ 0.98	-	\$ -	
Equity awards exercised	(55,932 )	\$ 3.49	(1,500 )	\$ 2.09	
Equity awards forfeited, cancelled or expired	(36,667 )	\$ 6.45	(4,167 )	\$ 4.13	
Equity awards outstanding at June 30, 2013	4,017,281	\$ 2.74	13,667	\$ 3.03	7.1
Aggregate intrinsic value of outstanding awards June 30, 2013	\$25,600		\$13,940		
Equity awards exercisable at June 30, 2013	2,662,879	\$ 2.26			6.1
Aggregate intrinsic value of awards exercisable at June 30, 2013	\$8,440				

Total compensation cost related to employee stock options and restricted stock awards amounted to \$471,481 and \$269,756 for the three months ended June 30, 2013 and 2012, respectively. Total compensation cost related to employee stock options and restricted stock awards amounted to \$734,673 and \$557,021 for the six months ended June 30, 2013 and 2012, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset as of June 30, 2013 and 2012.

As of June 30, 2013, there was \$1.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.7 years. The weighted average grant-date fair value was \$0.98 and \$1.48 per share for the options granted during the six months ended June 30, 2013 and 2012, respectively. The weighted average grant-date fair value was \$2.09 for the restricted stock awards granted during the six months ended June 30, 2012. No restricted stock awards were granted during the first six months of 2013.

During the first six months of 2013, the Company received gross proceeds of approximately \$0.2 million from the exercise of options to purchase 55,932 shares of common stock. Collectively, for all the stock option plans as of June 30, 2013, there were a total of 5,380,756 shares reserved, which were comprised of 4,030,948 equity awards granted and 1,349,808 equity awards available for future issuance.

## Note 11. Warrants

### Common Stock Warrants

Following is a summary of all warrant activity for the first six months of 2013:

<b>Warrants</b>	<b>Number of Warrants Issued</b>	<b>Weighted Average Exercise Price</b>
Warrants outstanding at December 31, 2012	7,863,653	\$ 3.37
Warrants granted in connection with the Preferred Stock Offering, as more fully described in Note 9	6,036,219	\$ 1.18
Warrants exercised for common stock	(71,250 )	3.25
Warrants outstanding at June 30, 2013	13,828,622	\$ 2.42

Aggregate intrinsic value of outstanding warrants at June 30, 2013	\$-
Weighted average remaining contractual terms (in years)	4.0

During the first six months of 2013, the Company received gross proceeds of approximately \$0.2 million from the exercise of warrants to purchase 71,250 shares of common stock.

#### Common Stock Warrant Liability

In September 2009, the Company closed a registered direct offering with a select group of institutional investors that raised gross proceeds of \$7.1 million and net proceeds of \$6.3 million. In connection with this registered direct offering, the Company issued 2,018,153 shares of its common stock and warrants to purchase 1,009,076 shares of common stock. The warrants have an exercise price of \$5.24 per share and are exercisable at any time on or after the six month anniversary of the date of issuance and on or prior to 66 months after the date of issuance. Under the terms of the warrants, upon certain transactions, including a merger, tender offer or sale of all or substantially all of the assets of the Company, each warrant holder may elect to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model. Accordingly, pursuant to ASC 815.40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the warrants are recorded as a liability and then marked to market each period through the Statement of Operations in other income or expense. At the end of each subsequent quarter, the Company will revalue the fair value of the warrants and the change in fair value will be recorded as a change to the warrant liability and the difference will be recorded through the Statement of Operations in other income or expense.



As more fully described in Note 9, concurrent with the closing of the Common Stock Offering, the institutional investors agreed to waive their rights to exercise the Waived Warrants to purchase 6,294,674 shares of common stock of the Company until the Company has obtained stockholders' approval of increasing the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the Waived Warrants are required to be liability classified immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to satisfy the terms of the Waived Warrants if they were exercised. Therefore, the Company has reclassified the fair value of the Waived Warrants totaling approximately \$9.1 million from equity to a liability as of June 3, 2013. The Waived Warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings.

The fair value of the warrants at June 30, 2013 and December 31, 2012 was \$4,733,817 and \$4,283,932, respectively, calculated using the Black-Scholes option-pricing model with the following ranges of assumptions:

	<b>June 30, 2013</b>		<b>December 31, 2012</b>	
Risk-free interest rate	0.36	- 1.41 %	0.73	%
Expected volatility	103.4-	147.3%	92.0	%
Expected life (in years)	0.9	- 4.7	1.13	
Expected forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.00	%	0.00	%

In connection with the Common Stock Offering, the Company recorded an additional warrant liability of \$9.1 million immediately after the closing of the Common Stock Offering. As a result of this change in the warrant liability in the aggregate at June 30, 2013, the Company recorded a non-cash benefit of \$8.7 million in the six months ended June 30, 2013. The following is a summary of the changes in the common stock warrant liability for the six months ended June 30, 2013:

Beginning balance as of January 1, 2013	\$4,283,932
Warrant liability classification (see Note 9)	9,110,302
Gain from the adjustment for the change in fair value included in net income	(8,660,417)
Ending balance as of June 30, 2013	\$4,733,817

## Note 12. Contingent Liabilities and Commitments

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a

term of 66 months and provides for 6 months of free rent; with the first monthly rent payment of approximately \$23,000 paid in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired. In connection with the \$50,000 reduction of the standby letter of credit in April 2013, the Company reduced the escrow deposit by \$50,000.

### **Note 13. Technology Development and Licensing Agreements**

On May 7, 2012 the Company entered into a long term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registration and bioequivalence studies, technical transfer costs, Celsion consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Celsion will repay Hisun for the aggregate amount of these development costs and fees commencing on the successful completion of three registration batches of ThermoDox®. Hisun is also obligated to certain performance requirements under the agreement. The agreement will initially be limited to a percentage of the production requirements of ThermoDox® in the China territory with Hisun retaining an option for additional global supply after local regulatory approval in the China territory. In addition, Hisun will collaborate with Celsion around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (SFDA). As of June 30, 2013, the Company has incurred approximately \$371,000 in costs to be reimbursed to Hisun.

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in mainland China, Hong Kong and Macau. Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Celsion and Hisun have agreed that the Technology Development Contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate and are evaluating the next steps in relation to ThermoDox, which include the sub-group analysis of patients in the Phase III HEAT Study for the hepatocellular carcinoma clinical indication and other activities to further the development of ThermoDox for the Greater China market. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, until such time as the parties find a mutually acceptable path forward on the development of ThermoDox based on findings of the ongoing post-study analysis of the HEAT Study data.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration will focus on next generation liposomal formulation development with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

Among the key provisions of the Celsion-Hisun Memorandum of Understanding are:

Hisun will provide the Company with non-dilutive financing and the investment necessary to complete the technology transfer of its proprietary manufacturing process and the production of registration batches for the China territory;

Hisun will collaborate with the Company around the clinical and regulatory approval activities for ThermoDox® as well as other liposomal formulations with the SFDA; and

Hisun will be granted a right of first offer for a commercial license to ThermoDox® for the sale and distribution of ThermoDox® in the China territory.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co. (the Yakult Agreement) under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and may receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. Under the Yakult Agreement, we will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur and we also will be the exclusive supplier of ThermoDox® to Yakult. Concurrent with a convertible preferred

stock equity financing in January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in accelerated partial payments to us on a drug approval milestone. The terms of the Yakult Agreement provided for the payment to us of \$2.0 million upon the closing of the preferred equity financing. The second \$2.0 million was conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study, which has not been resumed. In consideration of the \$2.0 million accelerated milestone payment from Yakult, we have agreed to reduce future drug approval milestone payments by approximately twenty percent (20%). All other milestone payments are unaffected.

## **Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

### **Forward-Looking Statements**

*Statements and terms such as “expect”, “anticipate”, “estimate”, “plan”, “believe” and words of similar import regarding our expectations as to the development and effectiveness of our technologies, the potential demand for our products, and other aspects of our present and future business operations, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, readers should specifically consider the various factors contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on March 18, 2013 and our Amendment No. 1 to the Annual Report on Form 10-K/A filed on April 30, 2013 with the Securities and Exchange Commission, which factors include, without limitation, plans and objectives of management for future operations or programs or proposed new products or services; changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing; possible changes in capital structure, financial condition, working capital needs and other financial items; changes in approaches to medical treatment; clinical trial analysis and future plans relating thereto; introduction of new products by others; possible licenses or acquisitions of other technologies, assets or businesses; and possible actions by customers, suppliers, partners, competitors and regulatory authorities. These and other risks and uncertainties could cause actual results to differ materially from those indicated by forward-looking statements.*

*The discussion of risks and uncertainties set forth in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K, as well as in other filings with the SEC, is not necessarily a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is constantly evolving. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any forward-looking statement. We disclaim any obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf.*

### **Strategic and Clinical Overview**

Celsion is an oncology drug development company focused on the development of treatments for those suffering with difficult to treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this

drug technology is to maximize efficacy while minimizing side-effects common to cancer treatments.

Our lead product, ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study) and a Phase II clinical trial for recurrent chest wall breast cancer. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at mild hyperthermia temperatures (greater than 39.5 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

On January 31, 2013, we announced that ThermoDox® in combination with radio frequency ablation did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma, also known as primary liver cancer. Specifically, we determined, after conferring with the HEAT study independent Data Monitoring Committee, that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for the HEAT study. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. We will continue to follow the patients enrolled in the HEAT study to the secondary endpoint, overall survival. We are also conducting additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox®.

Following the announcement of the Phase III HEAT study results, the Company has conducted a comprehensive analysis of the clinical data with key principal investigators, data experts and liver cancer experts. Emerging data from the HEAT Study post hoc analysis demonstrates that ThermoDox® markedly improves progression free survival (PFS) and overall survival (OS) in patients who had optimal RFA. The post hoc analysis indicates that if patients' lesions undergo RFA for 45 minutes or more, they clearly benefitted from ThermoDox®. These findings apply to HCC lesions from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a sizable subgroup of approximately 300 patients. This data is subject to further verification and review by the HEAT Study Steering Committee.

As part of this analysis, we are also assessing our product pipeline and research and development priorities. In April 2013, we announced the deferral of expenses associated with the Company's Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases (The ABLATE Study) until such time as the Company finalizes its plans for the continuation of its development program with ThermoDox® in HCC.

In April 2013, the Company engaged Cantor Fitzgerald & Co. to conduct a comprehensive review of merger and acquisition opportunities with the goal of identifying novel products with high potential, or companies, for Celsion to acquire. Strategic alternatives the Company may pursue could include, but are not limited to, continuing its current operating plan, partnering or other collaboration agreements, acquisition of another company's business or assets, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. As demonstrated by the HEAT Study results, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition and market value.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co. (the Yakult Agreement) under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and may receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. Under the Yakult Agreement, we will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur and we also will be the exclusive supplier of ThermoDox® to Yakult. Concurrent with a convertible preferred stock equity financing in January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in an accelerated partial payment to us of a future drug approval milestone which included \$2.0 million paid to us upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study. In consideration of these accelerated milestone payments from Yakult, we agreed to reduce future drug approval milestone payments by approximately forty percent (40%). All other milestone payments are unaffected.

On May 6, 2012, we entered into a long term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun the related development costs and fees, which we expect to be approximately \$2.0 million in total, commencing on the successful completion of three registration batches of ThermoDox®. As of June 30, 2013, the Company has incurred approximately \$371,000 in costs to be reimbursed to Hisun. On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox®

and we will provide research data and other technical support in relation to a regulatory filing by Hisun in the China territory for approval of ThermoDox®. Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Celsion and Hisun have agreed that the Technology Development Contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate and are evaluating the next steps in relation to ThermoDox®, which include the sub-group analysis of patients in the Phase III HEAT Study for the hepatocellular carcinoma clinical indication and other activities to further the development of ThermoDox for the China territory.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the greater China territory. This expanded collaboration will focus on next generation liposomal formulation development with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.



Among the key provisions of the Celsion-Hisun Memorandum of Understanding are:

Hisun will provide the Company with non-dilutive financing and the investment necessary to complete the technology transfer of its proprietary manufacturing process and the production of registration batches for the China territory;

Hisun will collaborate with the Company around the clinical and regulatory approval activities for ThermoDox® as well as other liposomal formations with the China state Food and Drug Administration (SFDA); and

Hisun will be granted a right of first offer for a commercial license to ThermoDox® for the sale and distribution of ThermoDox® in the China territory.

Our current business strategy includes the possibility of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one or more of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. We may also apply for subsidies, grants, or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, it is clear we will need significant additional capital to develop our product candidates through clinical development, manufacturing, and commercialization. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in "Item 1A. Risk Factors" under "Part II: Other Information" included herein.



**FINANCIAL REVIEW FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2013 and 2012****Results of Operations**

For the three months ended June 30, 2013, our net income was \$0.4 million compared to a net loss of \$6.1 million for the same period of 2012. For the six months ended June 30, 2013, our loss was \$0.2 million compared to a net loss of \$12.3 million for the same period of 2012. As of June 30, 2013, we had \$48.9 million in cash and short-term investments including accrued interest from short term investments.

	<b>Three Months Ended June 30,</b>			
	(\$ amounts in		Change	
	2013	2012	Increase (Decrease) \$	%
<b>Licensing Revenue:</b>	\$125	\$-	\$125	100 %
<b>Operating Expenses:</b>				
Clinical Research	1,503	2,840	(1,337)	(47.1)%
Chemistry, Manufacturing and Controls	520	1,272	(752 )	(59.1)%
Research and development	2,023	4,112	(2,089)	(50.1)%
General and administrative	1,950	1,595	355	22.3 %
Total operating expenses	3,973	5,707	(1,734)	(30.3)%
<b>Loss from operations</b>	<b>\$(3,848)</b>	<b>\$(5,707)</b>	<b>\$1,859</b>	<b>32.6 %</b>

	<b>Six Months Ended June 30,</b>			
	(\$ amounts in		Change	
	2013	2012	Increase (Decrease) \$	%
<b>Licensing Revenue:</b>	\$250	\$-	\$125	100 %
<b>Operating Expenses:</b>				
Clinical Research	3,536	6,349	(2,813)	(44.3)%
Chemistry, Manufacturing and Controls	1,690	2,456	(766 )	(31.2)%
Research and development	5,226	8,805	(3,579)	(40.6)%
General and administrative	3,639	3,166	473	14.9 %

Total operating expenses	8,865	11,971	(3,106)	(25.9)%
<b>Loss from operations</b>	<b>\$(8,615)</b>	<b>\$(11,971)</b>	<b>\$3,356</b>	<b>28.0 %</b>

*Comparison of the three months ended June 30, 2013 and 2012*

Licensing Revenue

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, therefore we recorded deferred revenue of \$125,000 for the three months ended June 30, 2013. We had no licensing revenue in 2012.

Research and Development Expenses

Research and development (R&D) expenses decreased by \$2.1 million from \$4.1 million in the second quarter of 2012 to \$2.0 million in the same period of 2013. Costs associated with the HEAT Study decreased to \$0.8 million in the second quarter of 2013 compared to \$1.9 million in the same period of 2012 primarily due to reduced costs associated with the HEAT Study after the data results were announced on January 31, 2013. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.1 million in the second quarter of 2013 compared to the same period of 2012. Costs associated with our colorectal liver metastases trial were insignificant in the second quarter of 2013 compared to \$0.1 million in the same period of 2012. Other R&D costs related to preclinical operations and regulatory operations decreased to \$0.3 million in the second quarter of 2013 compared to \$0.4 million in the same period of 2012. Costs associated with the production of ThermoDox® decreased to \$0.5 million in the second quarter of 2013 compared to \$1.3 million the same period of 2012.

In April 2013, the Company has implemented a restructuring program to lower its operating costs to conserve capital to ensure that our costs are adequately aligned with our resources and business strategy. The program included elimination of approximately one-third of Celsion's workforce and the deferral of expenses associated with the Company's Phase II study for colorectal liver metastasis (the ABLATE Study).

General and Administrative Expenses

General and administrative (G&A) expenses increased to \$2.0 million in the second quarter of 2013 compared to \$1.6 million in the same period of 2012. The Company recorded a one-time severance charge of \$0.3 million in the second quarter of 2013 as a result of the workforce reduction. We expect G&A costs to decrease throughout the remainder of 2013 compared to 2012 as we continue to reduce our operating costs and expenses.

Other Expense and Income and Interest Expense

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. In connection with a securities purchase agreement and offering in the second quarter of 2013, whereby the investors in the offering agree to waive their rights to exercise the warrants to purchase 6,294,674 shares of common stock of the Company until the Company has obtained stockholders' approval of increasing the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock, the Company reclassified the fair value of these warrants totaling \$9.1 million from equity to a liability on the date of the closing of the offering on June 3, 2013. Prior to the offering the warrants described above were originally recorded as equity at the fair value on the date of their issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, these warrants are required to be liability classified immediately after the

closing of the common stock offering on June 3, 2013 because there were an insufficient number of common shares authorized to satisfy the terms of the warrants if they were exercised. Therefore, these warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings.

This liability associated with these warrants is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. For the second quarter of 2013, we recorded a non-cash benefit of \$4.4 million based on the change in the fair value of the warrants compared to a non-cash charge of \$0.4 million in the same period of 2012.

In connection with the credit facility entered into with Oxford Financial LLC and Horizon Technology Finance Corporation during the second quarter of 2012, the Company incurred \$0.2 million in interest expense in the second quarter of 2013. Interest in the same period of 2012 was insignificant.

### *Comparison of the six months ended June 30, 2013 and 2012*

#### Licensing Revenue

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, therefore we recorded deferred revenue of \$250,000 for the six months ended June 30, 2013. We had no licensing revenue in 2012.

#### Research and Development Expenses

Research and development (R&D) expenses decreased by \$3.6 million from \$8.8 million in the first six months of 2012 to \$5.2 million in the same period of 2013. Costs associated with the HEAT Study decreased to \$2.2 million in the six months of 2013 compared to \$4.4 million in the same period of 2012 primarily due to reduced costs associated with the HEAT Study when the data results were announced on January 31, 2013. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.2 million in the first six months of 2013 compared to the same period of 2012. Costs associated with our colorectal liver metastases trial were insignificant in the first six months of 2013 compared to \$0.1 million in the same period of 2012. Other R&D costs related to preclinical operations and regulatory operations decreased to \$0.5 million in the first six months of 2013 compared to \$0.8 million in the same period of 2012. Costs associated with the production of ThermoDox® decreased to \$1.7 million in the first six months of 2013 compared to \$2.6 million the same period of 2012.



In April 2013, the Company has implemented a restructuring program to lower its operating costs to conserve capital to ensure that our costs are adequately aligned with our resources and business strategy. The program included elimination of approximately one-third of Celsion's workforce and the deferral of expenses associated with the Company's Phase II study for colorectal liver metastasis (the ablate study).

#### General and Administrative Expenses

General and administrative (G&A) expenses increased to \$3.6 million in the first six months of 2013 compared to \$3.2 million in the same period of 2012. The Company recorded a one-time severance charge of \$0.3 million in the second quarter of 2013 as a result of the workforce reduction. We expect G&A costs to decrease throughout the remainder of 2013 compared to 2012 as we continue to reduce our operating costs and expenses.

#### Other Expense and Income and Interest Expense

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. In connection with a securities purchase agreement and offering in the second quarter of 2013, whereby the investors in the offering agree to waive their rights to exercise the warrants to purchase 6,294,674 shares of common stock of the Company until the Company has obtained stockholders' approval of increasing the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock, the Company reclassified the fair value of these warrants totaling \$9.1 million from equity to a liability on the date of the closing of the offering on June 3, 2013. Prior to the offering the warrants described above were originally recorded as equity at the fair value on the date of their issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, these warrants are required to be liability classified immediately after the closing of the common stock offering on June 3, 2013 because there were an insufficient number of common shares authorized to satisfy the terms of the warrants if they were exercised. Therefore, these warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings.

This liability associated with these warrants is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. For the six months ended June 30, 2013, we recorded a non-cash benefit of \$8.7 million based on the change in the fair value of the warrants compared to a non-cash charge of \$0.4 million in the same period of 2012.

In connection with the credit facility entered into with Oxford Financial LLC and Horizon Technology Finance Corporation during the second quarter of 2012, the Company incurred \$0.4 million in interest expense in the first six months of 2013. Interest in the same period of 2012 was insignificant.



## Financial Condition, Liquidity and Capital Resources

Since inception, excluding the net aggregate payments received from Boston Scientific of \$43 million through the divestiture of our medical device business in 2007 (which we received in installments of \$13 million in 2007 and \$15 million in each of 2008 and 2009), we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds we received in this divestiture, subsequent sales of equity, credit facilities and amounts received under our product licensing agreement with Yakult and our technology agreement with Hisun. The process of developing and commercializing ThermoDox® requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenues, and we had an accumulated deficit of \$156 million at June 30, 2013.

As of June 30, 2013, we had total current assets of \$49.6 million (including cash, short term investments and related accrued interest on the short term investments of \$48.9 million) and current liabilities of \$5.7 million, resulting in working capital of \$43.9 million. At December 31, 2012, we had total current assets of \$23.6 million (including cash and short term investments and related accrued interest on the short term investments of \$23.1 million) and current liabilities of \$5.0 million, resulting in working capital of \$18.6 million.

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox® in mainland China, Hong Kong and Macau.

On February 1, 2013, the Company entered into a Controlled Equity Offering SM Sales Agreement (the “ATM Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which Celsion may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to \$25.0 million (the “ATM Shares”) pursuant to the Company’s previously filed and effective Registration Statement on Form S-3. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the our common stock or to or through a market maker.

The Company is not obligated to sell any ATM Shares under the ATM Agreement. Subject to the terms and conditions of the ATM Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell ATM Shares from time to time based upon the Company’s instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. In addition, pursuant to the terms and conditions of the ATM Agreement and subject to the instructions of the Company, Cantor may sell ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The ATM Agreement will terminate upon the earlier of (i) the sale of ATM Shares under the ATM Agreement having an aggregate offering price of \$25.0 million and (ii) the termination of the ATM Agreement by Cantor or the Company. The ATM Agreement may be terminated by Cantor or Celsion at any time upon 10 days' notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in Celsion. The Company will pay Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of ATM Shares and has agreed to provide Cantor with customary indemnification and contribution rights. The Company reimbursed Cantor for legal fees and disbursements of \$50,000 in connection with entering into the ATM Agreement. In connection with the preferred stock offering in February 2013 discussed below, the Company agreed to not sell any ATM Shares for a period of one year from February 26, 2013. From February 1, 2013 through February 25, 2013, the Company has sold and issued an aggregate of 5,381,670 shares under the ATM Agreement, receiving approximately \$6.8 million in net proceeds.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company agreed to sell, in a registered offering, an aggregate of 15,000.00422 shares of its Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock, for an aggregate purchase price of approximately \$15.0 million (the February 2013 Preferred Stock Offering). The closing of the February 2013 Preferred Stock Offering occurred on February 26, 2013, in which the Company received approximately \$15.0 million in gross proceeds. Subject to certain ownership limitations, shares of Series A 0% convertible preferred stock are convertible, at the option of the holder thereof, into an aggregate of up to 12,072,438

shares of common stock, and the warrants are exercisable to purchase an aggregate of up to 6,036,219 shares of common stock. Each warrant has an exercise price of \$1.18 per share, equal to the closing bid price of common stock on February 21, 2013. The warrants are immediately exercisable and expire five years after its issuance. As of June 30, 2013, the Company issued 12,072,438 shares of common stock upon conversion of all 15,000.0042 shares of the Series A 0% convertible preferred stock.

Upon issuance, we estimated the fair value of the warrants issued in the February 2013 Preferred Stock Offering to be approximately \$5.4 million using the Black-Scholes pricing model. Also, upon issuance, we recognized approximately \$4.6 million as a one time non-cash deemed dividend related to the beneficial conversion feature connected to the preferred stock in the Preferred Stock Offering.

On May 30, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 6,264,492 shares of its common stock for an aggregate purchase price of approximately \$9.8 million (the "Common Stock Offering"). The closing of the Common Stock Offering occurred on June 3, 2013. The issuance of Common Stock in the Common Stock Offering was made pursuant to the Company's previously filed and effective Registration Statement on Form S-3 (File No. 333-183286), the base prospectus dated September 14, 2012 filed as part of such Registration Statement, and the prospectus supplement filed with the Securities and Exchange Commission on June 3, 2013. The Securities Purchase Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

Prior to the closing of the Common Stock Offering, there were an insufficient number of authorized shares to complete the transaction. The Common Stock Offering institutional investors also held warrants to purchase previously reserved and registered shares of common stock of the Company which were issued in conjunction with previous offerings. Concurrent with the closing of the Common Stock Offering, the institutional investors agreed to waive their rights to exercise these warrants to purchase 6,294,674 shares of common stock of the Company (the "Waived Warrants") until the Company has obtained stockholders' approval of increasing the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. At the Company's 2013 Annual Meeting of Stockholders held on July 19, 2013, the Company's stockholders voted to approve the proposal to grant discretionary authority to the Board of Directors to amend the Certificate of Incorporation of the Company, as amended, to effect, at any time on or prior to the date of the 2014 Annual Meeting of Stockholders, a reverse stock split at an exchange ratio within the specified range and to set the number of authorized shares effective immediately after the reverse stock split at 75 million shares.

Prior to the closing of the Common Stock Offering, the warrants described above were originally recorded as equity at the fair value on the date of issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the Waived Warrants are required to be liability classified immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to satisfy the terms of the warrants. Therefore, the Company has reclassified the fair value of the Waived Warrants totaling approximately \$9.1 million from equity to a liability as of June 3, 2013. The Waived Warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings.

The Company is currently reassessing the application of ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity* as it relates to the 8% Series A Redeemable Convertible Preferred Stock Offering completed in January 2011 (the January 2011 Preferred Offering). The Company received gross proceeds from the January 2011 Preferred Offering of approximately \$5.1 million in which it sold 5,000 shares of 8% redeemable convertible preferred stock with a stated value of \$1,000 per share, each share convertible into 416.6667 shares of common stock, and warrants to purchase up to approximately 2.1 million shares of common stock. All 5,000 shares of preferred stock sold in the January 2011 Preferred Offering were converted into the stated number of common stock shares as of August 2011. ASC 815-40 requires the Company to value the preferred stock and common stock warrants, any resulting beneficial conversion feature(s) resulting from the valuation of these securities and to determine and record the value of each of these securities or conversion feature as debt or equity based on the interpretation and application of ASC 815-40. In a draft report to the Company's independent registered public accounting firm, the Public Company Accounting Oversight Board has indicated that it believes the Company has not accounted for the January 2011 Preferred Offering properly. The Company believes it had properly accounted for the transaction in all material respects but is currently reviewing the accounting treatment in light of the report. The Company believes that any resulting adjustment, reclassification, or restatement of our financial statements, if necessary, would be isolated to 2011, would be non-cash in nature, would have no effect on the cash proceeds received or the stock or warrants issued in the Preferred Offering, would result in no additional cash interest or dividends being paid, and would not have any financial impact on the Company's 2012 or 2013 financial statements.

Net cash used in operating activities for the first six months of 2013 was \$3.6 million. Our net loss for the first six months of 2013 included \$0.7 million in non-cash stock-based compensation expense and \$8.7 million in non-cash

benefit based on the change in the common stock warrant liability.

Net cash provided by financing activities was \$29.4 million during the first six months of 2013 which consisted of approximately \$6.7 million of net proceeds from sale of 5,381,670 million shares of the Company's common stock in connection with the ATM Agreement, approximately \$13.6 million of net proceeds from sale of approximately 15,000 shares of the Company's Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock in the Preferred Stock Offering, approximately \$9.1 million of net proceeds from the sale of 6,264,492 shares of its common stock and approximately \$0.4 million of gross proceeds from the exercise of options and warrants to purchase approximately 0.1 million shares of the Company's common stock. This was partially offset by approximately \$0.3 million of principal payment on its notes payable.

We will require additional capital to develop our product candidates through clinical development, manufacturing, and commercialization or to pursue licensing or strategic transactions. We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements or some combination of these alternatives. If we raise additional funds through the issuance of equity securities, stockholders will likely experience dilution and the equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities would have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products which we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us.

The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. In addition, we may continue to seek government sponsored research collaborations and grants.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or eliminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

#### **Off-Balance Sheet Arrangements and Contractual Obligations**

We have no off-balance sheet financing arrangements. There were no material changes during the six months ended June 30, 2013 to our operating leases, which are disclosed in the contractual commitments table in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on March 18, 2013 and our Amendment No. 1 to the



### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK .**

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio. We maintain a portfolio of various issuers, types, and maturities. These securities are classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive income (loss) included in stockholders' equity.

### **Item 4. CONTROLS AND PROCEDURES**

We have carried out an evaluation, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2013, which is the end of the period covered by this report, our disclosure controls and procedures are effective at the reasonable assurance level in alerting them in a timely manner to material information required to be included in our periodic reports with the Securities and Exchange Commission.

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that occurred during the six months ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.





## **PART II: OTHER INFORMATION**

### **Item 1. Legal Proceedings**

None.

### **Item 1A. Risk Factors**

The following is a summary of the risk factors, uncertainties and assumptions that we believe are most relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ significantly from anticipated or historical results and our forward-looking statements. Additional risks that we currently believe are immaterial may also impair our business operations. Investors should carefully consider the risks described below before making an investment decision, and you should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise. The description provided in this Item 1A includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on March 18, 2013 and our Amendment No. 1 to the Annual Report on Form 10-K/A filed on April 30, 2013 with the Securities and Exchange Commission. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q and our Annual Report on Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on March 18, 2013 and our Amendment No. 1 to the Annual Report on Form 10-K/A filed on April 30, 2013 with the Securities and Exchange Commission including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission.

## **RISKS RELATED TO OUR BUSINESS**

**We have a history of significant losses from continuing operations and expect to continue such losses for the foreseeable future.**

Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$156 million at June 30, 2013. Because we presently have no product revenues and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the U.S. Food and Drug Administration (FDA) and successfully marketed.

**Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Our lead drug candidate failed to meet its primary endpoint in the Phase III HEAT study.**

We have a number of drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky. It will take us several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer (the HEAT study). We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox®. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. Even with success in preclinical testing and previously completed clinical trials, the risk of clinical failure for any drug candidate remains high prior to regulatory approval. Even if ThermoDox® has positive results in its Phase II clinical trials, there is a substantial risk that it will fail to have sufficiently positive results in Phase III clinical trials with regard to efficacy, safety or other clinical outcomes. One or more of our clinical studies could fail at any time, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT study. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

**If we do not obtain or maintain FDA and foreign regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.**

To obtain regulatory approvals from the FDA and foreign regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or foreign regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

**We do not expect to generate significant revenue for the foreseeable future.**

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical trials and obtain all necessary governmental approvals. Our lead product candidate, ThermoDox®, is still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint of progression free survival, we will continue to follow the patients enrolled in the Heat study to the secondary endpoint, overall survival. ThermoDox® is currently also being evaluated in Phase II clinical trials and other preclinical studies. We do not expect to realize any revenues from product sales in the next several years, if at all. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be successfully tested, approved by the FDA or foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.**

As of June 30, 2013, we had approximately \$48.9 million in cash, cash equivalents and short-term investments. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages. For example, ThermoDox® is being evaluated in a Phase II clinical trial for colorectal liver metastasis, a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. We will conduct additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox® and are performing sub-group analysis of the Chinese cohort of patients in the HEAT study and other activities for further development of ThermoDox® for mainland China, Hong Kong and Macau. To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we cannot raise additional capital, we may be required to delay, reduce or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

**We have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.**

We currently have no sales, marketing or distribution capabilities. We intend to market our products, if and when such products are approved for commercialization by the FDA and foreign regulatory agencies, either directly or through other strategic alliances and distribution arrangements with third parties. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

**Our business depends on license agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products.**

Our success will depend, in a substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-sensitive liposome technology. The Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. Additionally, we have a joint research agreement with Philips Healthcare, a division of Royal Philips Electronics, to evaluate the combination of Philips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers. If we breach any provisions of the license and research agreements, we may our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We may be required to alter any of our potential products or processes, or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and commercializing the product. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights.

**We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.**

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

**Our products may infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.**

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we currently are not involved in any material litigation involving patents, a third party patent holder may assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain. We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms, or may not be available at all. Any modification to include a non-infringing technology may not be possible or if possible may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

**We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.**

We rely, and expect to continue to rely, on third-party clinical research organizations to conduct our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials. If these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

**Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.**

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are all subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers, are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with the FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.



We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

Many states in which we do or may do business, or in which our products may be sold, if at all, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

**Legislative and regulatory changes affecting the healthcare industry could adversely affect our business.**

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. health care system.

**The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.**

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

**Our products may not achieve sufficient acceptance by the medical community to sustain our business.**

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, which would have an adverse effect on our business, financial condition and results of operations.

**The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.**

It is very difficult to predict the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.

**Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.**

Various methods for treating cancer currently are, and in the future are expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

**We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our products and business.**

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our products and businesses. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

**Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.**

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our business effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

**If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.**

We may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

issue equity securities that would dilute our current stockholders' percentage ownership;

incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;

assume substantial actual or contingent liabilities;

reprioritize our development programs and even cease development and commercialization of our drug candidates;

suffer the loss of key personnel, or

merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.



Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

**We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.**

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

**We may be subject to significant product liability claims and litigation.**

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a severe adverse effect on our business. Whether or not we are ultimately successful in any product liability litigation, such litigation would harm the business by diverting the attention and resources of our management, consuming substantial amounts of our financial resources and by damaging our reputation. Additionally, we may not be able to maintain our product liability insurance at an acceptable cost, if at all.

**RISKS RELATED TO OUR SECURITIES**

**The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.**

The trading price for our common stock has been, and we expect it to continue to be, volatile. Our January 31, 2013 announcement that the HEAT study failed to meet its primary endpoint has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that could result in securities litigation. Plaintiffs' securities litigation firms have publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock had a high price of \$4.23 and a low price of \$1.69 in the 52-week period ended December 31, 2011, a high price of \$8.83 and a low price of \$1.64 in the 52-week period ended December 31, 2012 and a high price of \$9.35 and a low price of \$0.76 from January 1, 2013 through August 7, 2013. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of our common stock by our stockholders; and



the trading volume of our common stock.

In addition, the stock markets, in general, the NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

**Future sales of our common stock in the public market could cause our stock price to fall.**

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of August 7, 2013, we had 61,154,295 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

**Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.**

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock. Our stockholders may experience significant dilution as a result of future equity offerings or issuance. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of June 30, 2013, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, 13,818,772 shares of common stock issuable upon exercise of warrants outstanding, 4,030,948 options to purchase shares of our common stock and restricted stock awards outstanding, and 2,306,490 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering SM Sales Agreement entered into with Cantor Fitzgerald & Co. on February 1, 2013, we may offer and sell, from time to time through “at-the-market” offerings, up to an aggregate of \$25 million of shares of our common stock. In connection with the Series A 0% convertible preferred stock offering, the Company agreed to not sell any ATM Shares for a period of one year from February 26, 2013. In connection with the Common Stock Offering, the Company agreed to not sell any ATM Shares for an extended period of one year from June 3, 2013.

**We may be unable to maintain compliance with NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.**

Our common stock is currently listed on The NASDAQ Capital Market. To maintain the listing of our common stock on The NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and stockholders’ equity of at least \$2.5 million; or (ii) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and a total market value of listed securities of at least \$35 million. As of August 7, 2013, the closing bid price of our common stock was \$1.29 the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately \$78 million and the total market value of our listed securities was approximately \$79 million. As of June 30, 2013, we had stockholders’ equity of \$33 million. However, there is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements.

At the Company’s 2013 Annual Meeting of Stockholders held on July 19, 2013, the Company’s shareholders voted to approve a proposal to grant discretionary authority to the Board of Directors to amend the Certificate of Incorporation of the Company, as amended, to effect, at any time on or prior to the date of the 2014 Annual Meeting of Stockholders, a reverse stock split at an exchange ratio within the specified range and to set the number of authorized shares effective immediately after the reverse stock split at 75 million shares was approved based upon the following

votes

If the closing bid price of our common stock is below \$1.00 per share or the total market value of our publicly held shares of common stock is below \$35 million for 30 consecutive business days, we could be subject to delisting from The NASDAQ Capital Market. If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules regarding “penny stock,” which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to investors in penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher priced stock, would further limit the ability and willingness of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

**Public Company Accounting Oversight Board indicates it does not agree with the Company’s accounting of its preferred stock offering in 2011.**

The Company completed a preferred stock financing in 2011. In a draft report to the Company’s independent registered public accounting firm, the Public Company Accounting Oversight Board has indicated that it believes the Company may not have accounted for the January 2011 Preferred Offering properly. The Company believes it had properly accounted for the transaction in all material respects but is currently reviewing the accounting treatment in light of the report. The Company believes that any resulting adjustment, reclassification, or restatement of our financial statements, if necessary, would be isolated to 2011, would be non-cash in nature, would have no effect on the cash proceeds received or the stock or warrants issued in the January 2011 Preferred Offering, would result in no additional cash interest or dividends being paid, and would not have any financial impact on the Company’s 2012 or 2013 financial statements. Nonetheless, if a restatement were required that could attract securities litigation or result in a reduction of our stock price.

**The adverse capital and credit market conditions could affect our liquidity.**

Adverse capital and credit market conditions could affect our ability to meet liquidity needs, as well as our access to capital and cost of capital. The capital and credit markets have experienced extreme volatility and disruption in recent years. Our results of operations, financial condition, cash flows and capital position could be materially adversely affected by continued disruptions in the capital and credit markets.



**Our ability to use net operating losses to offset future taxable income are subject to certain limitations.**

We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During 2012 and 2011, the Company performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carryforwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with its registered direct and private placement offerings on July 25, 2011. As a result, the utilization of the Company’s federal tax net operating loss carryforwards generated prior to the ownership change is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

**We have never paid dividends on our common stock in the past and do not anticipate paying cash dividends on our common stock in the foreseeable future.**

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future for holders of our common stock.

**Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.**

Our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of “blank check” preferred stock. This preferred stock may be issued by our board of directors on such terms as it determines, without further stockholder approval. Therefore, our board of directors may issue such preferred stock on terms unfavorable to a potential bidder in the event that our board of directors opposes a merger or acquisition. In addition, our classified board of directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on our board of directors. Certain other provisions of our bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

34

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**Item 6. Exhibits.**

- 10.4 Securities Purchase Agreement, dated February 22, 2013, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed with the SEC on February 26, 2013.
- 31.1+ Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2+ Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- + Filed herewith.

101\*\* The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Balance Sheets, (ii) the unaudited Statements of Operations, (iii) the unaudited Statements of Comprehensive Loss, (iv) the unaudited Statements of Cash Flows, (v) the unaudited Statements of Change in Stockholders' Equity (Deficit), and (vi) Notes to Financial Statements.

\* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.

\*\* Exhibit 101 is being furnished and, in accordance with Rule 406T of Regulation S-T, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act.

\*\*\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, amended, and the omitted material has been separately filed with the Securities and Exchange Commission.

**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.

August 8, 2013

CELSION CORPORATION

Registrant

By: */s/ Michael H. Tardugno*  
Michael H. Tardugno  
President and Chief Executive Officer

By: */s/ Jeffrey W. Church*  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer